



NEWS FLASH

December 11, 2009

NEW SINGLE SOURCE GENERICS

(Brand products with generic name)

clonidine

(Tris Pharma)

0.09 mg/mL ER suspension;
0.17mg ER tab; 0.26mg ER tab
Approval

Omeprazole/sodium

bicarbonate/magnesium hydroxide

(Santarus)
20mg/750mg/343mg tab;
40mg/750mg/343mg tab
Approval

FDA NEWS

HUMULIN 50/50 - Eli Lilly and Company will stop producing HUMULIN 50/50 (isophane insulin and regular insulin) due to declining use. Based on current patient demand and inventory, HUMULIN 50/50 should be available until December 2009, rather than the April 2010 date originally projected. All subsequently shipped cartons will be printed with the notice: "HUMULIN 50/50 is being discontinued. Contact your physician to change to another insulin. For information call 1-800-545-5979." Lilly is also providing copies of the patient information sheet to health care providers for distribution to patients who currently use HUMULIN 50/50 to avoid confusion, informing them about the discontinuation and providing answers to possible questions. Additional questions about the HUMULIN 50/50 discontinuation should be directed to Lilly at 1-800-545-5979 from 9 AM to 5 PM eastern time, Monday through Friday. It is estimated that approximately 3,000 patients nationwide will be affected by this discontinuation.

NEW FDA DRUG APPROVALS / INDICATION

BRAND NAME	STRENGTH	FDA APPROVED INDICATION	MARKET STATUS
AGRIFLU Influenza vaccine <i>NOVARTIS VACCINES</i>	Injectable	For adults 18 years and older to prevent disease caused by influenza virus subtypes A and B (seasonal flu). As a part of the accelerated approval process, Novartis is required to conduct further studies to verify that the vaccine induces antibody levels in the blood that are effective in preventing seasonal influenza.	Approval
KALBITOR ecallantide <i>DYAX CORPORATION</i>	Injectable	A subcutaneous treatment for acute attacks of hereditary angioedema (HAE) in patients 16 years of age and older. Dyax and the FDA have also established a Risk Evaluation and Mitigation Strategy (REMS) program to communicate anaphylaxis risks and the importance of distinguishing between a hypersensitivity reaction and HAE attack symptoms.	Approval
WILATE Von Willebrand factor/coagulation factor VIII <i>OCTAPHARMA USA</i>	Injectable	For the treatment of spontaneous and trauma-induced bleeding episodes in patients with severe von Willebrand disease (VWD), as well as in patients with mild or moderate VWD in whom desmopressin use is known or suspected to be ineffective or contraindicated.	Expected in early 2010
ZEGERID OTC Omeprazole/sodium bicarbonate <i>MERCK</i>	20mg/1100mg tab	For the over-the-counter treatment of frequent heartburn. ZEGERID OTC combines omeprazole with sodium bicarbonate, which protects omeprazole from acid in the stomach.	Expected in first semester 2010
SEROQUEL XR quetiapine fumarate <i>ASTRAZENECA</i>	50mg, 150mg, 200mg, 300mg, 400mg tab	NEW INDICATION: as adjunctive treatment to antidepressants in adults with major depressive disorder. SEROQUEL XR is also approved for the treatment of acute manic episodes associated with bipolar I disorder (as either monotherapy or adjunct therapy to lithium or divalproex), depressive episodes associated with bipolar disorder, maintenance of bipolar I disorder as adjunct therapy to lithium or divalproex, and for the treatment of schizophrenia.	Available
ZYPREXA olanzapine <i>ELI LILLY</i>	2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg tab	NEW INDICATION: for the treatment of schizophrenia and manic or mixed episodes associated with bipolar I disorder in adolescents 13 to 17 years of age.	Available

FDA ALERTS

NORPRAMIN (desipramine) - Sanofi-Aventis has issued a Dear Health Care Professional Letter notifying of changes to the Warnings and Overdosage sections of the prescribing information for its product *Norpramin* (desipramine hydrochloride), indicated for the treatment of depression. Extreme caution should be used when Norpramin is given to patients with a family history of sudden death, cardiac dysrhythmias, and cardiac conduction disturbances. Seizures could also occur before cardiac dysrhythmias and death in some patients

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