MC-Rx
Powered by ProCare Rx

https://www.cdc.gov/coronavirus/2019-ncov/index.html

Volume 2020 #07

Prepared for 03/09/2020

Drug Information Updates

Generic to Daraprim Approved by FDA **02/28/2020**

The FDA approved the first AB-rated generic to Vyera Pharmaceutical's Daraprim® (pyrimethamine) tablets. Daraprim is known for its controversial high price. Pyrimethamine tablets by Cerovene are indicated for treating toxoplasmosis (*toxoplasma gondii*) when used in combination with a sulfonamide antibiotic. Toxoplasmosis is a parasite that can cause damage to eyes and other organs when a person consumes contaminated water, infected cat feces or undercooked meat and shellfish. Pyrimethamine will be available in 25mg oral tablets, similar to Daraprim.

Neohalers by Sunovion Discontinued **03/09/2020**

Sunovion has announced that it will stop shipping all three products in its line of oral dry-powder inhalers, Arcapta® Neohaler® (indacaterol), Seebri® Neohaler (glycopyrrolate) and Ultibron® Neohaler (indacaterol/glycopyrrolate) on March 31, 2020. All are used for the maintenance treatment of chronic obstructive pulmonary disease (COPD). Their market withdrawal is due to business reasons, not safety issues. Although some of the products will remain available until the currently stocked inventory runs out, no new units will be produced. Sunovion did inform patients and prescribers of the discontinuation, but patients still using one of the discontinued inhalers should talk with their healthcare providers as soon as possible to determine alternative treatment options. Individuals needing more information may contact Sunovion at 844.276.8262 until March 31, 2020.

After the end of March, information will be available from Novartis at 888.669.6682 or novartis.email@novartis.com.

Montelukast Update **03/04/2020**

The FDA has required manufacturers of products containing montelukast to intensify a warning about possible mental health problems that may be associated with its use. Available as a brand, Singulair®, and multiple generics, montelukast tablets are approved to treat and prevent asthma and to treat allergies. For some of its indications, it can be used for children as young as six months old. Now, all montelukast products must include a boxed warning that it may cause mood changes or behavioral issues. Patients and caregivers are cautioned to watch for signs of new or increased anxiety, confusion, depression, irritability, restlessness, sleeping problems and other unusual behaviors while taking it. If moods or behaviors change significantly, montelukast should be stopped and the patient should consult with a medical provider.

More information is in the FDA's safety notice: https://www.fda.gov/drugs/drug-safety-and-availability/fda-requires-boxed-warning-about-serious-mental-health-side-effects-asthma-and-allergy-drug.

IMPENDING FDA REVIEWS SCHEDULED FOR THE NEXT 2 WEEKS:

None scheduled

GENERAL INFORMATION:

More information will be provided as it becomes available. Visit FDA.gov for more information.

For more information on the Coronavirus (COVID-19), visit the CDC website shown on the cover of this newsletter.