New Molecular Entities of 2010

New molecular entities, biologic agents, drug formulations/combinations, and drug indications approved during 2010 (including indication, approval date, and comments) are presented in this issue of Pharmacy Précis. An explanation of the FDA classification of the new drugs also is included. If you need any additional information regarding these agents, please call the Samford University Global Drug Information Service at (205) 726-2659.

**New Format!!** Much of the information presented in this issue of the Précis is in the form of a table. First, the classification definitions used by the FDA are presented. Following this, are tables containing each newly approved molecular entity, biologic agent, formulation, and indication from the year 2010. For more information about each drug, simply click on the highlighted portion of the drug name. To return to the main table, click ‘Back to table’, and you will return to the original starting point.

FDA classification for newly approved drugs is based on chemical classification and is outlined below.

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<th>FDA Classifications</th>
<th>Therapeutic Classification</th>
<th>Additional Classification</th>
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<td>CHEMICAL CLASSIFICATION</td>
<td>THERAPEUTIC CLASSIFICATION</td>
<td>ADDITIONAL CLASSIFICATION</td>
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<tr>
<td>1. New molecular entity - drug not marketed in U.S. by any manufacturer</td>
<td>S = Standard review - assigned to drugs that appear to have therapeutic qualities similar to drugs already approved</td>
<td>AA = AIDS drugs (always classified as P)</td>
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<tr>
<td>2. New salt - active moiety is marketed in the U.S., but this particular salt, ester, or derivative is not</td>
<td>P = Priority review - assigned to drugs that appear to have therapeutic gain over drugs currently available</td>
<td>E = Drugs that treat life-threatening or severely debilitating diseases</td>
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<td>3. New formulation - drug marketed in the U.S., but this particular formulation is not</td>
<td>O = Orphan designation - Pursuant to Section 526 of the Orphan Drug Act (Public Law 97-414 as amended).</td>
<td>F = Possible fraudulently submitted data</td>
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<tr>
<td>4. New combination - two or more ingredients in combination not marketed in the U.S.</td>
<td>1. Providing effective therapy or diagnosis for a disease not adequately treated or diagnosed by any marketed drug</td>
<td>G = Data from a type F classification is validated</td>
</tr>
<tr>
<td>5. New manufacturer - already marketed by another firm; duplicated salt, formulation or combination</td>
<td>2. Providing improved treatment or greater effectiveness or safety</td>
<td>N = Nonprescription drug</td>
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<td>6. New indication - already marketed by same firm but used primarily for new indications</td>
<td>3. Having a modest, but real advantage over convenience, elimination of troublesome side-effects, or treatment of a specific sub-population of patients</td>
<td>V = Designated orphan drug</td>
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<td>7. Marketed without an approved NDA</td>
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<td>8. OTC Switch</td>
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### New Molecular Entities of 2010

<table>
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<th>Generic Name (Brand Name)</th>
<th>Sponsor</th>
<th>Category</th>
<th>Approval Date</th>
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<td>Dalfampridine (Ampyra)</td>
<td>Acorda</td>
<td>1P</td>
<td>January 22</td>
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<tr>
<td>Liraglutide recombinant (Victoza)</td>
<td>Novo Nordisk</td>
<td>1S</td>
<td>January 25</td>
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<tr>
<td>Velaglucerase alfa (VPRIV)</td>
<td>Shire Human Genetic</td>
<td>1P</td>
<td>February 26</td>
</tr>
<tr>
<td>Caroglimic acid (Carbaglu)</td>
<td>Orphan Europe</td>
<td>1P</td>
<td>March 18</td>
</tr>
<tr>
<td>Polidocanol (Asclera)</td>
<td>Chemisch FBRK KRSSLR</td>
<td>1S</td>
<td>March 20</td>
</tr>
<tr>
<td>Pancrelipase (Pancreaze)</td>
<td>Ortho McNeil Janssen</td>
<td>7S</td>
<td>April 12</td>
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<tr>
<td>Everolimus (Zortress)</td>
<td>Novartis</td>
<td>1S</td>
<td>April 20</td>
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<tr>
<td>Dienogest; Estradiol valerate (Natazia)</td>
<td>Bayer Healthcare</td>
<td>1S</td>
<td>May 6</td>
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<tr>
<td>Cabazitaxel (Jevtana Kit)</td>
<td>Sanofi-Aventis</td>
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<td>June 17</td>
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<td>Alcaftadine (Lastacaft)</td>
<td>Vistakon Pharms</td>
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<td>Ulipristal acetate (Ella)</td>
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<td>Fingolimod (Gilenya)</td>
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<td>Tesamorelin Acetate (Egrifta)</td>
<td>Theratechnologies</td>
<td>1S</td>
<td>November 10</td>
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<tr>
<td>Eribulin Mesylate (Halaven, Eisai Inc)</td>
<td>Eisai Inc</td>
<td>1P</td>
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<tr>
<td>Sacrosidase (Sucraid)</td>
<td>QOL MEDCL</td>
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### New Biologic Approvals of 2010

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<td>Genentech</td>
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<td>Collagenase clostridium histolyticum (Xiaflex)</td>
<td>Auxilium Pharma</td>
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<td>Alglucosidase alfa (Lumizyme)</td>
<td>Genzyme</td>
<td>May 24</td>
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<tr>
<td>Denosumab (Prolia)</td>
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<tr>
<td>IncobotulinumtoxinA (Xeomin)</td>
<td>Merz Pharma</td>
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<td>Pegloticase (Krystexxa)</td>
<td>Savient Pharma</td>
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### New Drug Formulations / Combinations of 2010

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<tr>
<td>Pregabalin (Lyrica)</td>
<td>Pfizer</td>
<td>January 4</td>
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<td>Lamotrigine (Lamictal XR)</td>
<td>Smithkline Beecham</td>
<td>January 29</td>
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<tr>
<td>Trazadone (Oleptro)</td>
<td>Labopharm</td>
<td>February 2</td>
</tr>
<tr>
<td>Ritonavir (Norvir)</td>
<td>Abbott Labs</td>
<td>February 10</td>
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<tr>
<td>Aztrenam (Cayston)</td>
<td>Gilead</td>
<td>February 22</td>
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<tr>
<td>Articaine hydrochloride; Epinephrine bitartrate (Articaine HCl with Epinephrine)</td>
<td>Pierrel</td>
<td>February 26</td>
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<tr>
<td>Hydromorphine hydrochloride (Exalgo)</td>
<td>Mallinckrodt</td>
<td>March 1</td>
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<tr>
<td>Triptorelin pamoate (Trelstar)</td>
<td>Watson</td>
<td>March 10</td>
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<tr>
<td>Doxepin hydrochloride (Silenor)</td>
<td>Somaxon</td>
<td>March 17</td>
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<tr>
<td>Adepalene (Differin)</td>
<td>Galderma</td>
<td>March 17</td>
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<tr>
<td>Pramipexole dihydrochloride (Mirapex ER)</td>
<td>Boehringer Ingelheim</td>
<td>March 19</td>
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<td>Miconazole (Oravig)</td>
<td>Bioalliance Pharma</td>
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<td>Lacosamide (Vimpat)</td>
<td>Schwarz Biosciences</td>
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<td>Esomeprazole magnesium; Naproxen (Vimovo)</td>
<td>AstraZeneca</td>
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<td>Tramadol hydrochloride (Ryzolt)</td>
<td>Cipher Pharma</td>
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<td>Ketorolac tromethamine (Sprix)</td>
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<td>Hexaminolevulinate hydrochloride (Cysview Kit)</td>
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<td>Dutasteride; Tamsulosin hydrochloride(Jalyn)</td>
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### NEW DRUG FORMULATIONS / COMBINATIONS of 2010
(Click on generic drug name for further information)

