



# NEWS FLASH

February 19, 2010

## NEW GENERICS

### indomethacin

(Bedford Labs)

Injectable

Reference Brand: INDOCIN I.V.

### APPROVAL

## NEW FDA APPROVALS / NEW INDICATIONS

BRAND NAME	STRENGTH	FDA APPROVED INDICATION	MARKET STATUS
<b>BENICAR</b> olmesartan medoxomil <i>DAICHI SANKYO</i>	5mg, 20mg, 40mg tabs	<b>NEW INDICATION:</b> For the treatment of hypertension in children and adolescents 6 to 16 years of age. BENICAR is also approved for the treatment of hypertension in adults.	Available
<b>CRESTOR</b> rosuvastatin calcium <i>ASTRAZENECA</i>	5mg, 10mg, 20mg, 40mg tabs	<b>NEW INDICATION:</b> to reduce the risk of stroke, myocardial infarction and arterial revascularization procedures in individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age (men aged 50 or older and women aged 60 or older), high-sensitivity C-reactive protein $\geq$ greater than or equal to 2 mg/L, and the presence of at least one additional CVD risk factor, such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease.	Available

## MEDICATION SHORTAGES

The following medications are reportedly in short supply and may be temporarily unavailable in pharmacies nationwide:

- ◆ Acyclovir tablets (all strengths)
- ◆ Amnesteem 20mg capsule
- ◆ Armour Thyroid tablets (all strengths)
- ◆ Buprenorphine tablets (all strengths)
- ◆ Clonidine patches (all strengths)
- ◆ Gemfibrozil 600mg tablets
- ◆ Hydromorphone 1mg/mL syringe
- ◆ Hydromorphone 2mg/mL syringe
- ◆ Levothyroid tablets (all strengths)
- ◆ Lexapro 5mg/5mL oral solution
- ◆ Ortho Tri-Cyclen Lo tablets
- ◆ Promethegan 25mg suppository
- ◆ Propofol 10mg/mL vial
- ◆ Valacyclovir 500mg tablets
- ◆ Vivelle-Dot 0.075mg/24hr patches

## FDA NEWS / ALERTS

**PROCRT, EPOGEN & ARANESP** - The FDA and Amgen are notifying health care providers and patients that all erythropoiesis-stimulating agents (ESAs), including PROCRT, EPOGEN, and ARANESP, must be prescribed and used under a risk evaluation and mitigation strategy (REMS) to ensure safe use. Studies show that ESAs can increase the risk of tumor growth and shorten survival rates in cancer patients, in addition to increasing the risk of heart attack and heart failure, stroke, or blood clots. As part of the REMS, a Medication Guide must be provided to all patients explaining the risks and benefits associated with ESA use. The FDA has also required Amgen to develop the ESA APPRISE (Assisting Providers and Cancer Patients with Risk Information for the Safe use of ESAs) Oncology program to train health care professionals in the prescribing and dispensing of ESAs. Only those who complete the training will be allowed to prescribe and dispense ESAs. PROCRT, EPOGEN, and ARANESP are approved for the treatment of anemia that may occur due to kidney failure, certain kinds of chemotherapy, and zidovudine administration and anemia occurring in certain patients undergoing surgery.

**SEREVENT & FORADIL** - Due to safety concerns, the FDA is requiring changes to how long-acting inhaled medications called Long-Acting Beta-Agonists (LABAs) are used in the treatment of asthma. These changes are based on FDA's analyses of studies showing an increased risk of severe exacerbation of asthma symptoms, leading to hospitalizations in pediatric and adult patients as well as death in some patients using LABAs for the treatment of asthma. LABAs are approved as single-ingredient products (SEREVENT and FORADIL) and as an ingredient in combination products containing inhaled corticosteroids (ADVAIR and SYMBICORT) for the treatment of asthma and chronic obstructive pulmonary disease (COPD). They work by relaxing muscles in the airway and lungs, which helps patients breath easier, and lessens symptoms such as wheezing and shortness of breath. To ensure the safe use of these products, the following guidelines should be followed:

- ◆ The use of LABAs is contraindicated without the use of an asthma controller medication such as an inhaled corticosteroid. Single-ingredient LABAs should only be used in combination with an asthma controller medication; they should not be used alone.
- ◆ LABAs should only be used long-term in patients whose asthma cannot be adequately controlled on asthma controller medications.
- ◆ LABAs should be used for the shortest duration of time required to achieve control of asthma symptoms and discontinued, if possible, once asthma control is achieved. Patients should then be maintained on an asthma controller medication.
- ◆ Pediatric and adolescent patients who require the addition of a LABA to an inhaled corticosteroid should use a combination product containing both an inhaled corticosteroid and a LABA, to ensure compliance with both medications.

The FDA is also requiring a risk management program REMS for these products. The REMS for LABAs will include a revised Medication Guide written specifically for patients, and a plan to educate healthcare professionals about the appropriate use of LABAs. The FDA has determined that the benefits of LABAs in improving asthma symptoms outweigh the potential risks when used appropriately with an asthma controller medication in patients who need the addition of LABAs.

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