Product Update

ADVISORIES

The European Medicines Agency (EMA) has issued recommendations restricting the use of **calcitonin** because of evidence suggesting an increased risk of cancer associated with its long-term administration. Health Canada is aware of these recommendations and is informing consumers and health professionals that it is currently assessing appropriate action for Canadians. Calcitonin is available as a nasal spray used in the treatment of osteoporosis in postmenopausal women. It is also available in an injectable form used to treat Paget's disease and severe hypercalcemia. The recommendations from the EMA include: 1) Calcitonin nasal spray to no longer be prescribed for the treatment of osteoporosis; 2) Calcitonin injectable to be used in patients with Paget's disease only when other treatments have not worked or are not appropriate, with treatment duration limited to 3 months; 3) Calcitonin injectable to be used only for hypercalcemia secondary to cancer. Health Canada will communicate any resulting new safety information to Canadians once its review is completed. To date, there have been no reports of cancer associated with calcitonin use submitted to Health Canada. Advise patients to contact their health care professionals should they require more information on calcitonin.

Sanofi Pasteur and Health Canada inform health care professionals that the distribution for **ImmuCyst** (*Bacillus Calmette-Guerin* [BCG] sub-strain Connaught) has been halted. Environmental monitoring of the production facility showed increasing levels of microorganisms, including mould, and one of the required release tests that

confirms the sterility of the product failed to demonstrate an acceptable ability to detect mould and yeast. Sanofi Pasteur is currently renovating the facility, during which time the production of BCG has temporarily been suspended. Thus far, there is no evidence of contamination in released lots and there have been no infections that might be caused by contamination reported in postmarketing surveillance. The company estimates that supplies of ImmuCyst will resume in late 2013.

AstraZeneca Canada Inc. and Health Canada inform consumers and health care professionals of a small number of product complaints received related specifically to the delivery device of the **Pulmicort Turbuhaler**, budesonide 200 mcg per metered dose, a multidose, dry powder inhaler. Pulmicort Turbuhaler is used in the treatment of bronchial asthma in patients who require inhaled steroids and in patients for whom a reduction of systemic glucocorticoids is desirable. The product complaints are related to the delivery device not working properly resulting in a failure to dispense the intended dose of the medication. Advise patients that if they do not hear the "click" sound when the "turn grip" is rotated, the device is not working properly, and the intended dose will not be inhaled, resulting in the patient not receiving their medication at the prescribed dose. Pharmacists should reinforce proper inhaler technique with patients using Pulmicort Turbuhaler and advise patients to contact their health care professionals if they have any questions or concerns. AstraZeneca's medical information line is also available for further information at 1-800-668-6000 (English) or 1-800-461-3787 (French).

GlaxoSmithKline Inc. and Health Canada inform consumers and health care professionals that **Volibris** (ambrisentan) is contraindicated for use in patients with idiopathic pulmonary fibrosis with or without pulmonary hypertension. Volibris is approved for use to treat idiopathic pulmonary arterial hypertension and pulmonary arterial hypertension associated with connective tissue disease. A clinical trial (ARTEMIS-IPF) looking at patients with idiopathic pulmonary fibrosis treated with Volibris was prematurely discontinued due to lack of efficacy. In addition, the results of the trial revealed a higher rate of the composite primary endpoint, disease progression or death in patients in the Volibris arm relative to placebo. A further evaluation of the primary endpoint components revealed a higher rate of respiratory hospitalizations, mortality events and decreases in respiratory function in the Volibris arm versus placebo. The product monograph has been updated with this new information.

NEW PRODUCTS

Caldolor (ibuprofen solution for injection by Alveda) is available as 100 mg/mL solution for injection in 4 mL and 8 mL single dose vials. It is approved for the reduction of fever in adult patients where nonparenteral antipyretic medication is inappropriate or impossible and also for the management of moderate to severe pain as an adjunct to intravenous opioid analgesics. Given as an intravenous infusion, Caldolor should not be given as an intravenous bolus or an intramuscular injection. Ibuprofen is also available in oral dosage forms and suspensions.