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<thead>
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<th>GENERIC NAME (BRAND NAME)</th>
<th>SPONSOR</th>
<th>CATEGORY</th>
<th>APPROVAL DATE</th>
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<tr>
<td>Vardenafil hydrochloride (Staxyn)</td>
<td>Bayer Healthcare</td>
<td>3S</td>
<td>June 17</td>
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<tr>
<td>Memantine hydrochloride (Namenda XR)</td>
<td>Forest Labs</td>
<td>3S</td>
<td>June 21</td>
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<tr>
<td>Formoterol fumarate; Mometasone furoate (Dulera)</td>
<td>Schering</td>
<td>4S</td>
<td>June 22</td>
</tr>
<tr>
<td>Pilocarpine hydrochloride (Carpine)</td>
<td>Alcon</td>
<td>3P</td>
<td>June 22</td>
</tr>
<tr>
<td>Sumatriptan succinate (Alsuma)</td>
<td>King Pharms</td>
<td>3S</td>
<td>June 29</td>
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<tr>
<td>Buprenorphine (Butrans)</td>
<td>Purdue Pharma</td>
<td>3S</td>
<td>June 30</td>
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<tr>
<td>Ondansetron (Zuplenz)</td>
<td>Par Pharm</td>
<td>3S</td>
<td>July 2</td>
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<tr>
<td>Donepezil hydrochloride (Aricept)</td>
<td>Eisai Inc</td>
<td>3S</td>
<td>July 23</td>
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<tr>
<td>Amlodipine besylate; Hydrochlorothiazide; Olmesartan medoxomil (Tribenzor)</td>
<td>Daiichi Sankyo</td>
<td>4S</td>
<td>July 23</td>
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<tr>
<td>Glycopyrrolate (Cuvposa)</td>
<td>Shionogi Pharma</td>
<td>3S</td>
<td>July 28</td>
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<tr>
<td>Magnesium sulfate anhydrous; Potassium sulfate; Sodium sulfate (Suprep Bowel Prep Kit)</td>
<td>Braintree Labs</td>
<td>4S</td>
<td>August 5</td>
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<tr>
<td>Aliskiren hemifumarate; Amlodipine besylate (Tekamlo)</td>
<td>Novartis</td>
<td>4S</td>
<td>August 26</td>
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<tr>
<td>Buprenorphine; Naloxone (Suboxone)</td>
<td>Reckitt Benckiser</td>
<td>4S</td>
<td>August 30</td>
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<tr>
<td>Cetirizine hydrochloride (Zyrtec Allergy)</td>
<td>McNeil Consumer</td>
<td>3S</td>
<td>September 3</td>
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<tr>
<td>Drospirenone; Ethinyl estradiol; Levomefolate calcium (Beyaz)</td>
<td>Bayer Healthcare</td>
<td>4S</td>
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<td>Mannitol (Aridol)</td>
<td>Pharmaxis Inc</td>
<td>3S</td>
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<td>Risedronate sodium (Atelvia)</td>
<td>Warner Chilcott Inc</td>
<td>3S</td>
<td>October 8</td>
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<td>Acetaminophen (O firmev)</td>
<td>Cadence Pharms</td>
<td>5P</td>
<td>November 2</td>
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<tr>
<td>Saxagliptin/Metformin (Kombiglyze XR)</td>
<td>Bristol Myers Squibb</td>
<td>4S</td>
<td>November 5</td>
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<tr>
<td>Baclofen (Gablofen)</td>
<td>CNS Therapeutics Inc</td>
<td>5S</td>
<td>November 19</td>
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<tr>
<td>Moxifloxacin (Moxeza)</td>
<td>Alcon RES</td>
<td>3S</td>
<td>November 19</td>
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<tr>
<td>Testosterone (Axiron)</td>
<td>Acrux Pharma</td>
<td>3S</td>
<td>November 23</td>
</tr>
<tr>
<td>Drospirenone, Ethinyl Estradiol, Levomefolate calcium (Safyral)</td>
<td>Bayer Healthcare Pharms</td>
<td>5S</td>
<td>December 16</td>
</tr>
<tr>
<td>Amlodipine, Aliskiren, Hydrochlorothiazide (Amtumide)</td>
<td>Novartis PHARMS</td>
<td>4S</td>
<td>December 21</td>
</tr>
<tr>
<td>Norethindrone and Ethinyl Estradiol Chewable Tablets and Ferrous Fumarate Chewable Tablets</td>
<td>Warner Chilcott</td>
<td>5S</td>
<td>December 22</td>
</tr>
<tr>
<td>Testosterone (Fortesta)</td>
<td>ENDO PHARMS</td>
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### NEW DRUG INDICATIONS OF 2010
(Click on generic drug name for further information)

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<tbody>
<tr>
<td>Rifaximin (Xifaxan)</td>
<td>Salix Pharms</td>
<td>6P</td>
<td>March 24</td>
</tr>
<tr>
<td>Lisdexamfetamine Dimesylate (Vyvanse)</td>
<td>Shire Development</td>
<td>1S</td>
<td>November 10</td>
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<tr>
<td>Denosumab (Xgeva)</td>
<td>Amgen</td>
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New Molecular Entities

Dalfampridine (Ampyra, Acorda)
Pharmacology: Broad-spectrum potassium channel blocker elucidated to work by increasing conduction of action potentials in demyelinated axons through inhibition of potassium channels.
Indication: Treatment to improve walking in patients with multiple sclerosis (MS), demonstrated by increased walking speed.
Adverse Drug Reactions: Urinary tract infections (UTI), insomnia, dizziness, headache, nausea, asthenia, back pain, balance disorder, multiple sclerosis relapse, paresthesia, nasopharyngitis, constipation, dyspepsia, and pharyngolaryngeal pain.
Dose: Maximum recommended dose is 10mg twice daily, separated 12 hours apart, with or without food. Tablets should not be crushed, chewed, or dissolved.
Formulation: Oral, extended-release tablet (10mg)
Warnings/Contraindications: Contraindicated in patients with moderate to severe renal impairment and with a history of seizures. The risk of seizures increases as the dose of dalfampridine increases. Use in patients with creatinine clearance of ≤ 50mL/min is contraindicated because plasma levels increase and the risk of seizure is increased. Urinary tract infections were reported more frequently in patients receiving dalfampridine.

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Liraglutide Recombinant (Victoza, Novo Nordisk)
Pharmacology: Activates the membrane-bound cell-surface receptor GLP-1 coupled to adenyl cyclase by the stimulatory G-protein (Gs), increasing cyclic AMP (cAMP) to release insulin in the presence of elevated glucose.
Indication: Adjunct therapy to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus.
Adverse Drug Reactions: Nausea, vomiting, diarrhea, constipation, headache, anti-liraglutide antibodies.
Dose: Initial dose should be 0.6mg per day for 1 week to reduce gastrointestinal symptoms only, then increase the dose to 1.2mg per day for glycemic control; may increase dose to 1.8mg per day if glycemic control is not effective. Dose is administered once daily at any time of day, independent of meals, and is injected sub-Q in the arm, thigh, or upper abdomen, and should be rotated.
Formulation: Disposable, pre-filled, multi-dose pens (6mg/mL, 3mLs); can deliver 0.6-, 1.2-, or 1.8-mg.
Warnings/Contraindications: Counsel patients on the risk of medullary thyroid cancer and the symptoms of thyroid tumors due to reports of thyroid C-cell tumors in animal studies. Use caution in patients with a history of pancreatitis due to cases of pancreatitis occurring in clinical trials. Avoid concomitant use of liraglutide and a sulfonylurea agent (e.g., glipizide) due to severe hypoglycemic episodes.

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Velaglucerase alfa (VPRIV, Shire Human Genetic)
Pharmacology: Glucocerebroside-specific enzyme that catalyzes the hydrolysis of glucocerebroside to reduce the accumulation of glucocerebroside in the liver, spleen, bone marrow, and other organs.
Indication: Indicated for long-term enzyme replacement therapy (ERT) for pediatric and adult patients with type-1 Gaucher disease.
Adverse Drug Reactions: Infusion-related reactions, headache, dizziness, abdominal pain, nausea, back/joint pain, upper respiratory tract infections, activated PPT prolongation, fatigue/asthenia, pyrexia.
Dose: Recommended dose is 60units/kg administered every other week as a 60-minute IV infusion and should be administered under the supervision of a healthcare professional. Dose adjustments ranging from 15units/kg to 60units/kg are made based on achievement and maintenance of therapeutic goals.
Formulation: Lyophilized powder for reconstitution in single-use vials (200units/vial, 400units/vial).
Warnings/Contraindications: No contraindications exist to Velaglucerase alfa. Infusion-related reactions and hypersensitivity reactions related to the product should be monitored during the infusion.

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Carglumic acid (Carbaglu, Orphan Europe)

**Pharmacology:** Synthetic structural analogue of N-acetylglutamate (NAG), a mitochondrial enzyme, that works to activate carbamoyl phosphate synthetase (CPS-1), to convert ammonia to urea.

**Indication:** Hyperammonemia due to N-acetylglutamate synthase deficiency.

**Adverse Drug Reactions:** Infection, vomiting, abdominal pain, pyrexia, tonsillitis, anemia, ear infection, diarrhea, nasopharyngitis, and headache.

**Dose:** Initial daily dose should be 100mg/kg, up to 250mg/kg if necessary. Dose should be adjusted individually in order to maintain normal ammonia plasma levels.

**Formulation:** Oral tablet (200mg).

**Warnings/Contraindications:** Hypersensitivity to the active substance or to any excipients. Breast-feeding is contraindicated while using this agent. Monitor ammonia and amino acid levels to ensure the levels are maintained within normal limits. Liver, renal, cardiac, and hematological parameters should be monitored. Protein restriction and arginine supplementation may be indicated in case of low protein tolerance.

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Polidocanol (Asclera, Chemisch FBRK KRSSLR)

**Pharmacology:** Sclerosing agent that locally damages the endothelium of blood vessels allowing platelets to aggregate and adhere to the venous wall, replacing the occluded vein with connective fibrous tissue. This agent also increases the activity of clotting factors (8, 9, 11, 12) and proteins C and S.

**Indication:** Treatment of varicose veins, uncomplicated spider veins, and uncomplicated reticular veins.

**Adverse Drug Reactions:** Injection site hematoma, irritation, pain, pruritis, warmth, neovascularization, and clotting have been experienced. Reports of skin hyperpigmentation, allergic dermatitis, and hypertrichosis have occurred.

