New molecular entities, biologic agents, and drug formulations/combinations approved during 2011 (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.

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

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<td>S = Standard review - assigned to drugs that appear to have therapeutic qualities similar to drugs already approved</td>
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# New Molecular Entities of 2011

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### Ioflupane I 123 (DaTSCAN, GE Healthcare)

**Pharmacology:** A radiopharmaceutical with selectivity for the pre-synaptic dopamine transporter.

**Indication:** Diagnostic aid for use in the evaluation of patients with suspected Parkinsonian syndromes.

**Adverse Drug Reactions:** Nausea, xerostomia, dizziness, headache, vertigo.

**Dose:** 111 to 185 megabecquerels (3 to 5 millicuries) IV over at least 15 to 20 seconds.

**Formulation:** 0.07 to 0.13 mcg ioflupane, 74 MBq (2mCi) per mL at calibration: packaged in 2.5 mL.

**Warnings/Contraindications:** Hypersensitivity to the active substance, any of the excipients, or iodine.

**Notes:** Pre-medicate with a thyroid blocking agent at least one hour prior to administration. Hydrate frequently prior to and following administration.

### Spinosad (Natroba, ParaPRO)

**Pharmacology:** Topical antiparasitic agent; causes neuronal excitation, paralysis and death of lice.

**Indication:** Topical treatment of pediculosis capitis (head lice) infestation in patients >4 years of age.

**Adverse Drug Reactions:** Alopecia, erythema, skin irritation.

**Dose:** Shake bottle well. Apply enough topical suspension to cover dry scalp, then apply to dry hair. Leave on for 10 minutes, then rinse off with warm water. If live lice remain after 7 days, then a second treatment is warranted.

**Formulation:** 0.9% topical suspension: 4 oz. (120 mL) bottle.

**Warnings/Contraindications:** Contains benzyl alcohol which has been associated with adverse effects and death in neonates and low birth weight infants.

**Notes:** For topical use only. Avoid contact with eyes, mouth, or any mucus membrane.
Vilazodone hydrochloride (Viibryd, Trovis Pharmaceuticals)
**Pharmacology:** Selective serotonin reuptake inhibitor and 5-hydroxytryptamine (5-HT1A) receptor partial agonist.
**Indication:** Major depressive disorder in adults.
**Adverse Drug Reactions:** Diarrhea, nausea, drowsiness, decreased libido, abnormal dreams, dyspepsia.
**Dose:** Initiate with 10 mg once daily for 7 days, then 20 mg once daily for the next 7 days. The maximum dosage limit is 40 mg per day.
**Formulation:** 10-mg, 20-mg, 40-mg oral tablets.
**Warnings/Contraindications:** Contraindicated in patients receiving MAOI therapy or within 14 days of taking an MAOI.
**Notes:** Take with food. In the fasted state, blood levels may decrease by 50% resulting in decreased efficacy.

Sodium nitrite; sodium thiosulfate (Nithiodote, Hope Pharmaceuticals)
**Pharmacology:** Sodium nitrite: reacts with hemoglobin to form methemoglobin with a high affinity for cyanide. Sodium thiosulfate: detoxifies cyanide by aiding in its conversion to thiocyanate (SCN).
**Indication:** Sequential use for treatment of life-threatening acute cyanide poisoning.
**Adverse Drug Reactions:** Arrhythmias, hypotension, confusion, dizziness, nausea, acidosis, blurred vision, salty taste, prolonged bleeding time.
**Dose:** IV administration. **Adults:** Sodium nitrite – 10 mL at a rate of 2.5 to 5 mL/minute. Sodium thiosulfate – 50 mL immediately following sodium nitrite administration. **Children:** Sodium nitrite – 0.2 mL/kg (6 mg/kg or 6-8 mL/m² BSA) at a rate of 2.5 mL/minute not to exceed 10 mL. Sodium thiosulfate – 1 mL/kg of body weight (250 mg/kg or approximately 30-40 mL/m² BSA) not to exceed 50 mL; give total dose immediately following administration of sodium nitrite.
**Formulation:** Sodium nitrite injection, 300 mg/10 mL; sodium thiosulfate injection, 12.5 g/50 mL.
**Warnings/Contraindications:** Boxed warning: Sodium nitrate can cause life threatening hypotension and methemoglobinemia.
**Notes:** Use with caution if the diagnosis of cyanide poisoning is uncertain.

Azilsartan medoxomil (Edarbi, Takeda Pharmaceuticals North America)
**Pharmacology:** Angiotensin II receptor antagonist.
**Indication:** Used alone or in combination with other therapies for hypertension.
**Adverse Drug Reactions:** Diarrhea, hypotension.
**Dose:** 80 mg by mouth once daily. Consider 40 mg once daily in patients receiving high-dose diuretics.
**Formulation:** 40 mg and 80 mg oral tablets.
**Warnings/Contraindications:** Do not use in pregnant women. Avoid in neonates. Caution in patients with severe congestive heart failure, renal artery stenosis and volume depletion.
**Notes:** May take with or without food.

Roflumilast (Daliresp, Forest Research Institute)
**Pharmacology:** Phosphodiesterase 4 (PDE4) inhibitor.
**Indication:** Reduce COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations.
**Adverse Drug Reactions:** Diarrhea, weight loss, nausea, headache, back pain, influenza, insomnia, dizziness, decreased appetite.
**Dose:** 500 mcg by mouth once daily.
**Formulation:** 500-mcg oral tablet.
**Warnings/Contraindications:** Acute bronchospasm, psychiatric events, weight loss, moderate to severe liver impairment.
**Notes:** May take with or without food.

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Gadobutrol injection (Gadavist, Bayer Healthcare)
Pharmacology: Gadolinium-based contrast agent (GBCA).
Indication: Intravenous contrast agent used in adults and children >2 years of age for diagnostic MRI procedures to identify areas with disrupted blood brain barrier and/or abnormal CNS vascularity.
Adverse Drug Reactions: Headache, nausea, injection site reaction, dysgeusia, feeling hot.
Dose: 0.1 mmol/kg bolus at a 2 mL/sec flow rate.
Formulation: Available in vials or pre-filled syringes.
Warnings/Contraindications: Anaphylactic reactions ranging from mild to severe have uncommonly occurred. Higher than recommended dosing can increase risk of nephrogenic systemic fibrosis.
Notes: Screen patients for acute kidney injury and other disease states which impair renal function as this may lead to nephrogenic systemic fibrosis. GBCAs should be avoided in this population.