Dificid (fidaxomicin 200 mg film-coated tablets by Optimer Pharmaceuticals Canada Inc.) is a narrow spectrum macrocyclic antibacterial agent approved for the treatment of *Clostridium difficile* infection (CDI) in adults ≥ 18 years of age. Two clinical trials have demonstrated that fidaxomicin is non-inferior to vancomycin for clinical cure and superior to vancomycin in preventing CDI recurrence in the subgroup of patients with non-BI strain of *Clostridium difficile*. Dificid has low systemic absorption; it exerts its antibacterial effect locally in the gastrointestinal tract. The recommended dose for adults ≥ 18 years of age is one tablet orally twice daily for 10 days with or without food. As experience with fidaxomin use is limited in patients with severe hepatic and renal insufficiency, use caution when the medication is used in these patients. Commonly reported adverse effects in clinical trials include nausea, constipation and vomiting. Rash or pruritus have also been reported; symptoms were mild and self-limiting or resolved with antihistamine treatment. Review and reassess patients' current medications prior to initiation of Dificid (e.g., antimotility agents), and administer under the conditions listed in the Product Monograph.

NEW INDICATIONS

Cialis (tadalafil 2.5 mg and 5 mg tablets by Eli Lilly Canada Inc.) is now approved for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH).

Cymbalta (duloxetine by Eli Lilly Canada Inc.) is now approved for the management of chronic pain associated with osteoarthritis of the knee.

Emend IV (fosaprepitant by Merck Canada Inc.) is now approved for the prevention of nausea and vomiting in women due to treatment with

moderately emetogenic cancer chemotherapy.

Olmetec (olmesartan by Merck Canada Inc.) is now approved for use in pediatrics (6 to 16 years of age).

Onglyza (saxagliptin by Bristol Myers Squibb Canada) is now approved for use in patients with type 2 diabetes mellitus to improve glycemic control in combination with premixed or long/intermediate acting insulin (with or without metformin) when premixed or long/intermediate acting insulin (with or without metformin) used alone, with diet and exercise, do not provide adequate glycemic control.

Rebif (interferon beta-1a by EMD Serono, a division of EMD Inc. Canada) is now approved for the treatment of patients who have experienced a single demyelinating event, accompanied by an active inflammatory process and an abnormal MRI scan with lesions typical of multiple sclerosis, who are determined to be at high risk of developing clinically definite MS (extension of indication).

Tarceva (erlotinib by Hoffmann-La Roche Limited) is now approved as monotherapy for the first-line treatment of patients with locally advanced (stage IIIB, not amenable to curative therapy) or metastatic (stage IV) non-small cell lung cancer with EGFR-activating mutations.

Votrient (pazopanib by GlaxoSmithKline Inc.) is now approved for the treatment of adult patients with selective subtypes of advanced soft tissue sarcoma (STS) who have received prior chemotherapy for metastatic disease or who have progressed within 12 months after (neo)adjuvant therapy. Patients were required to have disease progression on or after, or be intolerant to, an anthracycline-based regimen in

the pivotal phase III study in STS.

NEW DOSAGE FORM

Apresoline (hydralazine by SteriMax Inc.) is available as a 20 mg/mL intravenous solution. It is also available as 10 mg, 25 mg and 50 mg tablets.

Banzel (rufinamide by Eisai Limited) will be available as 40 mg/mL oral suspension. It is currently available as 100 mg, 200 mg and 400 mg tablets.

Targin (oxycodone-naloxone controlled release tablets by Purdue Pharma) is now available in 5 mg/2.5 mg tablets in addition to the existing 10 mg/5 mg, 20 mg/10 mg and 40 mg/20 mg tablets.

CHANGES IN EXPIRATION

As of July 1, 2012, **clindoxyl** (clindamycin phosphate-benzoyl peroxide by Stiefel, a GSK company) will have instructions to dispense with a 60-day expiration date when stored at room temperature (15-25°C). This replaces the instructions to dispense with a 120-day expiration date.

NEW GENERICS

Exemestane 25 mg tablets are now available from Cobalt Pharmaceuticals Company. This is a new alternative to Aromasin.

Raloxifene 60 mg tablets are now available from Cobalt Pharmaceuticals Company. This is a new alternative to Evista.

Vancomycin 125 mg and 250 mg capsules are now available from Pharmaceutical Partners of Canada. ■

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