**Dose:** 0.3mL per injection, for a total of 10mL per session; separate sessions by 1 to 2 weeks.

**Formulation:** Solution; intravenous [10mg/2mL (5mg/mL), 20mg/2mL (10mg/mL)]

**Warnings/Contraindications:** Contraindicated in acute thromboembolic disease due to risk of thrombosis. Severe anaphylactic reactions have occurred. Intra-arterial administration may cause severe necrosis, ischemia, and gangrene.

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Pancrelipase (Pancreaze, Ortho McNeil Janssen)

**Pharmacology:** Acts as a digestive enzyme by catalyzing hydrolysis of fats, proteins, and starches.

**Indication:** Treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions.

**Adverse Drug Reactions:** Abdominal pain, upper abdominal pain, flatulence, diarrhea, abnormal feces, and fatigue.

**Dose:** Children 4 years of age and older should initiate dosing with 500 lipase units/kg per meal up to a maximum of 2,500 lipase units/kg per meal, or less than or equal to 10,000 lipase units/kg per day, or less than 4,000 lipase units per gram of fat ingested per day. Half of the prescribed dose should be given with each snack, with the total daily dose reflecting three meals plus two or three snacks.

**Formulation:** Oral capsule, delayed-release.

- Lipase: 4,200 USP units, Protease: 10,000 USP units, Amylase: 17,500 USP units per capsule.
- Lipase: 10,500 USP units, Protease: 25,000 USP units, Amylase: 43,750 USP units per capsule.
- Lipase: 16,800 USP units, Protease: 40,000 USP units, Amylase: 70,000 USP units per capsule.
- Lipase: 21,000 USP units, Protease: 37,000 USP units, Amylase: 61,000 USP units per capsule.

**Warnings/Contraindications:** No contraindications to pancrelipase exist. High-dose pancreatic enzyme replacement (> 2,500 lipase units/kg of body weight per meal) is associated with fibrosing colonopathy. Do not chew pancrelipase capsules or oral irritation may occur. Use caution in patients with gout, renal impairment or hyperuricemia. Exercise caution in patients with porcine allergy because pancreatic enzymes are porcine-origin derivatives.

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**Everolimus (Zortress, Novartis)**

**Pharmacology:** Inhibits antigentic and interleukin (IL-2 and IL-5) stimulated activation of T- and B-lymphocytes, which ultimately inhibits protein synthesis and cell proliferation to reduce kidney allograft rejection to prolong graft survival.

**Indication:** Prophylaxis of organ rejection in low-moderate immunologic risk patients receiving kidney transplants. Everolimus is to be administered in combination with basiliximab induction and concurrently with reduced doses of cyclosporine and corticosteroids.

**Adverse Drug Reactions:** Peripheral edema, constipation, hypertension, nausea, anemia, urinary tract infection (UTI), and hyperlipidemia.

**Dose:** For adults 18 years of age and older, initiate oral dose of 0.75mg twice daily and adjust maintenance dose to achieve trough concentrations within the 3 – 8 ng/mL target range. Initiate dose as soon as possible after transplant. Administer consistently with or without food.

**Formulation:** Oral tablet (0.25mg, 0.5mg, 0.75mg).

**Warnings/Contraindications:** Contraindicated in patients with known hypersensitivity to everolimus, sirolimus, or to drug components. A boxed warning exists for immunosuppression and renal function. Increased risk for lymphoma and other malignancies exist. An increased risk of bacterial, viral, fungal, and protozoal infections exists with this drug, including opportunistic infections. Increased risk of angioedema with concomitant use of ACE-inhibitor may occur when taking everolimus. Wound healing may be delayed with use of this drug. Elevations of serum cholesterol and triglycerides may cause hyperlipidemia. Higher trough concentrations increase the risk of proteinuria. Risk of latent virus activation may occur with the use this drug, including polyoma virus infections. Concomitant use of strong CYP-3A4 inducers or inhibitors warrants additional monitoring of everolimus trough levels. Elevations of blood glucose after transplantation may cause new onset diabetes. Male infertility may occur due to azospermia or oligospermia. Live vaccinations should be avoided when taking this drug.

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**Dienogest; Estradiol valerate (Natazia, Bayer Healthcare)**

**Pharmacology:** Suppress ovulation to lower the risk of becoming pregnant. Other mechanisms include cervical mucus changes to inhibit sperm penetration and endometrial changes to reduce the likelihood of implantation.

**Indication:** Combined oral contraceptive used by women to prevent pregnancy.

**Adverse Drug Reactions:** Headaches, irregular uterine bleeding, breast tenderness, nausea/vomiting, acne, and increased weight.

**Dose:** Take one tablet at the same time everyday in the order directed on the blister pack. Do not skip days or delay intake by more than 12 hours.

**Formulation:** Blister pack contains 28 film-coated, unscored tablets in the following order: 2 tablets of 3mg estradiol valerate; 5 tablets of 2mg estradiol valerate and 2 mg dienogest; 17 tablets of estradiol valerate and 3mg dienogest; 2 tablets of 1mg estradiol valerate; 2 inert tablets.

**Warnings/Contraindications:** Contraindicated in patients with high-risk of arterial or venous thrombotic disease, undiagnosed genital bleeding, breast cancer, or other estrogen- or progestin-sensitive cancers. Use caution in patients with vascular risks and discontinue therapy if a thrombotic event occurs. Discontinue drug if jaundice occurs for risk of liver disease. Do not use in women with uncontrolled hypertension or who have hypertension with vascular disease. Monitor prediabetic and diabetic women for carbohydrate and lipid metabolic effects, and consider changing to an alternate form of contraception. Discontinue drug if significant headaches develop. Monitor uterine bleeding and report any significant changes. Do not use this medication if currently taking strong CYP3A4 inducers (i.e., carbamazepine, phenytoin, rifampicin, and St. John’s Wort) due to decreased contraceptive efficacy.

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**Cabazitaxel (Jevtana Kit, Sanofi-Aventis)**

**Pharmacology:** Microtubule inhibitor that binds to tubulin and promotes assembly into microtubules while simultaneously inhibiting disassembly, leading to stabilization of the microtubules and inhibition of mitotic and interphase cellular functions.
**Indication:** Combination treatment with prednisone for patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

**Adverse Drug Reactions:** Neutropenia, anemia, leukopenia, thrombocytopenia, diarrhea, fatigue, nausea, vomiting, constipation, asthenia, abdominal pain, hematuria, back pain, anorexia, peripheral neuropathy, pyrexia, dyspnea, cough, arthralgia, and alopecia.

**Dose:** Recommended dose is 25mg/m² administered every three weeks as a one-hour IV infusion in combination with oral prednisone 10mg daily throughout cabazitaxel treatment. Dose is decreased to 20mg/m² if prolonged grade ≥ 3 neutropenia for more than one week despite appropriate treatment, or if grade ≥ 3 diarrhea, or persisting diarrhea despite appropriate medication, fluid, and electrolyte replacement.

**Formulation:** Solution for IV infusion (60mg/1.5mL)

**Warnings/Contraindications:** Contraindicated in patients with neutrophils count ≤ 1,500/mm³ or if history of severe hypersensitivity to cabazitaxel or polysorbate 80. Monitor blood counts for neutropenia and primary prophylaxis with G-CSF should be considered in high-risk patients. Pre-treat patient with corticosteroids and H₂ antagonists to avoid hypersensitivity reactions with administration. Rehydrate and treat with anti-emetics and anti-diarrheals as needed to avoid GI symptoms. Manage and address renal failure aggressively due to possibility of fatal outcomes. Monitor patients aged 65 years and older closely, as they are more likely to experience fatal outcomes with treatment. Hepatic impairment is likely to increase cabazitaxel concentrations.

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**Alcaftadine (Lastacaft, Vistakon Pharma)**

**Pharmacology:** H₁ histamine receptor antagonist and inhibitor of histamine release from mast cells. Decreased chemotaxis and inhibition of eosinophil activation have been demonstrated.

**Indication:** Prevention of itching associated with allergic conjunctivitis.

**Adverse Drug Reactions:** Eye irritation, burning or stinging upon instillation, eye redness, and eye pruritis.

**Dose:** Instill one drop in each eye once daily.

**Formulation:** Ophthalmic solution/drops (0.25%).

**Warnings/Contraindications:** Do not allow dropper tip to touch any surface to avoid risk of product contamination. Do not use to treat contact lens-related irritation. Remove contact lenses prior to instilling this product.

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**Ulipristal acetate (Ella, Lab HRA Pharma)**

**Pharmacology:** Progesterone agonist/antagonist to inhibit or delay ovulation to postpone follicular rupture. It may also cause alterations of the endometrium to affect implantation.

**Indication:** Prevention of pregnancy following unprotected intercourse or known/suspected contraception failure. It is not intended for routine use as a contraceptive.

**Adverse Drug Reaction:** Headache, abdominal pain, nausea, dysmenorrhea, fatigue, and dizziness.

**Dose:** One tablet orally as soon as possible, within 120 hours (5 days) after unprotected intercourse or known/suspected contraceptive failure. May take tablet with or without food.