Gabapentin enacarbil (Horizant, GlaxoSmithKline)
Pharmacology: Anticonvulsant.
Adverse Drug Reactions: Somnolence/sedation, dizziness.
Dose: 600 mg by mouth once daily taken with food at about 5 PM.
Formulation: 600-mg extended-release tablet.
Warnings/Contraindications: Dizziness and sedation/somnolence can occur with use. Gabapentin enacarbil is a prodrug of gabapentin, an antiepileptic drug. Antiepileptic drugs have shown an increased risk of suicidal thoughts or behaviors.
Notes: A daily dose of 1,200 mg provides no additional benefit compared to 600 mg once daily, but causes an increase in adverse reactions. For patients with compromised renal function (CrCl 30-59 mL/min), 600 mg should be administered on Day 1, Day 3, and once daily thereafter.

Vandetanib (Omvocate, AstraZeneca)
Pharmacology: Kinase inhibitor.
Indication: Treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease.
Adverse Drug Reactions: Diarrhea, rash, acne, nausea, hypertension, headache, fatigue, decreased appetite, abdominal pain, decreased calcium, increased ALT, decreased blood glucose.
Dose: 300 mg by mouth once daily.
Formulation: 100- and 300-mg tablets.
Warnings/Contraindications: Boxed warning for prolonged QT interval, torsades de pointes, and sudden death. Stevens-Johnson syndrome and interstitial lung disease resulting in death have been reported. Fetal harm can occur when administered to pregnant women.
Notes: Due to risks of QT prolongation, torsades de pointes and sudden death, vandetanib is available only through restricted use with the Vandetanib REMS Program.

Abiraterone acetate (Zytiga, Centocor Ortho)
Pharmacology: CYP17 inhibitor.
Indication: Treatment of metastatic castration-resistant prostate cancer in patients who have received prior treatment containing docetaxel.
Adverse Drug Reactions: Joint swelling or discomfort, hypokalemia, edema, muscle discomfort, hot flush, diarrhea, urinary tract infection, cough, hypertension, arrhythmia, urinary frequency, nocturia, dyspepsia, upper respiratory tract infection.
Dose: 1,000 mg by mouth once daily on an empty stomach, along with 5 mg prednisone twice daily.
Formulation: 25-mg tablet.
Warnings/Contraindications: Contraindicated in women who are pregnant or may become pregnant. Use with caution in patients with a history of cardiac disease. Monitor blood pressure, serum potassium and symptoms of fluid retention. Increased doses of corticosteroid may be needed before, during and after stressful events. Avoid use in patients with severe hepatic impairment. Liver enzyme elevation may occur; monitor liver function and discontinue abiraterone if needed.
Notes: Do not eat two hours before and for at least one hour after abiraterone administration.

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Linagliptin (Tradjenta, Boehringer Ingelheim)
Pharmacology: DPP-4 inhibitor.
Indication: Treatment of type 2 diabetes mellitus, in addition to diet and exercise.
Adverse Drug Reactions: nasopharyngitis (>5%), increased risk of hypoglycemia when used in combination with sulfonylurea.
Dose: 5 mg by mouth once daily taken with or without food.
Formulation: 5-mg tablet.
Warnings/Contraindications: Contraindicated in patients who have a history hypersensitivity reaction to linagliptin, such as urticaria, angioedema or bronchial hyperreactivity.
Notes: Consider lowering the dose of secretagogue (e.g., sulfonylurea) to reduce the risk of hypoglycemia. Can be used during pregnancy if need is clearly indicated. Caution should be exercised in breast-feeding mothers.

Boceprevir (Victrelis, Schering)
Pharmacology: Protease inhibitor.
Indication: Treatment for chronic hepatitis C, in combination with peginterferon alfa and ribavirin, in adult patients (≥18 years of age) with compensated liver disease, including cirrhosis, who are previously untreated or who have failed previous interferon and ribavirin therapy.
Adverse Drug Reactions: Fatigue, anemia, nausea, headache, and dysgeusia when taken in conjunction with peginterferon alfa and ribavirin (>35%).
Dose: 800 mg by mouth three times daily with a meal or light snack.
Formulation: 200 mg capsule.
Warnings/Contraindications: Contraindicated in patients who also have contraindications to peginterferon alfa and ribavirin as boceprevir must be used in conjunction with these agents. Contraindications for peginterferon alfa and ribavirin include pregnant women and men whose partners are pregnant and patients who are concomitantly taking potent CYP3A4 inhibitors or other agents which are highly dependent on CYP3A4 inhibitors. Anemia and neutropenia risk is increased when boceprevir is added to peginterferon alfa and ribavirin.
Notes: Prior to initiating boceprevir, patients must receive 4 weeks of treatment with peginterferon alfa and ribavirin. Female patients should have a negative pregnancy test before initiation of therapy and must use two or more forms of contraception in addition to monthly pregnancy tests.

Rilpirivine (Edurant, Tibotec)
Pharmacology: Non-nucleoside reverse transcriptase inhibitor.
Indication: Treatment of HIV-1 infection in treatment-naïve adult patients in combination with other antiretroviral agents
Adverse Drug Reactions: Depression, insomnia, headache and rash (>2%).
Dose: 25 mg by mouth once daily with a meal.
Formulation: 25-mg tablet.
Warnings/Contraindications: Contraindicated if co-administered with other agents which may decrease rilpirivine plasma concentration, which may result in loss of virologic response and subsequent resistance. Use caution when prescribing rilpirivine with drugs known to cause torsades de pointes or with drugs known to reduce exposure of rilpirivine; use caution in depressive disorders.
Notes: Co-administration of rilpirivine with drugs that increase gastric pH (e.g., proton pump inhibitors) may decrease plasma concentrations of rilpirivine. Use in pregnancy only if potential benefit outweighs potential risk. Mothers should not breastfeed due to the potential for HIV transmission.

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Telaprevir (Incivek, Vertex Pharmaceuticals)
Pharmacology: Protease inhibitor.
Indication: Treatment of hepatitis C virus (HCV), in combination with peginterferon alfa and ribavirin, in adults with compensated liver disease, including cirrhosis, who are treatment naïve or who have been previously treated with interferon-based treatment, including prior null responders, partial responders and relapsers.
Adverse Drug Reactions: Rash, pruritus, anemia, nausea, hemorrhoids, diarrhea, anorectal discomfort, dysgeusia, fatigue, vomiting, anal pruritis.
Dose: 750 mg by mouth three times daily (7-9 hours apart) with food (not low fat).
Formulation: 375-mg tablet.
Warnings/Contraindications: All contraindications to peginterferon alfa and ribavirin also apply since telaprevir must be administered with peginterferon alfa and ribavirin. Contraindicated in pregnant patients and in males whose female partners are pregnant and in patients who are concurrently being treated with any strong CYP3A4 inducer which may lead to lower exposure and loss of efficacy. Warnings include the development of a mild to moderate rash which should be monitored for progression. Patients should also be warned about serious skin reactions including Stevens-Johnson Syndrome.
Notes: Patients must have a negative pregnancy test prior to initiating therapy, use two forms of contraception and undergo monthly pregnancy tests. Safety and efficacy have not been established in pediatric patients.

