



NEWS FLASH

January 22, 2010

NEW GENERICS

No new approvals in this period

FDA ALERTS

MERIDIA (sibutramine) - The FDA has reviewed additional data that indicate an increased risk of heart attack and stroke in patients with a history of cardiovascular disease using sibutramine, marketed as the weight loss medication MERIDIA. The product label already includes warnings against the use of MERIDIA in patients with cardiovascular disease. However, based on the serious nature of the review findings, the FDA requested and the manufacturer agreed to add a new contraindication to the MERIDIA drug label. The contraindication will state that MERIDIA is not to be used in patients with a history of cardiovascular disease, including:

- History of coronary artery disease (e.g., heart attack, angina)
- History of stroke or transient ischemic attack (TIA)
- History of heart arrhythmias
- History of congestive heart failure
- History of peripheral arterial disease
- Uncontrolled hypertension (e.g., > 145/90 mmHg)

ALLI (orlistat) - The FDA is warning consumers about a counterfeit and potentially harmful version of ALLI 60 mg capsules (120 count refill kit).

Preliminary laboratory tests conducted by GlaxoSmithKline (GSK)—the maker of the FDA approved over-the-counter weight-loss product—revealed that the counterfeit version did not contain orlistat, the active ingredient in its product. Instead, the counterfeit product contained the controlled substance sibutramine. Sibutramine is a drug that should not be used in certain patient populations or without physician oversight. Sibutramine can also interact in a harmful way with other medications the consumer may be taking.

Consumers began reporting suspected counterfeit ALLI to GSK in early December 2009. GSK has determined that the counterfeit product has been sold over the internet. However, there is no evidence at this time that the counterfeit ALLI product has been sold through other channels, such as retail stores.

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NEW FDA DRUG APPROVALS / INDICATION

BRAND NAME	STRENGTH	FDA APPROVED INDICATION	MARKET STATUS
ACTEMRA tocilizumab <i>GENENTECH</i>	Injectable	For the once-monthly intravenous treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies. ACTEMRA may be used alone or in combination with methotrexate or other disease modifying anti-rheumatic drugs (DMARDs).	Available

FDA NEWS

Acyclovir Shortage - Teva Pharmaceuticals has reported a shortage of generic acyclovir tablets and capsules due to manufacturing delays, but plans to have the product available in the near future. Due to higher demand, GlaxoSmithKline has increased production and currently has the brand product ZOVIRAX (acyclovir) 200 and 400 mg tablets available; 800 mg tablets are on backorder until April 2010. Acyclovir is indicated for the short-term treatment of herpes zoster (shingles), for initial episodes and management of recurrent episodes of genital herpes, and varicella (chickenpox).

MOBAN (molindone hcl) Discontinuation- Endo Pharmaceuticals reported that it is discontinuing MOBAN 5, 10, 25, and 50 mg tablets, indicated for the management of schizophrenia. The remaining inventory is anticipated to be depleted by the end of June 2010.

Bacitracin ophthalmic ointment- Fera Pharmaceuticals reports that bacitracin ophthalmic ointment is now available through wholesalers, and chain, independent, and hospital pharmacies. The bacitracin supply has been an issue since July 2009, when the previous owner discontinued manufacturing bacitracin and only a limited quantity was made available during the transition period to Fera.

PLAVIX – Omeprazole Interaction - The FDA has recommended that the co-administration of clopidogrel (PLAVIX), a drug used to prevent blood clot formation, and omeprazole (PRILOSEC/PRILOSEC OTC), a proton pump inhibitor (PPI) used to reduce stomach acid, be avoided because omeprazole reduces the effectiveness of clopidogrel. The new recommendations are based on study results from the manufacturers of clopidogrel. The studies confirm that co-administration of omeprazole with clopidogrel results in decreased levels of clopidogrel's active metabolite (through inhibition of the enzyme that forms the active metabolite), reducing clopidogrel's anti-clotting effect.

Although no clinical outcomes data are available, the drug-drug interaction suggests that patients who are at risk for heart attacks or strokes may not get the full protective anti-clotting effect if they are using clopidogrel and omeprazole together.

Until further information is available, FDA recommends the following:

- Avoid using omeprazole and clopidogrel together and at any time of the day. Separating the dose of clopidogrel and omeprazole in time will not reduce this drug interaction.
- Avoid using other potent CYP 2C19 inhibitors, including esomeprazole (NEXIUM), and cimetidine (TAGAMET, TAGAMET HB) with clopidogrel.
- At this time, the FDA does not have enough information about drug interactions between clopidogrel and PPIs other than omeprazole and esomeprazole to advise on their use together.
- Patients who use clopidogrel and need a medication to reduce stomach acid can use antacids and H2 blockers such as ZANTAC (ranitidine), PEPCID (famotidine), and AXID (nizatidine).
- Patients taking clopidogrel should consult with their healthcare provider if they are currently taking or considering taking omeprazole, including Prilosec OTC.

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