**Formulation:** Oral tablet (30mg).

**Warnings/Contraindications:** Contraindicated with known or suspected pregnancy. Not indicated for termination of an existing pregnancy. Complaints of lower abdominal pain may warrant an evaluation for ectopic pregnancy. This agent may alter the next expected menses. If menses is delayed beyond 1 week, pregnancy should be ruled out. Ulipristal acetate does not protect against STI/HIV.

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**Fingolimod (Gilenya, Novartis)**

**Pharmacology:** Sphingosine 1-phosphate receptor modulator that binds with high affinity to sphingosine 1-phosphate receptors 1, 3, 4, and 5, blocking the egression of lymphocytes from lymph nodes, which
reduces the number of lymphocytes in peripheral blood, and subsequent migration of lymphocytes into the central nervous system.

**Indication:** Treatment of patients with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

**Adverse Drug Reactions:** Headache, influenza, diarrhea, back pain, liver transaminase elevations, and cough.

**Dose:** One 0.5mg capsule once daily, with or without food.

**Formulations:** Oral capsule (0.5mg)

**Warnings/Contraindications:** No contraindications exist to this agent. Monitor for signs and symptoms of bradycardia up to 6 hours after the first dose due to decreased heart rate and AV conduction. Obtain a CBC before initiating treatment and monitor for signs and symptoms of infection during treatment and two months after completion of therapy due to increased risk of infections. Perform an ophthalmic evaluation before initiating treatment and three to four months after completion of therapy due to risk of macular edema. Spirometry and diffusion lung capacity should be obtained if clinically indicated due to decreases in pulmonary function associated with this agent. Patients may experience liver enzyme elevation and assessment of liver enzymes may be necessary if symptoms present suggestive of hepatic injury. Women of child-bearing age should use protection during treatment and two months after completion of therapy to avoid fetal harm or injury.

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**Tesamorelin Acetate (Egrifta, Theratechnologies)**

**Pharmacology:** Growth hormone releasing factor analog.

**Indication:** Reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

**Adverse Drug Reactions:** Arthralgia, extremity pain, myalgia, injection site erythema/pruritus, peripheral edema.

**Dose:** 2 mg once daily.

**Formulation:** Subcutaneous injection.

**Warnings/Contraindications:** Contraindicated in patients with disruptions of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, or pituitary tumor/surgery, head irradiation, or head trauma, patients with active malignancies, known hypersensitivity to tesamorelin and/or mannitol, and pregnancy. Chemotherapy treatments should be completed prior to starting therapy. IGF-I may increase; monitor and discontinue if elevation is persistent. Fluid retention may occur and may include edema, arthralgia, and carpal tunnel syndrome. Glucose intolerance may occur; monitor prior to and during therapy. Hypersensitivity reactions may occur. Rotate injection sites to avoid injection site reactions. Consider discontinuation of therapy during acute critical illness.

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**Eribulin Mesylate (Halaven, Eisai Inc)**

**Pharmacology:** Microtubule inhibitor.

**Indication:** Metastatic breast cancer in patients who have received at least 2 prior chemotherapy regimens for late-stage disease.

**Adverse Drug Reactions:** Neutropenia, anemia, leukopenia, alopecia, fatigue, nausea, weakness, peripheral neuropathy, constipation.

**Dose:** 1.4 mg/m² intravenously over 2-5 minutes on day 1 and 8 of a 21-day cycle.

**Formulation:** 0.5 mg/mL injection.

**Warnings/Contraindications:** Monitor for neutropenia and peripheral neuropathy. Fetal harm may occur if administered during pregnancy. Monitor QT intervals in patients with congestive heart failure, bradyarrhythmias, drugs known to prolong the QT interval, and electrolyte abnormalities.

**Notes:** Before receiving, patients should have already received prior anthracyline- and taxane-based chemotherapy for early or late-stage breast cancer. Do not mix with other drugs or administer with dextrose-containing solutions.

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Sacrosidase (Sucraid, QOL MEDCL)
Pharmacology: Enzyme which breaks down the disaccharide sucrose to its monosaccharide components.
Indication: Replacement for sucrase deficiency.
Adverse Drug Reactions: Abdominal pain, constipation, diarrhea, nausea, vomiting
Dose: Adults and children > 15 kg: 17,000 IU (2 mL) orally per meal or snack; Infants > 5 months and Children < 15 kg: 8,500 IU (1 mL) orally per meal or snack.
Formulation: Oral solution containing 8,500 international units/mL.
Warnings/Contraindications: Hypersensitivity to yeast, yeast products, or glycerin. Hypersensitivity reactions have been reported. Administer initial dose in setting where acute hypersensitivity reactions may be treated promptly.

New Biologic Approvals

Tocilizumab (Actemra, Genentech)
Pharmacology: Binds and inhibits both soluble and membrane-bound interleukin-6 receptors.
Indication: Treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.
Adverse Drug Reactions: Upper respiratory tract infections, nasopharyngitis, headache, hypertension, and increased ALT.
Dose: Starting dose of 8 mg/kg as a single intravenous drip infusion over 1 hour, followed by an increase to 8 mg/kg based on clinical response. Recommended dosing interval is once every four weeks.
Formulation: Single-use, preservative-free vials (20 mg/mL): 80 mg/4mL, 200 mg/10mL, 400 mg/20mL.
Warnings/Contraindications: Contains boxed warning for increased risk of developing serious infections that may lead to hospitalization or death. If a serious infection develops, interrupt treatment until the infection is controlled. Reported infections included active tuberculosis (TB), invasive fungal infections, or bacterial/viral/other opportunistic infections. The risk and benefits of treatment should be considered prior to initiating tocilizumab in the following patients: those with chronic or current infection, those with TB exposure, those with a history of serious opportunistic infection, or those who have resided or traveled in areas of endemic TB. Use with caution in patients who may be at increased risk for gastrointestinal perforation. Laboratory monitoring is recommended due to potential consequences of treatment related changes in neutrophils, platelets, lipids, and liver function tests. Anaphylaxis or serious hypersensitivity reactions have occurred. Live vaccines should not be given with tocilizumab.

Collagenase clostridium histolyticum (Xiaflex, Auxilium Pharms)
Pharmacology: Hydrolyzes collagen resulting in lysis of collagen deposits.
Indication: Treatment of adult patients with Dupuytren’s contracture with a palpable cord.
Adverse Drug Reactions: Peripheral edema, contusion, injection site reaction, injection site hemorrhage, and pain in the injected extremity.
Dose: Inject 0.58mg into a palpable Dupuytren’s cord with a contracture of a metacarpophalangeal (MP) joint or a proximal interphalangeal (PIP) joint according to the injection procedure. The injection should be performed by healthcare provider with experience in injection procedures of the hand, and should only inject one contracture cord at a time.
Formulation: Lyophilized powder for reconstitution in single-use, glass vials (0.9mg/vial).
Warnings/Contraindications: No contraindications to collagenase clostridium histolyticum exist. Avoid injecting this agent into tendons, blood vessels, or other collagen-containing structures of the hand, or possible tendon rupture or ligament damage may occur. Monitor for severe allergic reactions. Use with caution in patients who have received anticoagulant medications within 7 days of the injection, other than low-dose aspirin.

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**Alglucosidase alfa (Lumizyme, Genzyme)**

**Pharmacology:** Binds to mannose-6-phosphate receptors on the cell surface of carbohydrate groups on the acid α-glucosidase (GAA) molecule, which is then internalized and transported into lysosomes where it undergoes proteolytic cleavage to result in increased enzymatic activity to cleave glycogen, providing an exogenous source of GAA.

**Indication:** Treatment of a lysosomal glycogen-specific enzyme indicated for patients 8 years and older with late (non-infantile) onset Pompe disease (GAA deficiency) who do not have evidence of cardiac hypertrophy.

**Adverse Drug Reactions:** Anaphylaxis, urticaria, diarrhea, vomiting, dyspnea, pruritus, rash/erythema, pharyngolaryngeal pain, neck pain, hypoacusis, flushing/feeling hot, pain in extremity, and chest discomfort.

**Dose:** Recommended dose is 20mg/kg administered every 2 weeks as an IV infusion.

**Formulation:** Lyophilized powder for solution (5mg/mL).

**Warnings/Contraindications:** No contraindications exist for alglucosidase alfa. Ensure appropriate medical support measures are in place in case anaphylactic reactions occur during infusion. Consider discontinuation of drug if severe anaphylactic reactions occur. Monitor patients for systemic immune complex-mediated reactions involving skin and other organs.

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**Denosumab (Prolia, Amgen)**

**Pharmacology:** Binds to RANK-L membrane protein to prevent the activation of its receptor (RANK) located on the osteoclast cells. Preventing this interaction between RANK-L and RANK will inhibit osteoclast formation, which will decrease bone resorption and increase bone mass and strength in cortical and trabecular bone.

**Indication:** Treatment of postmenopausal women with osteoporosis at high risk for fracture.

**Adverse Drug Reactions:** Back pain, pain in extremity, hypercholesterolemia, musculoskeletal pain, and cystitis, as well as some reports of pancreatitis.

**Dose:** Administer subcutaneous injection of 60mg every 6 months into the upper arm, upper thigh, or abdomen. Patients should be instructed to take calcium 1000mg and vitamin D 400IU daily with denosumab treatment.