Fidaxomicin (Dificid, Optimer Pharma)
Pharmacology: Macrolide antibiotic.
Indication: Indicated in adults (≥18 years old) for the treatment of Clostridium difficile-associated diarrhea.
Adverse Drug Reactions: Nausea, vomiting, abdominal pain, gastrointestinal hemorrhage, anemia, neutropenia (2%).
Dose: 200 mg by mouth twice daily for 10 days with or without food.
Formulation: 200-mg film-coated tablet.
Warnings/Contraindications: No contraindications. Do not use fidaxomicin for systemic infections, and only use fidaxomicin for infections strongly suspected to be caused by C. difficile.
Notes: Safety and efficacy have not been established in patients <18 years of age.

Ezogabine (Potiga, Valeant Pharmaceuticals)
Pharmacology: Potassium channel opener.
Indication: Adjunctive treatment for partial-onset seizures in patients >18 years old.
Adverse Drug Reactions: Dizziness, somnolence, fatigue, confusional state, vertigo, tremor, abnormal coordination, diplopia, disturbance in attention, memory impairment, asthenia, blurred vision, gait disturbance, aphasia, and dysarthria and balance disorder.
Dose: Initial dose: 100 mg three times a day, with or without food, for one week. Then follow maintenance dose.
Maintenance dose: 200-400 mg three times a day, with or without food.
Formulation: 50-mg, 200-mg, 300-mg and 400-mg tablets.
Warnings/Contraindications: No contraindications. Warnings: Monitor for dizziness and somnolence, monitor for urinary retention in patients with urologic problems, monitor to suicidal ideation, monitor QT interval in patients who concomitantly take other medications known to prolong the interval.
Notes: Safety and efficacy in patients ≤18 have not been established. May cause fetal harm based on animal studies.

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Indacaterol maleate (Ar capita Neohaler, Novartis)
Pharmacology: Long-acting beta₂-adrenergic agonist (LABA).
Indication: Maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.
Adverse Drug Reactions: Cough, oropharyngeal pain, nasopharyngitis, headache, nausea.
Dose: 75 mcg inhaled daily.
Formulation: 75-mcg inhalation powder hard capsules.
Warnings/Contraindications: Indacaterol is indicated for treatment of COPD, not asthma. LABAs are contraindicated in patients with asthma without use of a long-term asthma control medication. Indacaterol can increase the risk of asthma-related deaths. Indacaterol should not be used for the relief of acute symptoms and should not be used more than once daily. Excessive use may result in potentially fatal cardiovascular effects; use caution in patients with cardiovascular or convulsive disorders, thyrotoxicosis, or sensitivity to sympathomimetic drugs.
Notes: Indacaterol capsules should be stored in blister packs and removed immediately before use to maintain maximal efficacy. Capsules are for inhalation only and are not to be swallowed.

Rivaroxaban (Xarelto, Johnson and Johnson)
Pharmacology: Factor Xa inhibitor.
Indication: Prophylaxis of deep vein thrombosis (DVT) which may lead to pulmonary embolism (PE) in patients undergoing knee or hip replacement surgery, and to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.
Adverse Drug Reactions: Bleeding, syncope, wound secretion, pain in extremities, muscle spasm, pruritus, blisters.
Dose: For prophylaxis of DVT post-knee or hip replacement surgery: 10 mg orally, once daily with or without food. For stroke prophylaxis in non-valvular atrial fibrillation: 20 mg once daily with evening meal (CrCl >50 mL/min), 15 mg once daily with evening meal (CrCl 15 - 50 mL/min). Avoid use in patients with CrCl <15 mL/min.
Formulation: 10-mg, 15-mg, and 20-mg tablets.
Warnings/Contraindications: Contraindicated in patients with major active bleeding. Caution in pregnant patients due to risk of obstetric hemorrhage or emergent delivery. Epidural or spinal hematomas may occur in patients who are anticoagulated and are receiving neuraxial anesthesia or undergoing spinal puncture. Consider risk when scheduling patients for spinal procedures as these hematomas may result in paralysis. Avoid use in patients with severe renal impairment and severe or moderate hepatic impairment. Use caution in patients with moderate renal impairment.
Notes: No routine monitoring required.

Ticagrelor (Brilinta, AstraZeneca)
Pharmacology: P2Y12 platelet inhibitor.
Indication: To reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome (ACS) (unstable angina, non-ST elevation myocardial infarction, or ST elevation myocardial infarction).
Adverse Drug Reactions: Bleeding, dyspnea.
Dose: Initiate treatment with 180 mg (two 90 mg tablets) oral loading dose along with an oral loading dose of aspirin (usually 325 mg). Continue treatment with 90 mg twice daily, with a daily maintenance dose of aspirin of 75-100 mg.
Formulation: 90-mg tablet.
Warnings/Contraindications: The dose of aspirin when used in combination with ticagrelor should not exceed 100 mg/day, as this has shown to decrease effectiveness. Contraindicated in patients with a history of intracranial hemorrhage, active pathological bleeding, or severe hepatic impairment. Avoid in patients with severe hepatic impairment and use cautiously in patients with moderate hepatic impairment.
Notes: Counsel patients about bleeding risk; patients should avoid other treatments that may increase risk, including prescription and non-prescription drugs. Premature discontinuation of ticagrelor increases the risk of myocardial infarction, stent thrombosis, and death.

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Vemurafenib (Zelboraf, Hoffmann La Roche)
Pharmacology: Kinase inhibitor.
Indication: Unresectable or metastatic melanoma with BRAF V600E mutation.
Adverse Drug Reactions: Arthralgia, rash, alopecia, fatigue, photosensitivity reaction, nausea, pruritus, skin papilloma.
Dose: 960 mg by mouth twice daily, 12 hours apart with a glass of water; do not chew or crush.
Formulation: 240-mg tablet.
Warnings/Contraindications: Cutaneous squamous cell carcinomas and new primary malignant melanomas have been reported; dermatologic evaluations should be performed prior to initiation of therapy and every two months while on therapy. Serious hypersensitivity and dermatologic reactions, including anaphylaxis, Stevens Johnson syndrome, and toxic epidermal necrolysis have been reported during treatment. QT prolongation has been reported; ECG and electrolytes should be monitored. Monitor liver enzymes and bilirubin before initiation of treatment and monthly during treatment. Advise patients to avoid sun exposure due to risk of photosensitivity. Monitor patients regularly for ophthalmic reactions, including uveitis, iritis and retinal vein occlusion. Advise pregnant women of potential risk to the fetus, and women should not breastfeed while taking vemurafenib.
Notes: Management of symptomatic adverse drug reactions may require dose reduction, treatment interruption, or treatment discontinuation. Detection of BRAF mutation using an FDA-approved test is required for selection of patients appropriate for vemurafenib therapy.

