



## MaxorPlus Clinical Newsletter

March-April 2013

### Now available

**Ravicti®** ([glycerol phenylbutyrate](#)) is indicated for the treatment of hyperammonemia in patients with urea cycle disorders. **Ravicti®** must be used in combination with dietary protein restrictions. Dosing 5-12.4 G/m<sup>2</sup>/day divided in 3 equal doses, rounded up. AWP \$ 2,812.50/ 25ml bottle or average monthly dose AWP \$ 14,062.50

[Based on Ravicti®'s indication and cost, and that it is deemed an orphan drug, we recommend restricting to a specialty pharmacy](#)

**Kadcyla®** ([ado-trastuzumab emtansine](#)) is a HER-2- targeted antibody, indicated for HER2-positive, metastatic breast cancer. It is approved for use after patients have previously received [trastuzumab](#) and a taxane. Dosing is 3.6 mg/kg IV every 3 weeks. AWP \$ 3,280.28/100 mg vial and \$ 5,325.25/160 mg vial average every 3 week dose AWP \$ 8,653.53

[Based on Kadcyla®'s indication and cost, we recommend restricting to a specialty pharmacy.](#)

**Kynamro®** ([mipomersen](#)) is indicated to reduce cholesterol concentrations in patients with homozygous familial hypercholesterolemia. Dosing is 200 mg SC weekly. AWP \$ 4,067.33/200 mg vial or monthly AWP \$ 16,269.32

[Based on Kynamro®'s indication and cost, we recommend restricting to a specialty pharmacy.](#)

**Invokana®** ([canagliflozin](#)) is a sodium-glucose co-transporter 2 (SGLT2) inhibitors. It works by blocking the reabsorption of glucose by the kidney, which results in increase glucose excretion and lower blood glucose concentrations in patients with type 2 diabetes. Dosing is 100 mg once daily, taken before the first meal of the day. AWP \$ 10.54/100 mg tablet or monthly AWP \$ 316.20

**Varizig®** ([varicella-zoster immune globulin \(human\)](#)) is indicated for passive immunization of high-risk susceptible patients after exposure to chickenpox or herpes zoster. Dosing is 625 IU (5 vials) IM as soon as possible but within 96 hours of exposure.

AWP \$ 780.00/125 IU vial or \$ 3,900.00/ dose

**Fulyzaq®** ([crofelemer](#)) is indicated as an anti-diarrheal for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy. Dosing is 125 mg twice daily, taken with or without food.

AWP \$ 10.80/125 mg tablet or \$ 648.00/month

**TOBI Podhaler®** ([tobramycin inhalation powder](#)) indicated for the management of cystic fibrosis patients with *Pseudomonas aeruginosa*.

**Tecfidera®** ([dimethyl fumarate](#)) is indicated for adults with relapsing forms of multiple sclerosis. Dosing is 120 mg twice daily for 7 days, then 240 mg twice daily.

AWP \$ 90.00/either strength capsule or \$ 5,400.00/month

[Based on Tecfidera®'s indication and cost, we recommend restricting to a specialty pharmacy.](#)

**Cystaran®** ([cysteamine](#)) is used to treat the corneal cysteine crystal accumulation that occurs in patient with cystinosis, which is a rare autosomal recessive disease. Dosing is one drop in each eye every waking hour.

AWP \$ 1,050.00/15 ml bottle

#### **New generics available:**

- [mafenide ace pak](#) generic for **Sulfamylon Pak®** indicated for burn wound infection
- [buprenorphine/naloxone](#) generic for **Suboxone®** indicated for treatment of opiate agonist dependence
- [My Way](#) generic for **Plan B®** indicated for emergency contraception
- [zoledronic](#) generic for **Zometa®** indicated for treatment of hypercalcemia of malignancy or osteoporosis
- [zoledronic](#) generic for **Reclast®** indicated for treatment of hypercalcemia of malignancy or osteoporosis
- [l-methyl folate](#) generic for **Deplin®** indicated for treatment of major depression
- [tretinoin microsphere gel](#) generic for **Retin-A micro gel®** indicated for acne
- [Zenatane](#) another [isotretinoin](#) generic indicated for severe acne
- [desvenlafax](#) generic for **Pristiq®** indicated for treatment of major depression

## **New dosage form**

**Rebif Rebido®** comes in a pre-assembled, ready to use package

## **New dosage form**

**Viramune XR®** now comes in 100 mg strength

## **In Medical News**

**FDA Drug Safety Communication: Safety review update of **codeine** use in children; new **Boxed Warning** and **Contraindication** on use after tonsillectomy and/or adenoidectomy**

### **Safety Announcement**

The U.S. FDA is updating the public about new actions being taken to address a known safety concern with **codeine** use in certain children after tonsillectomy and/or adenoidectomy. Deaths have occurred post-operatively in children with obstructive sleep apnea who received **codeine** for pain relief following a tonsillectomy and/or adenoidectomy. **Codeine** is converted to morphine by the liver. These children had evidence of being ultra-rapid metabolizers of **codeine**, which is an inherited ability that causes the liver to convert **codeine** into life-threatening or fatal amounts of morphine in the body.

A new **Boxed Warning** will be added to the drug label of **codeine**-containing products about the risk of **codeine** in post-operative pain management in children following tonsillectomy and/or adenoidectomy. A **Contraindication** will be added to restrict **codeine** from being used in this setting.

**Health care professionals** should prescribe an alternate analgesic for post-operative pain control in children who are undergoing tonsillectomy and/or adenoidectomy. **Codeine** should not be used for pain in children following these procedures.

Parents and caregivers who observe unusual sleepiness, confusion, or difficult or noisy breathing in their child should stop giving codeine and seek medical attention **immediately**, as these are signs of overdose.