**Formulation:** Injectable, subcutaneous (60mg/mL).

**Warnings/Contraindications:** Contraindicated in patients with hypocalcemia, or calcium must be corrected before use. Monitor for serious skin infections, such as cellulitis, and seek medical attention if signs and symptoms develop. Reports of dermatitis, rash, and eczema have been reported. Consider discontinuation if severe dermatologic reactions develop. Osteonecrosis of the jaw has been reported.

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**Incobotulinumtoxin A (Xeomin, Merz Pharms)**

**Pharmacology:** Binds to the cholinergic nerve terminals to inhibit the release of acetylcholine from peripheral cholinergic nerve endings, resulting in decreased neuromuscular transmission at the neuromuscular junction. Formation of new nerve endings allows re-establishment of nerve transmission.

**Indication:** Treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain in both botulinum-naïve and previously treated patients. Also used for treatment of blepharospasm in adults previously treated with onabotulinumtoxinA (Botox).

**Adverse Drug Reactions:** In cervical dystonia treatment, adverse reactions include dysphagia, neck pain, muscle weakness, injection site pain, and musculoskeletal pain. In blepharospasm treatment, adverse reactions include eyelid ptosis, dry eye, dry mouth, diarrhea, headache, visual impairment, dyspnea, nasopharyngitis, and respiratory tract infection.

**Dose:** **Cervical dystonia:** Recommended dose is 120 units per session as an intramuscular injection into the sternocleidomastoid, splenius capitis, levator scapulae, scalenus, and/or the trapezius muscle(s); **Blepharospasm:** Recommended starting dose is 1.25 – 2.5 units per injection site.

**Formulation:** Lyophilized powder for solution for injection (50units/vial, 100units/vial).
**Warnings/Contraindications:** Contraindicated if hypersensitive to the active botulinum neurotoxin type A or any excipient. Also contraindicated if an infection exists at the proposed injection site. Do not convert Xeomin botulinum units to other botulinum type products because the biological units of activity are not interchangeable. Breathing difficulties may develop if spread of toxin occurs, and patients may require medical attention. Use caution in patients with compromised respiratory function or dysphagia. Concomitant neuromuscular disorders may exacerbate clinical effects of treatment. Indication-specific cautions for cervical dystonia include greater risk of dysphagia in patients receiving sternocleidomastoid injections with smaller neck mass. Indication-specific cautions for blepharospasm include corneal exposure and ulceration, reduced blinking with orbicularis oculi injections, and reoccurrence of diplopia with repeated injections.

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**Pegloticase (Krystexxa, Savient Pharms)**

**Pharmacology:** Recombinant uricase enzyme that catalyzes the oxidation of uric acid to allantoin (inert and water-soluble metabolite), which lowers the serum uric acid.

**Indication:** Treatment of chronic gout in adult patients refractory to conventional therapy, however, it is not recommended for asymptomatic hyperuricemia.

**Adverse Drug Reactions:** Gout flares, infusion reaction, nausea, contusion or ecchymosis, nasopharyngitis, constipation, chest pain, anaphylaxis, and vomiting.

**Dose:** Adult patients should receive an 8mg IV infusion over no less than 120 minutes via gravity feed, syringe-type pump, or infusion pump, administered every 2 weeks in a healthcare setting. Do not administer IV push or bolus. Pre-medicate with antihistamines and corticosteroids.

**Formulation:** Injectable concentrate for dilution (8mg of pegloticase protein).

**Warnings/Contraindications:** Contraindicated in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency due to increased risk of hemolysis and methemoglobinemia. Patients should have this medication administered in a healthcare setting due to anaphylactic reactions and delayed-type hypersensitivity reactions. Infusion reactions may also occur during administration of this drug. Prophylaxis drugs are recommended (NSAIDS or colchicine) during the first 6 months of therapy due to increased frequency of gout flares upon initiation of treatment. Exercise caution and closely monitor patients with heart failure due to potential exacerbation.

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**New Drug Formulations / Combinations**

**Pregabalin (Lyrica, Pfizer)**

**Pharmacology:** Binds with high affinity to the alpha2-delta site on voltage-gated calcium channels in central nervous system tissues, suggesting the binding is involved in pregabalin’s antinociceptive and antiseizure effects in animal models.

**Indication:** Neuropathic pain associated with diabetic peripheral neuropathy, postherpetic neuralgia, adjunct therapy for adult patients with partial onset seizures, and management of fibromyalgia.

**Dosage form:** Oral solution (20mg/mL)

**Dose:** Dose is indication specific, but 150mg per day in divided doses should be initiated. Dose may be increased to 300mg/day within 1 week of drug initiation.

**Lamotrigine (Lamictal XR, Smithkline Beecham)**

**Pharmacology:** The exact mechanism by which lamotrigine exerts its anticonvulsant effect is not known, however, one proposed mechanism involves the inhibition of voltage-gated sodium channels to modulate presynaptic release of glutamate and aspartate.

**Indication:** Adjunctive therapy for primary generalized tonic-clonic seizures and partial onset seizures with or without secondary generalization in patients > 13 years of age.

**Dosage form:** Oral tablet, extended-release (25mg, 50mg, 100mg, 200mg).

**Dose:** Dose is administered once daily and dose escalation kits are available for the first 5 weeks of treatment.
Trazadone (Oleptro, Labopharm)
Pharmacology: The mechanism of action is not fully understood, but is thought to be related to its potentiation of serotonergic activity in the CNS.
Indication: Treatment of major depressive disorder (MDD) in adults.
Dosage Form: Oral tablet, extended-release (150mg, 300mg).
Dose: Recommended starting dose is 150mg once daily, and may be increased by 75mg per day every three days (the dose on day 4 of therapy = 225mg). The maximum daily dose is 375mg per day. Tablets should be taken at the same time everyday, preferably at bedtime on an empty stomach.

Ritonavir (Norvir, Abbott Labs)
Pharmacology: An antiviral drug that is a peptidomimetic inhibitor of the HIV-1 protease, which renders this enzyme incapable of processing the gag-pol polyprotein precursor that ultimately leads to production of non-infectious immature HIV particles.
Indication: Combination therapy with other antiretroviral agents for the treatment of HIV-infection.
Dosage Form: Oral tablet (100mg).
Dose: The typical oral dose is 600mg twice daily. Administration of tablets should be taken with meals and swallowed whole, not chewed, broken, or crushed. Dose reduction is necessary when used with other protease inhibitors, such as amprenavir, atazanavir, darunavir, fosamprenavir, saquinavir, or tipranavir.

Aztreonam (Cayston, Gilead)
Pharmacology: Antibacterial drug that works by binding penicillin-binding proteins of susceptible bacteria, leading to inhibition of cell wall synthesis, including gram-negative aerobic pathogens such as Pseudomonas aeruginosa.
Indication: To improve respiratory symptoms in cystic fibrosis (CF) patients with known P. aeruginosa. Safety and efficacy have not been established in patients less than 7 years of age, or in patients colonized with Burkholderia cepacia.
Dosage Form: Inhalation for solution (75mg/vial); prepared in a 28-day course kit containing 84 sterile vials with diluent ampules.
Dose: Recommended dose for patients age 7 years and older is one single-use, reconstituted vial (75mg) administered three times daily separated by at least 4 hours, utilizing the Altera nebulizer system. The patient should complete a 28-day course, followed by 28 days off.

Articaine hydrochloride; Epinephrine bitartrate (Articaine HCl with Epinephrine, Pierrel)
Pharmacology: Two-drug combination product that serves as local anesthetic. Articaine hydrochloride blocks the generation and conduction of nerve impulses by slowing the propagation of the impulse and by reducing the rate of rise of the action potential. The addition of epinephrine, a vasoconstrictor, results in a 3- to 5-fold increase in plasma epinephrine concentrations, but without increases in blood pressure or heart rate in healthy adults.
Indication: Local, infiltrative, or conductive anesthesia in both simple and complex dental procedures.
Dosage Form: Inhalation for solution (75mg/vial).
Dose: The dose will vary by procedure, but the maximum recommended dosages are listed as follows: Healthy adult dosing should not exceed 7mg/kg (0.175mL/kg) of body weight, and pediatric doses (>4 years of age) should not exceed 7mg/kg (0.175mL/kg) of body weight.

Hydromorphone hydrochloride (Exalgo, Mallinckrodt)
Pharmacology: Opioid agonist binding specifically to mu-receptors in the central nervous system (CNS) to provide analgesia.
Indication: Once daily administration for the management of moderate to severe pain in opioid tolerant patients requiring continuous, around-the-clock opioid analgesia for an extended period of time. It is not intended for use as an as-needed analgesic.
**Dosage Form:** Oral tablet, extended release (8mg, 12mg, 16mg).
**Dose:** Administer 8mg to 64mg once daily with or without food.

**Triptorelin pamoate (Trelstar, Watson)**
**Pharmacology:** Agonist analog of gonadotropin releasing hormone (GnRH), which stimulates the release of luteinizing hormone.
**Indication:** Palliative treatment of advanced prostate cancer.
**Dosage Form:** Injectable; intramuscularly (22.5mg/vial).
**Dose:** Recommended dosage is 3.75mg injection every 4 weeks; 11.25mg injection every 12 weeks; 22.5mg injection every 24 weeks.