Icatibant acetate (Firazyr, Shire Orphan Therapies)
Pharmacology: Bradykinin B2 receptor antagonist.
Indication: Acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.
Adverse Drug Reactions: Injection site reactions, pyrexia, transaminase increase, dizziness, rash.
Dose: 30 mg injected subcutaneously in the abdominal area; additional injections of 30 mg may be administered at intervals of at least 6 hours if response is inadequate or symptoms occur. No more than 3 injections should be administered in 24 hours. Patients may self-administer upon recognition of an HAE attack.
Formulation: Prefilled 3 mL (10 mg/mL) syringe for injection.
Warnings/Contraindications: Following treatment of laryngeal attacks with icatibant, advise patients to seek immediate medical attention due to potential for airway obstruction.
Notes: Provide patient with patient information handout, which includes directions for administration.

Crizotinib (Xalkori, Pfizer)
Pharmacology: Kinase inhibitor.
Indication: Locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.
Adverse Drug Reactions: Vision disorder, nausea, diarrhea, vomiting, edema, constipation.
Dose: 250 mg by mouth twice daily with or without food. Dosing interruption and/or dose reduction to 200 mg twice daily may be required based on individual safety and tolerability; further reduction to 250 mg once daily may be necessary.
Formulation: 200-mg and 250-mg capsules.
Warnings/Contraindications: Severe, including fatal, treatment-related pneumonitis has been observed. Monitor patients for pulmonary symptoms and permanently discontinue in patients diagnosed with treatment-related pneumonitis. Monitor monthly for elevations in ALT and total bilirubin. May cause QT prolongation; periodically monitor electrolytes and ECG. Detection of ALK-positive NSCLC using an FDA-approved test is necessary for selection of patients for treatment with crizotinib. Can cause fetal harm when administered to pregnant women.
Notes: Ocular disturbances can occur with crizotinib; patients should inform their physician if any floaters or flashes are noticed. Avoid grapefruit or grapefruit juice while taking crizotinib. Patients of childbearing potential must use adequate contraceptive methods during therapy and for at least 90 days after completing therapy.

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Deferiprone (Ferriprox, Apopharma)
**Pharmacology:** Iron chelator.
**Indication:** Treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate.
**Adverse Drug Reactions:** Chromaturia, nausea, vomiting, abdominal pain, increased alanineaminotransferase, arthralgia, neutropenia.
**Dose:** 25 mg/kg to 33 mg/kg by mouth three times daily, for a total daily dose of 75 mg/kg to 99 mg/kg.
**Formulation:** 500-mg film-coated tablet with a functional score.
**Warnings/Contraindications:** Deferiprone has a black box warning for agranulocytosis that can lead to serious infections. Neutropenia can precede the development of agranulocytosis. Absolute neutrophil count (ANC) should be measured before initiation and during therapy with deferiprone. Deferiprone can cause fetal harm in pregnant women. If infection occurs while on deferiprone, interrupt therapy and monitor the ANC more frequently.
**Notes:** Taking deferiprone with meals may reduce nausea. Patients may experience a reddish/brown urine discoloration due to the excretion of the iron-deferiprone complex. Although deferiprone has been proven to reduce serum ferritin levels, it has not demonstrated a direct treatment benefit.

Clobazam (Onfi, Lundbeck)
**Pharmacology:** Benzodiazepine.
**Indication:** Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age or older.
**Adverse Drug Reactions:** Somnolence or sedation, drooling, constipation, cough, urinary tract infection, aggression, insomnia, dysarthria, fatigue.
**Dose:** ≤30 kg body weight: Initiate therapy at 5 mg daily; titrate as tolerated up to 20 mg daily. >30 kg body weight: Initiate therapy at 10 mg daily; titrate as tolerated up to 40 mg daily. Doses above 5 mg/day should be administered in two divided doses.
**Formulation:** 5-mg, 10-mg, or 20-mg tablets.
**Warnings/Contraindications:** Monitor patient for somnolence or sedation; risk may be increased in patients receiving other CNS depressants. Clobazam should be tapered for discontinuation due to risk of withdrawal. Patients with a history of substance abuse should be monitored for signs of habituation and dependence. Patients should be monitored for suicidal behavior and ideation.
**Notes:** Tablets can be administered whole or crushed and mixed in applesauce. Elderly patients, poor CYP2C19 metabolizers, and those with hepatic impairment require dosage adjustment. Women using hormonal contraception should be advised to use a non-hormonal method. A medication guide should be dispensed with clobazam.

Ruxolitinib (Jakafi, Incyte Corporation)
**Pharmacology:** Janus kinase (JAK) inhibitor.
**Indication:** Treatment of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia (post-ET) myelofibrosis.
**Adverse Drug Reactions:** Dizziness, headache, bruising, increased cholesterol, anemia, thrombocytopenia, neutropenia, increased ALT and AST, weight gain, flatulence, urinary tract infection, herpes zoster infection.
**Dose:** Initial dose (based on platelet count, titrate dose thereafter based on efficacy and safety): Platelets >200 x 10^9/L: 20 mg by mouth twice daily; platelets 100 – 200 x 10^9/L: 15 mg twice daily. All dosage modifications should be based on response. The dosage should not be increased during the initial 4 weeks and no more frequently than every 2 weeks. Maximum daily dosage: 50 mg.
**Formulation:** 5-mg, 10-mg, 15-mg, 20-mg, and 25-mg tablets.
**Warnings/Contraindications:** No contraindications. Dosage adjustments may be required for renal/hepatic impairment. There is a potential for CYP3A4 mediated interactions. Dosage adjustments may be necessary. Treatment should be discontinued if there is no reduction in spleen size or improvement by 6 months.
**Notes:** Patients should be monitored for signs and symptoms of infection.

(Back to New Molecular Entities table)
**Belimumab (Benlysta, Human Genome Sciences)**

**Pharmacology:** B-lymphocyte stimulator (BLYS)-specific inhibitor.

**Indication:** Treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy.

**Adverse Drug Reactions:** Nausea, diarrhea, pyrexia, nasopharyngitis, bronchitis, insomnia, pain in the extremities, depression, migraine, pharyngitis.

