

## Product Update

### Drug advisories

**Boehringer Ingelheim** is warning ophthalmologists about a potential association between tamsulosin (Flomax) and intraoperative floppy iris syndrome (IFIS) that has been observed in patients during cataract surgery. The company is recommending that surgeons use iris hooks, iris dilator rings, or viscoelastic devices such as Healon 5 to minimize the potential consequences of this syndrome.

**Talecris and Health Canada** have issued a warning about the potential association between immune globulin intravenous (IGIV) (Gamunex) and the incidence of hemolytic anemia. Since September 2003, 26 cases of suspected hemolytic reactions have been reported with Gammunex (20 cases in Canada) from a total exposure of 58,949 patient years. Higher doses of IGIV appear to play a factor in the development of hemolytic reactions.

**Bayer HealthCare** in collaboration with Health Canada issued a warning about the intravenous administration of nimodipine (Nimotop). Nimotop is available as a 30 mg capsule and the contents of this capsule must not be given by any parenteral routes. Nimodipine is in a vehicle of glycerin, peppermint oil, and polyethylene glycol 400. For patients who cannot swallow the Nimotop capsules, the contents of the capsule can be

withdrawn with an 18-gauge needle and syringe and administered down a nasogastric tube. The contents should be washed down with 30 mL of normal saline.

**GlaxoSmithKline and Health Canada** issued a warning about the potential dangers of paroxetine (Paxil) when taken during pregnancy. Retrospective analysis of 3581 pregnant women exposed to paroxetine revealed a twofold increase in overall major malformations and a twofold increase in cardiovascular malformations. Other studies of pregnancy outcomes following exposure to antidepressants (including paroxetine) have provided conflicting evidence. Women should speak to their physicians about this matter.

A health warning has been issued on the potential association of behavioural and emotional changes, including self-harm, and the use of **atomoxetine (Strattera)**. Recent analysis of placebo-controlled trials have revealed an incidence of suicidal ideation of 0.37% ( $n = 5/1357$ ) compared to 0% ( $n = 0/851$ ) in the placebo group. Patients (or the patient's caregiver) should inform their doctor if they develop symptoms or worsening of symptoms, including suicidal thoughts, hostility, and mood swings.

### New products

**Avastin** (bevacizumab by **Hoffman LaRoche Canada**) is a new agent approved for the first-line treatment of metastatic carcinoma of the colon

or rectum, when used in combination with fluoropyrimidine-based chemotherapy (e.g., 5-fluorouracil and leucovorin). Avastin works by inhibiting blood flow to tumours and helping to deliver the chemotherapy. The recommended dose is 5 mg/kg given every 14 days until disease progression. Avastin is available as 100 and 400 mg vials.

**Flexi-T** (intrauterine device by Prosan International) is a new T-shaped copper IUD. It is distributed in Canada by Trimed Supply Network (905-738-7272).

**Twinject** (epinephrine 1:1000 by Paladin Labs) is a new autoinjector for the management of severe (type 1) allergic reactions. Each autoinjector is equipped to deliver two doses of epinephrine. The first is an automatic dose and the second is a manual back-up dose. Twinject is available in two strengths (0.3 mg and 0.15 mg per dose). The 0.3 mg dose is intended for use in adults and children weighing 30 kg or more. The 0.15 mg dose is intended for children weighing 15 to 30 kg. The first dose is administered as soon as possible and the second dose can be administered approximately 10 minutes after the initial dose if symptoms persist.

**Vivaxim** (inactivated hepatitis A vaccine and typhoid vaccine by Sanofi Pasteur) is a new combination travel vaccine. It allows for simultaneous vaccination against infections caused by *Salmonella typhi* (typhoid fever) and hepatitis

A virus. It is available as a dual chamber pre-filled syringe containing 0.5 mL of each vaccine.

### New dosage form/strength

**Gleevec** (imatinib mesylate by Novartis Oncology) is now available as a 400 mg tablet (will lower pill burden count). Also the 100 mg capsule form has been replaced with a 100 mg tablet formulation.

**Trusopt** (dorzolamide 2% and timolol 0.5% eye drops by Merck Frosst Canada Ltd.) is now available as a preservative-free formulation. This new formulation will be packaged in cartons of 60 unit doses of 0.2 mL.

### New indications

**Diovan** (valsartan 80 and 160 mg tablets by Novartis Pharmaceuticals Canada Inc.) is now approved to reduce cardiovascular death in patients at high risk (i.e., heart failure or left ventricular dysfunction) following a heart attack. This new indication is based on data from the VALIANT trial.

**Taxotere** (docetaxel 20 and 50 mg vials by Aventis Pharma Inc.) has been approved for the treatment of androgen-independent (hormone-refractory) metastatic prostate cancer (in combination with prednisone or prednisolone). The dose for this indication is 75 mg/m<sup>2</sup> every three weeks, given as a one-hour infusion. Prednisone or prednisolone is administered at a dose of 5 mg bid continuously.

— Denis Bélanger, BScPhm