**Doxepin hydrochloride (Silenor, Somaxon)**
**Pharmacology:** Binds with high affinity to the histamine (H1) receptor where it functions as an antagonist.
**Indication:** Treatment of insomnia characterized by difficulties with sleep maintenance.
**Dosage Form:** Oral tablet (3mg, 6mg).
**Dose:** Initial recommended dose for adults is 6mg, and for elderly is 3mg, taken within 30 minutes before bedtime. Dose should not exceed 6 mg and should not be taken within 3 hours of a meal.

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**Adapalene (Differin, Galderma)**
**Pharmacology:** Retinoid product binds to specific retinoid receptors but does not bind to cytosolic receptor protein. Modulates cellular differentiation, keratinization, and inflammatory processes.
**Indication:** Topical treatment of acne vulgaris in patients 12 years and older.
**Dosage Form:** Topical lotion (0.1%).
**Dose:** Apply a thin film (nickel-size) of lotion to the entire face and other affected areas of the skin once daily. Do not apply around eyes, lips, or mucous membranes, and do not use for oral, ophthalmic, or intravaginal use.

**Pramipexole dihydrochloride (Mirapex ER, Boehringer Ingelheim)**
**Pharmacology:** Non-ergot dopamine agonist with high affinity for the D3 receptor subtype, followed by D2 and D4 subtypes. The mechanism for Parkinson’s disease treatment is unknown, but thought to be related to stimulation of dopamine receptors in the striatum.
**Indication:** Treatment of the signs and symptoms of idiopathic Parkinson’s disease.
**Dosage Form:** Oral tablet, extended-release (0.375mg, 0.75mg, 1.5mg, 3mg, 4.5mg).
**Dose:** Recommended starting dose is 0.375mg once daily, with gradual increases every 5 to 7 days, starting with an initial increase to 0.75mg, followed by dose increment increases of 0.75mg every 5 to 7 days to reach a maximum dose of 4.5mg per day. Patients with moderate renal impairment (CrCl of 30 – 50mL/min) require dosing adjustments, and patients with severe renal impairment (CrCl < 30mL/min) should avoid use of this drug.

**Miconazole (Oravig, Bioalliance Pharma)**
**Pharmacology:** Azole antifungal that inhibits ergosterol synthesis by interacting with 14-alpha demethylase.
**Indication:** Local treatment of oropharyngeal candidiasis in adults.
**Dosage Form:** Buccal tablet (50mg).
**Dose:** Application of one 50mg tablet to the gum region once daily for 14 consecutive days. Do not crush, chew, or swallow tablet.

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**Lacosamide (Vimpat, Schwarz Biosciences)**
**Pharmacology:** Antiepileptic with hypothesized mechanism of stabilizing hyperexcitable neuronal membranes and inhibiting repetitive neuronal firing, by selectively slowing the inactivation of voltage-gated sodium channels.
**Indication:** Adjunct therapy in patients ≥ 17 years of age for partial-onset seizures.
Dosage Form: Oral solution (10mg/mL).
Dose: Initial dose is 50mg (5mL) twice daily, with weekly increases of 100mg (10mL) per day as two divided doses, up to 200 to 400mg per day.

**Esomeprazole magnesium; Naproxen (Vimovo, AstraZeneca)**
Pharmacology: Two-drug combination with multiple indications. Esomeprazole magnesium is a proton pump inhibitor that suppresses gastric acid secretion; naproxen is an NSAID with analgesic and antipyretic properties possibly due to prostaglandin synthetase inhibition.
Indication: Relief of signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, and to decrease the risk of developing NSAID-associated gastric ulcers.
Dosage Form: Oral tablet, delayed-release (20mg/500mg, 20mg/375mg).
Dose: Recommended dose is one tablet twice daily, using the lowest effective dose. Not recommended for use in moderate to severe renal insufficiency or in severe hepatic insufficiency.

**Tramadol hydrochloride (Ryzolt, Cipher Pharmas Inc)**
Pharmacology: Centrally-acting synthetic opioid analgesic works by binding the mu-opioid receptors and weakly inhibiting the reuptake of norepinephrine and serotonin.
Indication: Management of moderate to moderately severe chronic pain in adults who require around-the-clock treatment of their pain for an extended period of time.
Dosage Form: Oral capsule, extended-release (100mg, 200mg, 300mg).
Dose: Extended-release tablets should be taken once daily. Do not split, chew, dissolve, or crush tablets.

**Ketorolac tromethamine (Sprix, Roxro Pharma Inc)**
Pharmacology: NSAID drug producing analgesic effect by inhibiting the cyclooxygenase (COX) enzyme to reduce synthesis of prostaglandins, thromboxanes, and prostacyclin.
Indication: Short-term management (up to 5 days) of moderate to moderately severe pain.
Dosage Form: Nasal spray, metered (15.75mg/spray).
Dose: Patients < 65 years of age: 31.5mg dose (one 15.75mg spray in each nostril) every 6 to 8 hours, with a maximum daily dose of 126mg. Patients ≥ 65 years of age, renally impaired, or patients less than 50kg: 15.75mg dose (one 15.75mg spray in one nostril only) every 6 to 8 hours, with a maximum daily dose of 63mg.

**Hexaminolevulinate hydrochloride (Cysview Kit, Photocure)**
Pharmacology: Bladder instillation of the drug allows entry into the bladder mucosa and into the intracellular space of mucosal cells, where it is used as a precursor in the formation of the photoactive intermediate protoporphyrin IX (PpIX) and other photoactive porphyrins. These photoactive porphyrins are known to accumulate in neoplastic cells and the kit can detect cystoscopic lesions with the application of wavelengths between 360 and 450nm, which appear red and demarcated.
Indication: Used in cystoscopic detection of non-muscle invasive papillary cancer of the bladder. However, it is not intended to replace random biopsies or other cancer detection procedures of the bladder, and repetitive use is not recommended.
Dosage Form: Intravesical solution (100mg/vial).
Dose: Instill 50mL of reconstituted solution into the emptied bladder via intravesical catheter and retain solution in the bladder for 1 hour before evacuation prior to the light procedure.

**Dutasteride; Tamsulosin hydrochloride (Jalyn, GlaxoSmithKline)**
Pharmacology: A combination of 2 drugs exerts a different mechanism of action to improve symptoms in patients with benign prostatic hyperplasia (BPH). Dutasteride is a 5α-reductase inhibitor that prevents the conversion of testosterone to dihydrotestosterone, which is primarily responsible for prostate enlargement, therefore reducing prostate inflammation; tamsulosin is an alpha-1 antagonist that prevents smooth muscle adrenergic activation to allow the bladder neck and prostate to relax, which results in improved urine flow and reduced BPH symptoms.
Indication: Treatment of symptomatic BPH in men with an enlarged prostate.
Dosage Form: Oral capsule (0.5mg/0.4mg).
**Vardenafil hydrochloride (Staxyn, Bayer Healthcare)**

**Pharmacology:** Phosphodiesterase-5-inhibitor to enhance erectile function by increasing the amount of cGMP, a chemical in the body that triggers smooth muscle relaxation, to increase blood flow to the penis and causing erection during sexual stimulation.

**Indication:** Treatment of erectile dysfunction.

**Dosage Form:** Tablet, orally disintegrating (10mg) to provide higher systemic exposure.

**Dose:** Place one 10mg tablet on the tongue and allow it to disintegrate. Maximum recommended dose is one 10mg tablet per day as needed, taken with or without food, but not taken with liquid.

**Memantine hydrochloride (Namenda XR, Forest Labs)**

**Pharmacology:** Binds preferentially to the NMDA receptor-operated cation channels, with low-to-moderate, uncompetitive (open-channel) affinity. This binding decreases the activation of the NMDA receptors in the central nervous system, to reduce the symptomatology of Alzheimer’s disease.

**Indication:** Treatment of moderate-to-severe dementia of the Alzheimer’s type.

**Dosage Form:** Oral capsule, extended-release (7mg, 14mg, 21mg, 28mg).

**Dose:** Recommended starting dose is 5mg once daily, with a target dose of 20mg daily. Doses can be increased in weekly intervals in the following order: 10mg day (5mg twice daily) for one week, 15mg/day (5mg in the AM and 10mg in the PM) for one week, then 20mg/day (10mg in the AM and 10mg in the PM). Dose can be taken with or without food.

**Formoterol fumarate; Mometasone furoate (Dulera, Schering)**

**Pharmacology:** Formoterol is a long-acting, beta-2 selective agonist that acts locally in the lung to allow bronchodilation; mometasone is a corticosteroid that exhibits anti-inflammatory action on many cell types, including mast cells, eosinophils, neutrophils, macrophages and lymphocytes.

**Indication:** Combination product for the treatment of asthma in patients 12 years of age and older, and not for relief of acute bronchospasm.