**Dose:** 10 mg/kg administered as an IV infusion over 1 hour at 2-week intervals for the first 3 doses and at 4-week intervals thereafter.

**Formulation:** Single-use vials of lyophilized powder for reconstitution, dilution, and IV infusion: 120 mg in a 5 mL single-use vial; 400 mg in a 20 mL single-use vial.

**Warnings/Contraindications:** More deaths were reported with belimumab than with placebo during clinical trials. Serious infections have been reported in patients receiving immunosuppressive agents. Use caution in patients with chronic infections. Hypersensitivity reactions, depression, and suicidality have been reported. Live vaccines should not be given concurrently with belimumab. Contraindications include previous anaphylaxis to belimumab.

**Notes:** The efficacy of belimumab has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. It has also not been studied in combination with other biologics or IV cyclophosphamide. Store vials refrigerated between 2° and 8°C.

**Ipilimumab (Yervoy, Bristol-Myers Squibb)**

**Pharmacology:** Human cytotoxic T-lymphocyte antigen 4 (CTLA-4) blocking antibody.

**Indication:** Treatment of unresectable or metastatic melanoma.

**Adverse Drug Reactions:** Fatigue, diarrhea, pruritus, rash, colitis.

**Dose:** 3 mg/kg administered IV over 90 minutes every three weeks for a total of four doses.

**Formulation:** Single-use vials of 50 mg/10 mL and 200 mg/40 mL.

**Warnings/Contraindications:** Immune-mediated adverse reactions involving any organ system can occur and warrant discontinuation of therapy. There are no contraindications at this time.

**Notes:** Monitor immune-mediated adverse events and evaluate liver function tests, thyroid function tests, and clinical chemistry panels prior to each dose.

**Belatacept (Nulojix, Bristol-Myers Squibb)**

**Pharmacology:** Selective T-cell costimulation blocking antibody.

**Indication:** Organ rejection prophylaxis in adults receiving a kidney transplant.

**Adverse Drug Reactions:** Diarrhea, nausea, vomiting, urinary tract infection, peripheral edema, constipation, hypertension, pyrexia, graft dysfunction, anemia, hypokalemia, hyperkalemia, leukopenia, cough.

**Dose:** Administered as a 30-minute IV infusion. Initial phase: 10 mg/kg on day 1 and day 5, end of weeks 2 and 4, and end of week 8 and 12; maintenance phase: 5 mg/kg at end of week 16 and every 4 weeks thereafter.

**Formulation:** Lyophilized powder for injection, 250 mg per vial.

**Warnings/Contraindications:** Boxed warnings: increased risk of developing post-transplant lymphoproliferative disorder (PTLD), often of CNS origin, especially in patients without immunity to Epstein-Barr virus (EBV); increased susceptibility to infection and malignancies; not indicated for use in liver transplant patients due to increased risk of graft loss and death. Contraindicated in patients who are EBV seronegative and those whose EBV status is unknown.
Notes: Due to the risk of PTLD, patients should report any neurological, cognitive, and behavioral changes to their physician. Use of live vaccines should be avoided during belatacept therapy.

**Brentuximab vedotin (Adcetris, Seattle Genetics)**

**Pharmacology:** CD30-directed antibody-drug conjugate.

**Indication:** Treatment of Hodgkin lymphoma after failure of autologous stem cell transplant (ASCT) or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates; treatment of systemic anaplastic large cell lymphoma after failure of at least one prior multi-agent chemotherapy regimen.

**Adverse Drug Reactions:** Neutropenia, peripheral sensory neuropathy, fatigue, nausea, anemia, upper respiratory tract infection, diarrhea, pyrexia, rash, thrombocytopenia, cough, vomiting.

**Dose:** 1.8 mg/kg administered as an IV infusion over 30 minutes every 3 weeks. Continue treatment for a maximum of 16 cycles or until disease progression or unacceptable toxicity occurs.

**Formulation:** 50-mg single-use vial.

**Warnings/Contraindications:** Precautions include peripheral neuropathy, infusion reactions, neutropenia, tumor lysis syndrome, Stevens Johnson syndrome, and progressive multifocal leukoencephalopathy (PML) and should be monitored accordingly. Fetal harm can occur if used during pregnancy.

**Notes:** Advise patients to contact their health care provider if a fever of 100.5˚F or greater or other evidence of potential infection such as chills, cough, or pain on urination develops.

**Asparaginase Erwinia chrysanthemi (Erwinaze, EUSA Pharma)**

**Pharmacology:** Antineoplastic agent.

**Indication:** Acute lymphoblastic leukemia.

**Adverse Drug Reactions:** Allergic reaction/hypersensitivity (includes anaphylaxis, urticaria), thrombosis, fever, glucose intolerance, hyperglycemia, pancreatitis, nausea, vomiting, coagulation abnormalities, increased transaminases.

**Dose:** As a substitute for pegaspargase: 25,000 units/m² 3 times/week (Mon, Wed, Fri) for 6 doses for each planned pegaspargase dose. As a substitute for asparaginase (E. coli): 25,000 units/m² for each planned asparaginase (E. coli) dose.

**Formulation:** 10,000 int. units (contains glucose 5 mg/vial).

**Warnings/Contraindications:** History of serious hypersensitivity reactions, including anaphylaxis to asparaginase (Erwinia) or any component of the formulation; history of serious pancreatitis, serious thrombosis, or serious hemorrhagic event with prior asparaginase treatment.

**Notes:** Volume at each injection site should be no more than 2 mL; multiple injections are required for volumes >2 mL. Doses should be withdrawn into a polypropylene syringe within 15 minutes of reconstitution. Reconstituted solutions should not be frozen or refrigerated and should be discarded if not administered within 4 hours. Erwinaze™ is distributed through Accredo Health Group (1-877-900-9223).

**Afiblercept (Eylea, Regeneron Pharmaceuticals)**

**Pharmacology:** VEGF inhibitor.

**Indication:** Treatment of neovascular (wet) age-related macular degeneration (AMD).

**Adverse Drug Reactions:** Conjunctival hemorrhage, injection site pain, eye pain, cataract, vitreous detachment, vitreous floaters, increased intraocular pressure, conjunctival hyperemia, corneal erosion, foreign body sensation, increased lacrimation, retinal pigment epithelium detachment, blurred vision, retinal pigment epithelium tear.

**Dose:** Intravitreal injection: 2 mg (0.05 mL) every 4 weeks for 3 months then every 8 weeks thereafter. Formulation: 40 mg/mL (0.05 mL); derived from or manufactured using Chinese hamster ovary cells.

**Warnings/Contraindications:** Hypersensitivity to afiblercept or any component of the formulation; current ocular or periocular infection; active intraocular inflammation.

