CENTER FOR HEALTHCARE INNOVATION AND PATIENT OUTCOMES RESEARCH

McWHORTER SCHOOL OF PHARMACY SAMFORD UNIVERSITY
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NEW DRUG FAX SHEET

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This issue of *New Drug FAX Sheet* briefly reviews topics that include new drug approvals, new drug formulations, and new drug indications. If you need further information, please contact the Center for Healthcare Innovation and Patient Outcomes Research (CHIPOR) at chipor@samford.edu.

NEW DRUG APPROVALS

Oxycodone Hydrochloride and Naltrexone Hydrochloride (Troxyca ER, Pfizer Inc.)

Pharmacology: Opioid agonist/opioid antagonist combination product.
Indication: Management of severe pain, requiring daily, long-term opioid therapy and for which no other alternative therapy is available.
Adverse Drug Reactions: Nausea, constipation, vomiting, headache, somnolence.
Dose: 10mg/1.2mg, 20mg/2.4mg, 30mg/3.6mg, 40mg/4.8mg, 60mg/7.2mg, 80mg/9.6mg capsules.
Formulation: Extended-release capsules for oral use.
Warnings/Contraindications: Risks of addiction, misuse, abuse, and fatal respiratory depression. Contraindicated in patients with significant respiratory depression, gastrointestinal obstruction, bronchial asthma without access to resuscitative equipment, and hypersensitivity to oxycodone or naltrexone.
Notes: Prolonged use in pregnancy can result in neonatal opioid withdrawal syndrome. Concomitant use with CYP3A4 inhibitors, or the discontinuation of CYP3A4 inducers can result in a fatal overdose. When discontinuing the product, taper dose by 25-50% every 2-4 days. Capsules should be swallowed intacted or sprinkled over applesauce.

Etanercept-szzs (Erelzi, Sandoz Inc.)

Pharmacology: Biosimilar of the biologic product, etanercept (Enbrel).
Indication: Rheumatoid arthritis, polyarticular juvenile idiopathic arthritis in patients aged 2 years and older, psoriatic arthritis, ankylosing spondylitis, plaque psoriasis.
Adverse Drug Reactions: Infections and injection site reactions.
Dose: 50 mg once weekly administered subcutaneously for all indications except plaque psoriasis and juvenile idiopathic arthritis; 50 mg twice weekly for 3 months for plaque psoriasis, followed by 50 mg once weekly; weight-based dosing for juvenile idiopathic arthritis of 0.8 mg/kg once weekly with a maximum dose of 50 mg once weekly.
Formulation: Subcutaneous injection as 25 mg/0.5mL and 50 mg/mL prefilled syringes.
Warnings/Contraindications: Increased risk for developing infections that may lead to hospitalization or death.
Notes: Live vaccines should not be given with this product. Test and treat latent tuberculosis prior to initiation. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections prior to initiation.

NEW DRUG FORMULATIONS

Granisetron (Sustol, Heron Therapeutics)

Pharmacology: Selective serotonin 5-hydroxytryptamine$_3$ (5-HT$_3$) receptor antagonist.
Indication: In combination with other antiemetics for the prevention of nausea and vomiting associated with moderately emetogenic chemotherapy or anthracycline and cyclophosphamide combination therapy.
Dosage form: Extended release subcutaneous injection as 10 mg/0.4 mL prefilled syringe.
Dose: 10 mg administered subcutaneously; dose may not be repeated more frequently than 7 days apart

Palonosetron Hydrochloride (Palonosetron Hydrochloride, Excela Pharma SCS LLC)

Pharmacology: Selective serotonin 5-hydroxytryptamine$_3$ (5-HT$_3$) receptor antagonist.
Indication: Prevention of nausea and vomiting associated with moderately and highly emetogenic chemotherapy.
Dosage form: Intravenous injection as a 2 mg (0.125 mg/mL) single-dose vial.
Dose: 0.25 mg administered intravenously.

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NEW DRUG INDICATIONS

Pembrolizumab (Keytruda, Merck Sharpe, and Dohme Corp.)

Pharmacology: Antineoplastic, anti (programmed cell death-1) PD-1 monoclonal antibody.

New Indication: Recurrent head and neck squamous cell carcinoma (HNSCC) with disease progression on or after platinum-containing chemotherapy.

Dose: 200 mg administered intravenously over 30 minutes every 3 weeks.