NEW DRUG FAX SHEET

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Volume 18 (Issue 7)  
February 18, 2013

This issue of New Drug FAX Sheet briefly reviews topics that include new drug approvals, new drug formulations, and new drug indications for January 2013. If you need further information, please contact the Samford University Global Drug Information Service at (205) 726-2659.

NEW DRUG APPROVALS

Alogliptin (Nesina, Takeda Pharms USA)
Pharmacology: Dipeptidyl peptidase-4 (DPP-4) inhibitor

Indication: Adjunctive therapy to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Adverse Drug Reactions: The most common adverse reactions include: nasopharyngitis, headache, and upper respiratory infections.

Dose: The recommended dose is 25 mg orally once daily.

Formulation: Available as 6.25-mg, 12.5-mg, and 25-mg tablets.

Warnings/Contraindications: Alogliptin has the potential to elevate serum alanine aminotransferase and has been associated with both fatal and non-fatal hepatic failure. It is important to measure baseline liver function and to use caution in patients with abnormal liver tests.

Notes: There have been reports of acute pancreatitis associated with alogliptin, therefore it is important to monitor patients for initial signs and symptoms. If pancreatitis is suspected, it is important to discontinue alogliptin and initiate appropriate management.

Alogliptin; Metformin hydrochloride (Kazano, Takeda Pharms USA)
Pharmacology: Dipeptidyl peptidase-4 (DPP-4) inhibitor and a biguanide combination product

Indication: Adjunctive therapy to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Adverse Drug Reactions: The most common adverse reactions include: upper respiratory tract infection, nasopharyngitis, diarrhea, hypertension, headache, back pain, and urinary tract infection.

Dose: Individualize the starting dose based on the patient’s current regimen. Doses may be adjusted on effectiveness and tolerability while not exceeding the maximum recommended daily dose of 25 mg of alogliptin and 2000 mg of metformin HCl.

Formulation: Available in fixed dose combination tablets in various strengths including: 12.5 mg/500 mg metformin HCl and 12.5 mg/1000 mg metformin HCl.

Warnings/Contraindications: Black box warning for lactic acidosis due to accumulation of metformin. Use is contraindicated in patients with renal impairment (SCr > 1.5 mg/dL in men, SCr > 1.4 mg/dL in women) and acute or chronic metabolic acidosis.

Notes: Temporarily discontinue in patients undergoing radiologic studies requiring IV administration of iodinated contrast materials or any procedure requiring restricted food or fluid intake.

Alogliptin; Pioglitazone (Oseni, Takeda Pharms USA)
Pharmacology: Dipeptidyl peptidase-4 (DPP-4) inhibitor and thiazolidinedione combination product

Indication: Adjunctive therapy to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Adverse Drug Reactions: The most common adverse reactions include: nasopharyngitis, back pain, and upper respiratory infection.

Dose: The recommended dose is to be based on patient’s current regimen and concurrent medical condition but not to exceed a daily dose of alogliptin 25 mg and pioglitazone 45 mg.

Formulation: Available in fixed dose combination tablets with various strengths including: 25 mg alogliptin/15 mg pioglitazone, 25 mg alogliptin/30 mg pioglitazone, 25 mg alogliptin/45 mg pioglitazone, 12.5 mg alogliptin/15 mg pioglitazone, 12.5 mg alogliptin/30 mg pioglitazone, 12.5 mg alogliptin/45 mg pioglitazone.

Warnings/Contraindications: Boxed warning for pioglitazone to cause or exacerbate congestive heart failure in some patients. Therefore after initiation, it is important to monitor for signs and symptoms of heart failure. Pioglitazone is contraindicated in patients with established NYHA class III or IV heart failure.

Notes: Oseni is not recommended for patients with severe renal impairment of end stage renal disease requiring dialysis.

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Mipomersen sodium (Kynamro, Genzyme Corp)

Pharmacology: Inhibitor of apolipoprotein-B synthesis.

Indication: As adjunct therapy to lipid lowering medications to reduce low density lipoprotein-cholesterol (LDL-C), apolipoprotein-B (apo B), total cholesterol (TC), and non-high density lipoprotein-cholesterol (HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH).

Adverse Drug Reactions: The most common adverse reactions include: injection site reactions, flu-like symptoms, nausea, headache, and elevations in serum transaminases, specifically ALT.

Dose: Recommended dose is 200 mg administered subcutaneously once a week.

Formulation: Available as a single-use vial containing 1 mL of a 200 mg/mL solution and as a single-use pre-filled syringe containing 1 mL of a 200 mg/mL solution.

Warnings/Contraindications: Boxed warning for increased transaminases as well as an increase in hepatic fat with or without concomitant increases in transaminases. Due to the risk of hepatotoxicity, mipomersen is available only through a restricted program called the Kynamro REMS program.

Notes: The safety and effectiveness of mipomersen has not been established in patients with hypercholesterolemia who do not have HoFH.

NEW DOSAGE FORM

Aspirin (Aspirin, PLX Pharma Inc)

Pharmacology: Salicylate.