**Notes:** Administer with supplied needles and syringes according to package instructions. Adequate anesthesia and a broad-spectrum antimicrobial agent should be administered prior to the procedure.

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### New Drug Formulations / Combinations of 2011

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**Fentanyl (Abstral, ProStrakan)**

**Pharmacology:** mu- and kappa-opiate receptor agonist.

**Indication:** Management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and are tolerant to opioid therapy.

**Dose:** First episode: one 100 mcg sublingual tablet. An additional 100 mcg tablet may be taken 30 minutes after the previous dose was given. Do not use more than 2 doses per episode. Two hours must elapse before treating another episode. The dose may be increased by 100 mcg/episode up to 400 mcg, over consecutive breakthrough episodes until adequate analgesia is attained.

**Formulation:** 100-mcg, 200-mcg, 300-mcg, 400-mcg, 600-mcg, 800-mcg sublingual tablets.
Gabapentin (Gralise, Depomed)
Pharmacology: Exact mechanism of action is unknown, but does not act at GABA receptors.
Indication: Postherpetic neuralgia pain in adults 18 years old and older.
Dose: Titrate to an 1800 mg dose taken once daily with the evening meal as follows: Day 1: 300 mg, Day 2: 600 mg, Days 3-6: 900 mg, Days 7-10: 1200 mg, Days 11-14: 1500 mg, Day 15: 1800 mg.
Formulation: 300-mg and 600-mg extended-release tablets.

Omeprazole; clarithromycin; amoxicillin (DAVA Pharmaceuticals)
Pharmacology: Proton pump inhibitor (omeprazole), protein synthesis inhibitor antibiotic (clarithromycin), and cell wall inhibitor antibiotic (amoxicillin).
Indication: Eradication of Helicobacter pylori in patients with active duodenal ulcer or history of duodenal ulcer.
Dose: Omeprazole 20 mg, clarithromycin 500 mg, and amoxicillin 1000 mg twice daily for 10 days.
Formulation: Omeprazole delayed-release 20 mg capsule, clarithromycin 500 mg tablet, and amoxicillin 500 mg capsule.

Rufinamide (Banzel, Eisai)
Pharmacology: Precise antiepileptic mechanism is unknown. Studies suggest principal mechanism is modulation of sodium channels and prolongation of the inactive state of the channel.
Indication: Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in children 4 years of age and older and adults.
Dose: Children 4 years and older: Treatment should be initiated at a daily dose of approximately 10 mg/kg/day administered in two equally divided doses. The dose should be increased by approximately 10 mg/kg increments every other day to a target dose of 45 mg/kg/day or 3200 mg/day, whichever is less, administered in two equally divided doses. Adults: Initiate treatment at a daily dose of 400-800 mg/day administered in two equally divided doses. The dose should be increased by 400-800 mg every other day until a maximum dose of 3200 mg/day, administered in two equally divided doses, is reached.
Formulation: 200-mg, 400-mg film-coated tablets; 40 mg/mL oral suspension.

Nevirapine (Viramune XR, Boehringer Ingelheim)
Pharmacology: Non-nucleoside reverse transcriptase inhibitor (NNRTI).
Indication: Treatment of HIV-1 infection in adults in combination with other antiretroviral agents.
Dose: Adult patients must initiate therapy with one 200 mg tablet of immediate-release nevirapine once daily for the first 14 days, followed by one 400 mg tablet of nevirapine extended-release once daily. Adult patients already receiving immediate-release nevirapine twice daily can be switched to nevirapine extended-release 400 mg once daily without the 14 day lead-in phase.
Formulation: 400-mg extended-release tablet.

Loteprednol etabonate (Lotemax, Bausch and Lomb)
Pharmacology: Corticosteroid.
Indication: Treatment of post-operative inflammation and pain following ocular surgery.
Dose: Apply a small amount into the conjunctival sac four times daily starting 24 hours after surgery. Continue throughout the first 2 weeks of the post-operative period.
Formulation: Ophthalmic ointment 0.5%.

Calcium acetate (Phoslyra, Fresenius)
Pharmacology: Phosphate binder.
Indication: Reduction of serum phosphorus in patients with end stage renal disease.
Dose: Recommended starting dose is 10 mL with each meal, then titrate dose every 2 to 3 weeks until acceptable serum phosphorus level is reached.
Formulation: Oral solution containing 667 mg calcium acetate per 5 mL.

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Famotidine; ibuprofen (Duexis, Horizon Pharmaceuticals)
Pharmacology: NSAID (ibuprofen) and H-2 receptor antagonist (famotidine).
Indication: Relief of signs and symptoms of rheumatoid arthritis and osteoarthritis while decreasing the risk of developing upper gastrointestinal ulcers.
Dose: One tablet by mouth three times a day.
Formulation: 800 mg ibuprofen/26.6 mg famotidine tablet.

Testosterone (Androgel, Abbott Products)
Pharmacology: Androgen replacement in the absence of endogenous testosterone.
Indication: Treatment of primary hypogonadism and hypogonadotropic hypogonadism (both congenital or acquired) in the absence of endogenous testosterone.
Dose: Starting dose: 2 pump actuations (40.5 mg testosterone total dose) applied once daily in the morning. Dose adjustment is 1 pump actuation (20.25 mg testosterone). Maximum daily dose should not exceed 4 pump actuations (81 mg).
Formulation: 1% gel for topical administration.

Hydrocodone, chlorpheniramine, pseudoephedrine (Zutripro, Cypress Pharmaceuticals)
Pharmacology: Mu opioid receptor agonist with antitussive effects and respiratory drying effects (hydrocodone); H-1 receptor antagonist which suppresses the formation of edema and pruritis (chlorpheniramine); alpha agonist that exerts an decongestant action on the nasal mucosa (pseudoephedrine).
Indication: Relief of cough and nasal congestion associated with the common cold and upper respiratory allergies.
Dose: 5 mL every 4 to 6 hours as needed. Maximum daily dose not to exceed 20 mL in 24 hours.
Formulation: Grape-flavored oral solution containing 5 mg hydrocodone, 4 mg chlorpheniramine and 60 mg pseudoephedrine per 5 mL.

Hydrocodone; pseudoephedrine (Rezira, Cypress Pharmaceuticals)
Pharmacology: Mu opioid receptor agonist with antitussive effects and respiratory drying effects (hydrocodone); alpha agonist which exerts an decongestant action on the nasal mucosa (pseudoephedrine).
Indication: Relief of cough and nasal congestion associated with the common cold.
Dose: 5 mL every 4 to 6 hours as needed. Maximum daily dose not to exceed 20 mL in 24 hours.
Formulation: Grape-flavored oral solution containing 5 mg hydrocodone and 60 mg pseudoephedrine per 5 mL.