**Dosage Form:** Aerosol inhalation, metered (0.005mg/0.1mg and 0.005mg/0.2mg per inhalation).

**Dose:** Use 2 inhalations twice daily.

**Pilocarpine hydrochloride (Carpine, Alcon)**

**Pharmacology:** Cholinergic substance that results in parasympathomimetic reactions by responsive tissues once applied to the eye.

**Indication:** Medical management of glaucoma, especially open-angle glaucoma, and also used in combination with other anticholinergics in acute, closed-angle glaucoma to relieve tension prior to emergency surgery. It can also be used to counter the effects of cycloplegics and mydriatics following surgery or ophthalmoscopic examination.

**Dosage Form:** Ophthalmic solution (1%, 2%, 4%).

**Dose:** Initial dose is 1 to 2 drops instilled into the affected eyes, repeated up to three to four times daily or as directed by a physician.

**Sumatriptan succinate (Alsuma, King Pharms)**

**Pharmacology:** Binds selectively to 5-HT1 receptor subtype in the certain cranial arteries to cause vasoconstriction and relieve migraine and cluster headaches.

**Indication:** Acute treatment of migraine attacks with or without aura, and also for acute treatment of cluster headache episodes.

**Dosage Form:** Injectable, subcutaneous (6mg/0.5mL).

**Dose:** Recommended single maximum dose is a 6mg subcutaneous injection, with a maximum daily dose of two 6mg injections, separated by at least one hour.
**Buprenorphine (Butrans, Purdue Pharma)**

**Pharmacology:** Partial agonist at mu opioid receptors, antagonist at kappa opioid receptors, agonist at delta opioid receptors, and a partial agonist at ORL-1 (nociceptin) receptors.

**Indication:** Management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time.

**Dosage Form:** Transdermal film, extended-release (5mcg/hour, 10mcg/hour, 20mcg/hour).

**Dose:** Initial dose in opioid-naïve patients should always be the 5mcg/hour patch worn for 7 days. For patients already receiving opioids, a specific conversion will be used to avoid the precipitation of withdrawal from the current opioid. Apply the patch to the upper arm, upper chest, upper back or side of the chest. Rotate these application sites with patch application. A minimum of 3 weeks must elapse before applying to the same site.

**Ondansetron (Zuplenz, Par Pharm)**

**Pharmacology:** Selective 5-HT3 receptor antagonist.

**Indication:** Prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, initial and repeat courses of moderately emetogenic cancer chemotherapy, radiotherapy in patients receiving total body irradiation, single high-dose fraction to abdomen, or daily fractions to the abdomen. Also for the prevention of postoperative nausea and/or vomiting.

**Dosage Form:** Oral film (4mg, 8mg).

**Dose:** The dosing recommendations are dependent on the severity and type of nausea:

- For prevention nausea and vomiting associated with highly emetogenic cancer chemotherapy: 24mg given as three 8mg films administered 30 minutes prior to the start of chemotherapy.
- For prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy: Patients 12 years of age and older receive one 8mg film 30 minutes prior to chemotherapy, followed by an additional 8mg film eight hours later. Administer one 8mg twice daily (every 12 hours) for 1 to 2 days after chemo completion. Patients 4 - 11 years of age receive one 4mg film three times daily. Administer one 4mg film 30 minutes prior to chemotherapy, followed by an additional 4mg film four hours and eight hours later. Administer one 4mg three times daily (every 8 hours) for 1 to 2 days after chemotherapy completion.
- For prevention of nausea and vomiting associated with radiotherapy: Recommended adult dosage is one 8mg film three times daily.
- For postoperative nausea and vomiting: Recommended adult dose is 16mg as two 8mg films one hour before anesthesia.

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**Donepezil hydrochloride (Aricept, Eisai Inc)**

**Pharmacology:** Reversible inhibition of acetylcholinesterase to increase the concentration of acetylcholine, resulting in enhanced cholinergic function in the presence of cholinergic neurotransmission deficiency.

**Indication:** Treatment of dementia of the Alzheimer’s type, including mild, moderate and severe forms.

**Dosage Form:** Oral tablet (23mg).

**Dose:** Patients should initiate therapy with 5mg for approximately 4 to 6 weeks, then titrate up to 10mg. A dose of 10mg daily should be maintained for at least 3 months before starting the dose of 23mg daily. Donepezil should be taken with or without food in the evening, just prior to retiring.

**Amlodipine besylate; Hydrochlorothiazide; Olmesartan medoxomil (Tribenzor, Daiichi Sankyo)**

**Pharmacology:** Dihydropyridine calcium channel blocker, AT1 receptor inhibitor, and diuretic combination.

**Indication:** Treatment of hypertension, but not as initial therapy.

**Dosage Form:** Oral tablets (5/12.5/20mg, 5/12.5/40mg, 5/25/40mg, 10/12.5/40mg, 10/25/40mg).

**Dose:** One tablet daily as an add-on therapy or switch therapy. Doses may be increased after 2 weeks of therapy to maximum of 40/25/10mg once daily. Doses are formulated to allow titration based on the individual components.
**Glycopyrrolate (Cuvposa, Shionogi Pharma)**

**Pharmacology:** Competitive inhibitor of acetylcholine receptors located in certain peripheral tissues, including salivary glands, to reduce the rate of salivation by preventing the stimulation of these receptors.

**Indication:** Reduce chronic severe drooling in patients aged 3 to 16 years with neurologic conditions associated with problem drooling (cerebral palsy).

**Dosage Form:** Oral solution (1mg/5mL).

**Dose:** Initial dose is 0.02mg/kg three times daily and titrate in increments of 0.02mg/kg every 5 to 7 days over a 4-week period based on response and adverse reactions. The maximum recommended dosage is 0.1mg/kg three times daily, not to exceed 1.5 – 3mg per dose. The dose should be given at least one hour before or two hours after meals, due to reduced bioavailability in the presence of high-fat food.

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**Magnesium sulfate anhydrous; Potassium sulfate; Sodium sulfate (Suprep Bowel Prep Kit, Braintree Labs)**

**Pharmacology:** Osmotic effect due to unabsorbed sulfate ions contained within the solution and the associated cations, causing water to be retained within the gastrointestinal tract.

**Indication:** Cleansing of the colon in preparation for colonoscopy in adults.

**Dosage Form:** Oral solution for dilution (1.6gm/bottle, 3.13gm/bottle, 17.5gm/bottle).

**Dose:** Split-dose (2-day) regimen recommends diluting one bottle to 16 oz. with water and drinking the entire amount on the evening before colonoscopy. Drink 32 oz. of water over the next hour. Repeat both steps using the second bottle the next morning. Entire preparation should be completed at least one hour before colonoscopy.

**Aliskiren hemifumarate; Amlodipine besylate (Tekamlo, Novartis)**

**Pharmacology:** Two-drug combination agent with different mechanisms to lower blood pressure: aliskiren hemifumarate is a direct renin inhibitor that significantly inhibits the renin-angiotensin-aldosterone system; amlodipine besylate is a calcium-channel blocker that causes peripheral arterial vasodilation to decrease peripheral vascular resistance.

**Indication:** Treatment of hypertension for patients not adequately controlled with monotherapy, needing multiple drugs to achieve their blood pressure goal.

**Dosage Form:** Oral tablet (150mg/5mg, 150mg/10mg, 300mg/5mg, 300mg/10mg).

**Dose:** Initial therapy or add-on therapy starting dose is one tablet of 150mg/5mg, with titration up to a maximum of 300mg/10mg. The blood pressure lowering effect is obtained within 1 - 2 weeks.

**Buprenorphine; Naloxone (Suboxone, Reckitt Benckiser)**

**Pharmacology:** Two-drug combination product: suboxone is a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor; naloxone is a potent antagonist at the mu-opioid receptor and produces opioid withdrawal signs and symptoms in individuals physically dependent on full opioid agonists when administered parenterally.

**Indication:** Maintenance treatment of opioid dependence, under the prescription use of the Drug Addiction Treatment Act.

**Dosage Form:** Sublingual film (2mg/0.5mg, 8mg/2mg).

**Dose:** Administer sublingual film as a single daily dose, with a recommended maximum daily dose of 16/4mg.

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**Cetirizine hydrochloride (Zyrtec Allergy, McNeil Consumer)**

**Pharmacology:** Histamine H-1 receptor antagonist that reduces the mediated effects of histamine on certain cell types, including fibroblasts, neutrophils, eosinophils, macrophages, platelets, and lymphocytes.

**Indication:** Temporary relief of symptoms due to hay fever or other respiratory allergies, such as runny nose, sneezing, itchy/watery eyes, or itching of the nose and throat.

**Dosage Form:** Tablet, orally-disintegrating (10mg).
**Dose:** Adults and children 6 years of age and older take one 10mg tablet daily. Do not exceed 10mg in 24-hour period.

**Drospirenone (DRSP); Ethinyl estradiol (EE); Levomefolate calcium (Beyaz, Bayer Healthcare)**

**Pharmacology:** Suppresses ovulation and changes the cervical mucus to inhibit sperm penetration and endometrium to reduce the likelihood of implantation.

**Indication:** Prevention of pregnancy, treat symptoms of premenstrual dysphoric disorder, treat moderate acne in women at least 14 years of age, and to raise folate levels.

