



## MaxorPlus Clinical Newsletter

May 2011

**Now available**

**Vandetanib®** ([vandetanib](#)) for the treatment of medullary thyroid cancer that cannot be removed by surgery. A Risk Evaluation and Mitigation Strategy (REMS) is required for [vandetanib](#) due to the risks of QT prolongation, Torsades de pointes, and sudden death. Only prescribers who are certified through the Vandetanib REMS Program, a restricted distribution program, will be able to prescribe vandetanib. To learn about the specific REMS requirements and to enroll in the Vandetanib REMS Program, health care professionals should call 1-800-236-9933 or visit [www.vandetanibrems.com](http://www.vandetanibrems.com). Dosing is 300 mg orally daily. AWP \$ 396 per tablet

Based on **Vandetanib's®** indication and cost, we recommend restricting to a specialty pharmacy.

**Morgidox Kit®** ([doxycycline](#)) is [doxycycline](#) packaged with a skin cleanser. AWP \$ 239.76/ 1 month kit

**Edarbi®** ([azilsartan medoxomil](#)) is an angiotensin II receptor antagonist approved for the treatment of hypertension either as monotherapy or in combination with other agents. Dosing is 40 to 80 mg daily. AWP \$ 2.94 for either strength

**Daliresp®** ([roflumilast](#)) a pill taken daily to decrease the frequency of flare-ups (exacerbations) or worsening of symptoms from severe chronic obstructive pulmonary disease (COPD). [Roflumilast](#), a new drug class for the treatment of COPD, is an inhibitor of an enzyme called phosphodiesterase type 4 (PDE-4). It is indicated for people with severe COPD to treat the symptoms of cough and excess mucus linked to bronchitis. [Roflumilast](#) is not intended to treat another form of COPD which involves primary emphysema. Dosing is 500 mcg daily. AWP \$ 6.90/tablet

**Horizant®** ([gabapentin enacarbil](#)) extended release tablets are indicated as a once-daily treatment for moderate-to-severe restless legs syndrome (RLS).

**Horizant®** contains [gabapentin enacarbil](#) that becomes gabapentin. It carries the warning that this medication may cause suicidal thoughts and actions. Dosing is 600 mg once daily in the evening. [Gabapentin](#) is available as a generic.

AWP \$ 3.96/tablet

**Sprix®** ([ketorolac](#)) nasal spray for the short-term treatment of moderate pain. Intranasal dosage is 1 spray (15.75 mg/spray) in each nostril (total dose of 31.5 mg) every 6 to 8 hours. Do not exceed daily maximum of 4 doses (8 sprays/126 mg) or treating longer than 5 days.

AWP \$ 33/ 1 bottle of 8 sprays (AWP for 5 days treatment \$165)

**Staxyn®** ([vardenafil](#)) orally disintegrating tablets indicated for treatment of erectile dysfunction. **Levitra®** is the original oral tablets of [vardenafil](#).

AWP \$ 13.98/tablet

**Tradjenta®** ([linagliptin](#)) to improve blood glucose control in adults with Type 2 diabetes. **Tradjenta®** is an oral dipeptidyl peptidase-4 (DPP-IV) inhibitors that has been studied as a stand-alone therapy and in combination with other Type 2 diabetes therapies including [metformin](#), [glimepiride](#), and [pioglitazone](#).

**Tradjenta®** has not been studied in combination with [insulin](#), and should not be used to treat people with Type 1 diabetes or in those who have increased ketones in their blood or urine (diabetic ketoacidosis). Dosing is 5 mg once daily.

AWP \$8.12/ tablet

**Zytiga®** ([abiraterone acetate](#)) indicated as a treatment for men with prostate cancer who have already undergone chemotherapy. [Testosterone](#) stimulates the growth of prostate tumors, and treatment can include drugs or surgery aimed at cutting the body's [testosterone](#) production. However some prostate tumors continue to grow even after those treatments. **Zytiga®** is designed to inhibit the enzyme that is required for androgen biosynthesis. Dosing is 1000 mg daily given with twice daily [prednisone](#) 5 mg.

AWP \$ 50/ 250 mg tablet or \$200 per daily dose.

**New generics available:**

[letrozole](#) generic for **Femara®** used for breast cancer

[Matzim LA](#) generic for **Cardizem LA®** used for hypertension

[methylphenidate ER](#) generic for **Concerta®** used for ADHD

[epinastine](#) generic for **Elestat®** ophth used for ocular pruritus associated with allergic conjunctivitis

**New OTC**

**Allegra allergy** used for allergic rhinitis.

## New indication

The U.S. Food and Drug Administration approved the use of **Menactra**® in children as young as 9 months for the prevention of invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135.

**Menactra**® already is approved for use in people ages 2 through 55 years.

The U.S. Food and Drug Administration approved **Afinitor**® ([everolimus](#)) to treat patients with progressive neuroendocrine tumors located in the pancreas (PNET) that cannot be removed by surgery or that have spread to other parts of the body (metastatic). **Afinitor**® was previously approved for advanced renal cell cancer.

## In the news

Researchers stopped one in a series of long-term studies testing the antiretroviral drug **Truvada**® on thousands of African women who are at high risk of HIV infection after preliminary data showed an equal HIV infection rate among both women who took **Truvada**® and those who took a placebo.

Many experts say they found the results of the study, known as FEM-PrEP, disappointing, since **Truvada**® is regarded as a groundbreaking drug for HIV prevention among gay men. Researchers believed **Truvada**® would also work for high-risk women in Africa.

Abcnews website 4-18-11

## Safety information

### **Lansoprazole Delayed-Release Orally Disintegrating Tablets by Teva Pharmaceuticals: Letter to Healthcare Professionals - Clogged, Blocked Oral Syringes and Feeding Tubes**

**ISSUE:** The FDA has received reports that Teva's [lansoprazole](#) delayed-release orally disintegrating tablet has clogged and blocked oral syringes and feeding tubes, including both gastric and jejunostomy types, when the drug is administered as a suspension through these devices. The tablets may not fully disintegrate when water is added to them and/or they may disintegrate but later form clumps. These clumps can adhere to the inside walls of oral syringes and feeding tubes. In some cases, patients have had to seek emergency medical assistance and their feeding tubes have had to be unclogged or removed and replaced.

Teva Pharmaceuticals has voluntarily withdrawn its [lansoprazole](#) delayed-release ODT product from distribution at this time. However, some product may remain in stock in pharmacies and other facilities, and some patients may still have the product in their possession.

FDAwebsite 4-15-11