Phentermine hydrochloride (Suprenza, Citius Pharmaceuticals)
Pharmacology: Sympathomimetic amine anorectic.
Indication: Short-term (a few weeks) adjunct in a regimen of weight reduction for obese patients (body mass index ≥30 kg/m², or ≥27 kg/m² in the presence of other risk factors) including exercise, behavioral modification and caloric restriction.
Dose: Use lowest effective dose to obtain adequate response. Usual dose is one tablet daily taken in the morning, with or without food.
Formulation: 15-mg and 30-mg orally disintegrating tablets.

Nitroglycerin (Rectiv, ProStrakan)
Pharmacology: Nitrate vasodilator.
Indication: Treatment of moderate to severe pain associated with chronic anal fissure.
Dose: One inch of ointment (375 mg of ointment equivalent to 1.5 mg of nitroglycerin) applied intra-anally every 12 hours up to 3 weeks.
Formulation: 0.4% w/w ointment (4 mg nitroglycerin per 1 g ointment).

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**Morphine sulfate (Morphine sulfate, Lannett Holdings)**

**Pharmacology:** Opioid analgesic.

**Indication:** Management of moderate to severe acute and chronic pain in opioid-tolerant patients.

**Dose:** 10 mg to 20 mg every four hours as needed. Verify prescribed dose in both milligrams and milliliters. Administer with supplied calibrated oral syringe.

**Formulation:** 20 mg/mL oral solution.

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**Fentanyl citrate (Lazanda, Archimedes)**

**Pharmacology:** Opioid analgesic.

**Indication:** Management of breakthrough pain in cancer patients, >18 years of age, who are already receiving and who are tolerant to opioid therapy for persistent cancer pain.

**Dose:** Initial dose, 100 mcg; titrate to effective dose, up to 800 mcg daily. Maximum dose is 1 spray per nostril for each episode; no more than four doses per 24 hours. Wait at least 2 hours between doses. During any episode, if adequate analgesia is not achieved within 30 minutes, rescue pain medication may be administered as directed by the healthcare provider.

**Formulation:** Nasal spray, 100 mcg/spray or 400 mcg/spray. Supplied in 5 mL bottle containing 8 sprays.

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**Gemcitabine hydrochloride (Gemcitabine, Hospira)**

**Pharmacology:** Nucleoside antimetabolite.

**Indication:** Ovarian cancer in combination with carboplatin, breast cancer in combination with paclitaxel, non-small cell lung cancer (NSCLC) in combination with cisplatin, and pancreatic cancer as a single-agent.

**Dose:** Ovarian cancer: 1000 mg/m² over 30 minutes on Days 1 and 8 of each 21-day cycle; breast cancer: 1250 mg/m² over 30 minutes on Days 1 and 8 of each 21-day cycle; NSCLC: 4-week schedule: 1000 mg/m² over 30 minutes on Days 1, 8, and 15 of each 28-day cycle; 3-week schedule: 1250 mg/m² over 30 minutes on Days 1 and 8 of each 21-day cycle; pancreatic cancer: 1000 mg/m² over 30 minutes once weekly for up to 7 weeks (or until toxicity necessitates reducing or holding a dose), followed by a week of rest from treatment.

**Formulation:** 200 mg/5.26 mL injection vial; 1 g/26.3 mL injection vial; 2 g/52.6 mL injection vial

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**Emtricitabine, rilpivirine, tenofovir disoproxil fumarate (Complera, Gilead Sciences)**

**Pharmacology:** Combination of two nucleoside analog HIV-1 reverse transcriptase inhibitors (emtricitabine and tenofovir disoproxil fumarate) and one non-nucleoside reverse transcriptase inhibitor (rilpivirine).

**Indication:** Complete regimen for the treatment of HIV-1 infection in treatment-naive adults.

**Dose:** One tablet taken once daily with a meal.

**Formulation:** 200-mg emtricitabine, 25-mg rilpivirine, and 300-mg tenofovir disoproxil fumarate tablet.

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**Tapentadol hydrochloride (Nucynta ER, Ortho McNeil Janssen)**

**Pharmacology:** Opioid analgesic.

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

**Dose:** 100 mg to 250 mg twice daily approximately every 12 hours not to exceed the maximum daily dose of 500 mg. Patients not currently taking opioid analgesics should begin Nucynta ER therapy with 50 mg twice a day. The dosing regimen of Nucynta ER should be individualized according to the severity of pain being treated, the previous experience with similar drugs and the ability to follow-up and provide oversight of treatment. Patients receiving Nucynta (immediate-release formulation) may be converted to Nucynta ER by administering the same total daily dose.

**Formulation:** 50-mg, 100-mg, 150-mg, 200-mg, 250-mg extended-release tablets

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**Fluoxetine (Fluoxetine, Edgemont Pharmaceuticals)**

**Pharmacology:** Selective serotonin reuptake inhibitor.

**Indication:** Major depressive disorder (MDD), obsessive compulsive disorder (OCD), bulimia nervosa, and panic disorder, with or without agoraphobia.

**Dose:**
- **MDD:** 20 mg/day in the morning as initial and target dose with a maximum of 80 mg/day in adults; 10-20 mg daily in patients ages 8-18.
- **OCD:** 20 mg/day in the morning initially, increasing to target of 20-60 mg/day; 10 mg/day initially in patients ages 7-17, increasing to 10-60 mg/day as target.
- **Bulimia nervosa:** 60 mg/day in the morning.
- **Panic disorder:** 10 mg/day as the initial dose, increasing to a target of 20 mg/day, with a maximum dose of 60 mg/day.

**Formulation:** 60-mg functionally scored tablet.

**Ipratropium bromide: albuterol sulfate** *(Combivent Respimat, Boehringer Ingelheim)*

**Pharmacology:** Combination of an anti-cholinergic (ipratropium) and beta2-adrenergic agonist (albuterol).

**Indication:** Patients with chronic obstructive pulmonary disease on a regular aerosol bronchodilator who continue to have evidence of bronchospasm and who require a second bronchodilator.

**Dose:** One inhalation four times a day, not to exceed six inhalations in 24 hours.

**Formulation:** 20 mcg ipratropium bromide and 100 mcg albuterol per actuation.

**Sitagliptin phosphate: simvastatin** *(Juvisync, Merck Sharp Dohme)*

**Pharmacology:** Dipeptidyl peptidase-4 (DPP-4) inhibitor (sitagliptin) and HMG-CoA reductase inhibitor (simvastatin).

**Indication:** *Sitagliptin:* adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. *Simvastatin:* adjunct to diet to reduce CHD deaths and risk of non-fatal myocardial infarction, stroke, and revascularization procedures in patients at high risk of coronary events; reduce elevated total-C, LDL-C, Apo B, TG and increase HDL-C in patients with primary hyperlipidemia and mixed dyslipidemia; reduce elevated TG in patients with hypertriglyceridemia and reduce TG and VLDL-C in patients with primary dysbetalipoproteinemia; and reduce total-C and LDL-C in adult patients with homozygous familial hypercholesterolemia.

