Umeclidinium–vilanterol inhaler approved for COPD

FDA on December 18 announced the approval of umeclidinium–vilanterol inhalation powder for maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD).

The GlaxoSmithKline product will be marketed as Anoro Ellipta. The company expects to launch the product in the United States during the first quarter of 2014.

Labeling for the combination product describes umeclidinium as a long-acting antimuscarinic agent that relaxes smooth muscles in the airways.

GlaxoSmithKline stated that the drug, in combination with the long-acting β₂-adrenergic agonist (LABA) vilanterol, is the first FDA-approved once-daily treatment for COPD that contains two long-acting bronchodilators in a single inhaler.

The combination product is not indicated for the treatment of acute bronchospasm or asthma. A boxed warning in the labeling states that patients with asthma who are treated with a LABA are at increased risk for death.

Anoro Ellipta contains lactose, and the product’s use is contraindicated in people who are severely allergic to milk products.

Among clinical trial participants treated with Anoro Ellipta, the most frequently reported adverse events included sore throat, sinusitis, lower-respiratory-tract infection, gastrointestinal symptoms, muscle spasms, and pain in the extremities, neck, and chest, according to GlaxoSmithKline.

The company stated that “significant hypokalemia” and transient hyperglycemia may occur in some patients who use the combination product.

Serious adverse events that may occur during treatment with Anoro Ellipta include paradoxical bronchospasm, cardiovascular effects, acute narrow-angle glaucoma, and worsening of urinary retention, according to FDA.

The labeling for Anoro Ellipta includes an FDA-required Medication Guide to educate patients about potential risks associated with the product and instructions for its proper use.

The inhalers will be supplied in 30- and 7-dose packs in sealed plastic trays that should remain unopened and stored at controlled room temperature until use. Instructions for using the inhalers are included in the labeling.

—Kate Traynor
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New drugs and dosage forms

Coagulation factor XIII A-subunit, recombinant, for injection (Tretten, Novo Nordisk): The recombinant product is indicated for the routine prophylaxis of bleeding in patients with congenital factor XIII A-subunit deficiency.

Epinephrine injection (Adrenalin, JHP Pharmaceuticals): The nonselective α- and β-adrenergic agonist is indicated for the emergency treatment of allergic reactions and the induction and maintenance of mydriasis during intraocular surgery.

Sapropterin dihydrochloride powder for oral solution (Kuvan, BioMarin Pharmaceutical): A formulation suitable for dissolution in water or apple juice was added to the product line.

Sucroferric oxyhydroxide chewable tablets (Velphoro, Fresenius Medical Care North America): The phosphate binder is indicated for the control of serum phosphorus concentration in patients with chronic kidney disease who are undergoing dialysis.

Treprostinil extended-release tablets (Orenitram, United Therapeutics): The oral formulation, intended for use two or three times daily, is indicated for the treatment of pulmonary arterial hypertension to improve patients’ exercise capacity.

New cholesterol guidelines mean major changes in care

The recent release of new prevention guidelines for the treatment of hypercholesterolemia in adults heralds major changes in how clinicians manage drug therapy for their patients.

Within weeks of the November 12 online publication of the guidelines, Clinical Pharmacist Tracy A. Martinez of the John D. Dingell Veterans Affairs Medical Center in Detroit was implementing the