**Dosage Form:** Blister pack containing 28 film-coated, biconvex tablets in the following order: 24 tablets each containing 3mg DRSP, 0.02mg EE, and 0.451mg of levomefolate calcium; 4 tablets each containing 0.451mg of levomefolate calcium.

**Dose:** One tablet daily at the same time everyday taken in the order directed on the blister pack.

**Mannitol (Aridol, Pharmaxis Inc)**

**Pharmacology:** Induces an increase in osmolarity upon inhalation, releasing a wide variety of mediators that induce bronchoconstriction in the inflammatory cells of the airways. These mediators produce an airway response that is more pronounced (hyperresponsiveness) in patients with asthma and exercise-induced asthma, which is then measured using FEV\(_1\) to aid in the diagnosis.

**Indication:** Identifying bronchial hyperresponsiveness to assist in the diagnosis of asthma.

**Dosage Form:** Powder for inhalation (5mg, 10mg, 20mg, 40mg).

**Dose:** The mannitol kit is supplied with enough capsules to complete one challenge, along with the Osmohaler\™ inhalation device and nose clips. Instruct patient to apply nose clip and breathe through the mouth. Insert 0mg capsule into device and puncture capsule by depressing buttons on the side of the device. Once patient has exhaled completely, they will inhale in a controlled, rapid deep inspiration. After inspiration, begin timing for 60 seconds and instruct patient to hold breath for 5 seconds before exhaling, prior to removal of nose clip. Obtain an FEV\(_1\) measurement at the end of 60 seconds to establish a baseline FEV\(_1\). Repeat the above process using a 5mg capsule in the inhalation device, and continue to repeat the process based on the dosing steps provided with the challenge kit until the patient has a positive response or a total of 635mg has been administered.

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**Risedronate sodium (Atelvia, Warner Chilcott Inc)**

**Pharmacology:** Antiresorptive agent with high affinity to hydroxyapatite crystals, inhibiting osteoclast activity at the cellular level and reducing bone turnover.

**Indication:** Treatment of postmenopausal osteoporosis.

**Dosage Form:** Oral tablet, delayed-release (35mg).

**Dose:** Take one 35mg delayed-release tablet once weekly in the morning immediately after breakfast with at least 4oz. of plain water. Do not lie down for 30 minutes after taking tablet.

**Acetaminophen (Ofirmev, Cadence Pharms INC)**

**Pharmacology:** Unknown, but thought to involve central actions.

**Indication:** Mild to moderate pain, moderate to severe pain with adjunctive opioid analgesics, and reduction of fever.

**Dosage Form:** 10mg/mL injection for intravenous infusion; available in 100mL vial.

**Dose:** Administer over 15 minutes; minimal dosing interval of 4 hours. *Adults and adolescents ≥50kg:* 1000 mg every 6 hours or 650 mg every 4 hours to a maximum of 4000 mg/day. *Adults and adolescents <50kg and Children ≥ 2 to 12 years:* 15mg/kg every 6 hours or 12.5mg/kg every 4 hours to a maximum of 75mg/kg/day.

**Saxagliptin/Metformin (Kombiglyze XR, Bristol Myers Squibb)**

**Pharmacology:** Dipeptidyl peptidase-4 inhibitor/biguanide.

**Indication:** Type 2 diabetes in adults as adjunct to diet and exercise.

**Dosage Form:** 2.5mg/1000mg, 5mg/500mg, and 5mg/1000mg extended-release tablets.

**Dose:** Base on patient's current regimen; not to exceed 5mg/2000mg daily. Administer once daily with evening meal.
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**Baclofen (Gablofen, CNS Therapeutics INC)**
**Pharmacology:** Gamma-aminobutyric acid (GABA) agonist.
**Indication:** Severe spasticity of cerebral or spinal origin in adults and children aged 4 years and older.
**Dose:** 100 mcg intrathecal bolus should be given to screen for responsive. If no response, implanted pumps for chronic infusion should not be considered. Dose should be titrated to effect. Generally, 300 to 800 mcg/day for spasticity of spinal cord origin and 90 to 700 mcg/day for spasticity of cerebral origin.
**Formulation:** 50 mcg/mL, 500 mcg/mL, and 2,000 mcg/mL injection.

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**Moxifloxacin (Moxeza, Alcon RES)**
**Pharmacology:** Fluoroquinolone antibiotic.
**Indication:** Bacterial conjunctivitis.
**Dose:** Instill 1 drop in the affected eye(s) 2 times daily for 7 days.
**Formulation:** 4 mL bottle containing 3 mL of moxifloxacin solution.

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**Testosterone (Axiron, Acrux Pharma)**
**Pharmacology:** Endogenous androgen which is responsible for normal growth and development of male sex organs and maintaining secondary sex characteristics.
**Indication:** Primary hypogonadism and hypogonadotropic hypogonadism.
**Dose:** 30mg (1 pumps) applied to each axilla once daily at the same time each morning (total dose=60mg).
**Formulation:** Topical solution available in a metered-dose pump. One pump, or activation=30mg of testosterone.

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**Drospirenone, Ethinyl Estradiol, Levomefolate calcium (Safyral, Bayer Healthcare Pharms)**
**Pharmacology:** Combined oral contraceptives (COCs) lower the risk of becoming pregnant primarily by suppressing ovulation. Other possible mechanisms may include cervical mucus changes that inhibit sperm penetration and endometrial changes that reduce the likelihood of implantation.
**Indication:** Indicated for use as an oral contraceptive by women to prevent pregnancy. It is indicated in women who choose an OC as their method of contraception, to raise folate levels for the purpose of reducing the risk of a neural tube defect in pregnancy conceived while taking the product or shortly after discontinuing the product.
**Dose:** Take one tablet by mouth daily.
**Formulation:** Available as tablets in blister packs.

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**Amlodipine, Aliskiren, Hydrochlorothiazide (Amturnide, Novartis PHARMS)**
**Pharmacology:** Dihydropyridine calcium channel blocker, direct rennin inhibitor, and diuretic combination.
**Indication:** Hypertension not controlled by monotherapy.
**Dosage Form:** Unscored, film-coated tablet ( Aliskiren/Amlodipine/HCTZ (mg): 150/5/12.5, 300/5/12.5, 300/10/12.5, 300/10/25).
**Dose:** The dosage may be increased after 2 weeks of therapy. Maximum recommended daily dose is 300/10/25.

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**Norethindrone and Ethinyl Estradiol Chewable Tablets and Ferrous Fumarate Chewable Tablets**
**Pharmacology:** COCs lower the risk of becoming pregnant primarily by suppressing ovulation. Other possible mechanisms may include cervical mucus changes that inhibit sperm penetration and endometrial changes that reduce the likelihood of implantation.
**Indication:** Prevention of pregnancy.
**Dose:** Chew one tablet without water at the same time everyday.
**Formulation:** Available as 28 tablets in a blister pack in the following order: 24 tablets containing 0.8 mg norethindrone and 0.025 mg ethinyl estradiol and 4 brown tablets each containing 75 mg ferrous fumarate which does not have therapeutic purpose.

**Testosterone (Fortesta, ENDO PHARMS)**
**Pharmacology:** Endogenous androgens, including testosterone and dihydrotestosterone (DHT), are responsible for the normal growth and development of the male sex organs and for the maintenance of secondary sex characteristics. Male hypogonadism results from insufficient production of testosterone and is characterized by low serum testosterone concentrations. Symptoms associated with male hypogonadism include erectile dysfunction and decreased sexual desire, fatigue and loss of energy, mood depression, regression of secondary sexual characteristics, and osteoporosis.

**Indication:** Primary hypogonadism, hypogonadotrophic hypogonadism (congenital or acquired).

**Dosage Form:** Gel in a metered-dose pump. Each pump delivers 10 mg of testosterone.

**Dose:** Initial dose is 40 mg of testosterone applied once daily in the morning. Dosing range is 10 mg up to 70 mg and is adjusted based on serum testosterone concentrations two hours after administration at approximately 14 and 35 days after initiation of therapy or dose adjustment.

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**New Drug Indications**

**Rifaximin (Xifaxan, Salix Pharmas)**
**Pharmacology:** Non-aminoglycoside antibacterial agent that binds to the beta-subunit of bacterial DNA-dependent RNA polymerase resulting in inhibition of bacterial RNA synthesis.

**New Indication:** Treatment of patients with diarrhea complicated by fever and blood in the stool, or diarrhea due to pathogens other than *Escherichia coli*.

**Dose:** Recommended dose is 200mg three times daily for 3 days, with or without food.

**Lisdexamphetamine Dimesylate (Vyvanse, Shire)**
**Pharmacology:** Prodrug of the CNS stimulant dexamphetamine.

**New Indication:** Attention-deficit/hyperactivity disorder in adolescents aged 13 to 17 years.

**Dose:** 30mg once daily in the mornings.

**Densoumab (Xgeva, Amgen)**
**Pharmacology:** RANK-ligand inhibitor.

**New Indication:** Prevention of skeletal-related events in patients with metastasis-related bone damage.

**Dose:** 120 mg every 4 weeks subcutaneously in the upper arm, upper thigh, or abdomen.

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