**Dose:**
- 100 mg/10 mg, 100 mg/20 mg, or 100 mg/40 mg once daily in the evening.

**Formulation:** Sitagliptin/simvastatin 100 mg/10 mg, 100 mg/20 mg, and 100 mg/40 mg tablets.

**Bupivacaine liposome** *(Exparel, Pacira Pharmaceuticals)*

**Pharmacology:** Local anesthetic.

**Indication:** Single-dose infiltration into the surgical site to produce postsurgical analgesia.

**Dose:** Based on the surgical site and the volume required to cover the area. Bunionectomy: dose of 106 mg, volume of 8 mL; hemorrhoidectomy: dose of 266 mg, volume of 20 mL.

**Formulation:** 10 mL single use vial, 1.3% (13.3 mg/mL) and 20 mL single use vial, 1.3% (13.3 mg/mL).

**Levetiracetam** *(Levetiracetam in sodium chloride Injection, HQ Specialty Pharma)*

**Pharmacology:** Antiepileptic.

**Indication:** Partial onset seizure, myoclonic seizures in patients with juvenile myoclonic epilepsy, and partial generalized tonic-clonic seizures when oral administration is temporarily not feasible, in adults ages 16 and older.

**Dose:**
- **Partial onset seizures:** Initial dose is 1000 mg/day, divided as 500 mg twice daily; increase dose as needed and tolerated in increments of 1000 mg/day, every 2 weeks to maximum daily dose of 3000 mg.
- **Myoclonic seizures in patients with juvenile myoclonic epilepsy:** Initial dose is 1000 mg/day, divided as 500 mg twice daily; increase dose by 1000 mg/day every 2 weeks to the recommended daily dose of 3000 mg.
- **Primary generalized tonic-clonic seizures:** Initial dose is 1000 mg/day, divided as 500 mg twice daily; increase dose by 1000 mg/day every 2 weeks to the recommended daily dose of 3000 mg. Efficacy of doses <3000 mg/day has not been studied. Administer dose-specific 100 mL bag intravenously over 15-minutes; do not dilute.

**Formulation:** Single-use 100 mL bags for injection: levetiracetam in 0.82 % sodium chloride (500 mg/100 mL); levetiracetam in 0.75 % sodium chloride (1000 mg/100 mL); levetiracetam in 0.54% sodium chloride (1500 mg/100 mL).

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Bupropion hydrochloride (Forfivo XL, IntelGenx)
Pharmacology: Aminoketone antidepressant.
Indication: Major depressive disorder.
Dose: 450 mg once daily without regard to food. Swallow the tablet whole.
Formulation: 450-mg extended-release tablets.

Zolpidem tartrate (Intermezzo, Transcept Pharmaceuticals)
Pharmacology: GABA agonist.
Indication: Insomnia when a middle-of-the night awakening is followed by difficulty returning to sleep.
Dose: 1.75 mg for women and 3.5 mg for men, taken only once per night, if needed.
Formulation: 1.75-mg and 3.5-mg sublingual tablets.

Darunavir (Prezista, Tibotec):
Pharmacology: Protease inhibitor.
Indication: Treatment of HIV-1 infection in adults and pediatric patients greater than 3 years of age.
Dose: Adults: Treatment naïve and experienced adults without darunavir resistance associated substitution: 800 mg taken with ritonavir 100 mg once daily with food. Treatment experienced adults with at least one darunavir resistance associated substitution: 600 mg taken with ritonavir 100 mg twice daily with food. Pediatric (3-18 years of age and weighing at least 10kg): Do not use once daily dosing. Darunavir suspension should be taken with ritonavir oral solution (80 mg/mL) twice daily with food. Children ≥6 years and adolescents ≥40 kg (with ritonavir 100 mg): 600 mg twice daily. Children ≥6 years and adolescents ≥30 kg and <40 kg (with ritonavir 60 mg): 450 mg twice daily. Children ≥6 years and adolescents ≥15 kg and <30 kg (with ritonavir 50 mg): 375 mg twice daily. Children 3 to <6 years weighing 14 kg to <15 kg (with ritonavir 48 mg): 280 mg twice daily. Children 3 to <6 years weighing 12 kg to <14 kg (with ritonavir 40 mg): 260 mg twice daily. Children 3 to <6 years weighing 10 kg to <12 kg (with ritonavir 32 mg): 220 mg twice daily. Children 3 to <6 years weighing 10 kg to <11 kg (with ritonavir 32 mg): 200 mg twice daily.
Formulation: 100 mg/mL oral suspension. Do not refrigerate.

Azilsartan medoxomil; chlorthalidone (Edarbyclor, Takeda):
Pharmacology: Angiotensin II receptor blocker (azilsartan) and thiazide-like diuretic (chlorthalidone).
Indication: Hypertension.
Dose: Initial dose: 40 mg/12.5 mg once daily. Dose may be increased to 40mg/25mg after 2-4 weeks as needed to achieve goal blood pressure.
Formulation: 40 mg/12.5 mg and 40 mg/25 mg tablets.

Ibuprofen, phenylephrine HCL, chlorpheniramine maleate (Advil Allergy and Congestion Relief, Pfizer Consumer Healthcare):
Pharmacology: Over-the-counter allergy and congestion formulation.
Indication: Temporary relief of symptoms associated with hay fever, respiratory allergies, or the common cold.
Dose: Dosage information not currently available.
Formulation: 200 mg/10 mg/4 mg oral tablet.

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**Raltegravir (Isentress, Merck Sharp Dohme):**

**Pharmacology:** Integrase inhibitor.

**Indication:** Treatment of HIV-1 infection in combination with other antiretrovirals in pediatric patients 2 to 12 years of age and weighing at least 10 kg.

**Dose:** Weight based to a maximum dose of 300 mg twice daily. For patients 2 to 12 years of age weighing 10 to <14 kg: 75 mg twice daily; 14 to <20 kg: 100 mg twice daily; 20 to <28 kg: 150 mg twice daily; 28 to <40 kg: 200 mg twice daily; ≥40 kg: 300 mg twice daily.

**Formulation:** 100 mg scored and 25 mg chewable oral tablets. May be chewed or swallowed whole. Do not substitute chewable tablets for the 400 mg film-coated tablet.

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