Indication: Indicated for temporary relief of minor aches and pains associated with a cold, headache, backache, toothache, premenstrual and menstrual cramps, minor pain of arthritis, and for temporary reduction in fever.

Dose: The recommended dose is 325 mg to 600 mg orally every 4 to 6 hours as needed with a maximum daily dose of 4 grams.

Sumatriptan (Zecuity, Nupathe Inc)

Pharmacology: Serotonin 1b/1d receptor agonist.

Indication: Acute treatment of migraine with or without aura in adult patients.

Dose: The recommended dose for acute treatment of migraine is to apply one transdermal system to dry, intact, non-irritated skin of the upper arm or thigh to deliver 6.5 mg of sumatriptan over 4 hours. Patients should use no more than two sumatriptan transdermal systems in a 24-hour period, with the second transdermal system to be applied no sooner than 2 hours after activation of the first sumatriptan transdermal system.

Testosterone (Testosterone, Perrigo Israel)

Pharmacology: Androgen.

Indication: As replacement therapy for males greater than 18 years of age, for conditions associated with a deficiency or absence of endogenous testosterone such as: primary hypogonadism or hypogonadotropic hypogonadism.

Dose: The recommended initial dose is 50 mg applied topically once daily in the morning and can be increased to 100 mg once daily on the basis of total serum testosterone concentration.

NEW FORMULATION

Budesonide (Uceris, Santarus)

Pharmacology: Glucocorticoid.

Indication: Induction of remission in patients with active, mild to moderate ulcerative colitis.

Dose: The recommended dose for the induction of remission in adult patients with active, mild to moderate ulcerative colitis is one 9 mg tablet to be taken once daily in the morning with or without food for up to 8 weeks.

Levonorgestrel (Skyla, Bayer Healthcare Pharms)

Pharmacology: Progestin.

Indication: To prevent pregnancy for up to 3 years.

Dose: Levonorgestrel is released in vivo at a rate of approximately 14 mcg/day after 24 days. This rate decreases to 5 mcg/day after 3 years. The average in vivo release rate of levonorgestrel is 6 mcg/day over a period of 3 years. Skyla must be removed at the end of the third year and can be replaced at the time of removal with a new Skyla if continued contraceptive protection is desired.
**Sodium sulfate, potassium sulfate, magnesium sulfate, sodium chloride, sodium bicarbonate, potassium chloride (Suclear, Braintree Labs)**

**Pharmacology:** Combination of osmotic laxatives.

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

**Dosage form:** Available as a 6 oz. bottle of oral solution containing 17.5 g of sodium sulfate, 3.13 g of potassium sulfate, and 1.6 g of magnesium sulfate and as a 2-L bottle with powder for solution containing 210 g of polyethylene glycol 3350 (PEG-3350), 5.6 g of sodium chloride, 2.86 g of sodium bicarbonate and 0.74 g of potassium chloride with the option to add a 1 g flavoring ingredient.

**Dose:** Two dosing regimens are available for administration of Suclear. The preferred regimen is the split-dose regimen and is as follows:

**Dose 1 – Evening before the colonoscopy (10 to 12 hours prior to Dose 2)**

a) Dilute the 6-oz oral solution prior to use by pouring the entire contents of the bottle into the 16-oz mixing container and then filling the container with cool water to the fill line and mix.

b) Drink the entire solution in the container. It is best to complete drinking the solution within 20 minutes.

c) Refill the container with 16 oz. of water to the fill line and drink it over the next 2 hours.

d) Refill the container with 16 oz. of water to the fill line and finish drinking it before going to bed.

**Dose 2 – Next morning on the day of the colonoscopy (start at least 3 ½ hours prior to colonoscopy)**

a) Dissolve the powder of Dose 2 by adding water to the fill line on the jug.

b) Shake the jug until all the powder is dissolved. The solution can be used with or without the addition of a flavor pack. Flavor packs are available in Cherry, Lemon-Lime, Orange and Pineapple. When dissolved in water to a volume of 2 liters, the solution is clear and colorless. The solution may be refrigerated after adding water. The solution should be used within 48 hours of reconstitution.

c) Using the 16-oz container provided with the kit, drink all the solution in the jug at a rate of one 16-oz container every 20 minutes (this is four 16-oz containers over a period of one and a half hours).

d) Complete drinking the solution at least 2 hours before the colonoscopy.

e) Consume only clear liquids until 2 hours prior to colonoscopy. Thereafter, nothing should be consumed until the completion of colonoscopy.

**Testosterone (Testosterone, Perrigo Israel)**

**Pharmacology:** Androgen

**Indication:** As replacement therapy for males greater than 18 years of age, for conditions associated with a deficiency or absence of endogenous testosterone such as: primary hypogonadism or hypogonadotropic hypogonadism.

**Dosage form:** Available as a gel for use in a metered-dose pump that delivers 12.5 mg of testosterone per actuation, or as unit dose packets containing 25 mg or 50 mg of testosterone gel.

**Dose:** The recommended initial dose is 50 mg applied topically once daily in the morning and can be increased to 100 mg once daily on the basis of total serum testosterone concentration.