Health Canada Santé Canada

Date issued June 7, 2006

NOTICE OF DECISION
for
PrSOMAVERT*

On October 17, 2005, Health Canada issued a Notice of Compliance to Pfizer Canada Inc. for the drug product Somavert.

Somavert contains the medicinal ingredient pegvisomant, which is a human growth hormone (GH) receptor antagonist manufactured by recombinant DNA technology.

Somavert is indicated for the treatment of acromegaly in patients who have had an inadequate response to surgery, and/or radiation therapy, and other medical therapies, or for whom these therapies are not appropriate. Acromegaly is a rare endocrine condition caused by the excessive secretion of GH. The resulting clinical effects are attributable to high serum concentrations of both GH and insulin-like growth factor-I (IGF-I), which is GH dependent. Treatment with Somavert aims to restore normal serum IGF-I levels and to improve clinical signs and symptoms. Somavert acts by blocking the cell surface GH receptor preventing its activation by the elevated levels of circulating GH.

Priority review status was granted for Somavert taking into consideration the severity of the disease that it treats, the lack of adequate treatment available, and the clinical evidence of efficacy (based on Health Canada's clinical evaluation). Somavert is an innovative therapy for acromegalic patients with a significantly better safety profile than that of other medical therapies.

The market authorization for Somavert was based on quality, pre-clinical, and clinical information submitted. It has exhibited adequate evidence of efficacy for the authorized indication and the data have shown that it is an effective therapy for normalizing IGF-I levels as well as improving the symptoms of acromegaly. Somavert should be administered under the conditions stated in the Product Monograph taking into consideration all potential risks associated with the administration of this drug product.

Somavert (10 mg, 15 mg or 20 mg per vial) is presented as a lyophilized powder. Each vial must be reconstituted with 1 mL of diluent provided in the package. A loading dose of 40 mg of Somavert should be administered subcutaneously under physician supervision. The patient should then be instructed to begin daily subcutaneous injections of 10 mg of Somavert. Serum IGF-I concentrations should be measured every 4 to 6 weeks and appropriate dose adjustment should be made in increments of 5 mg/day (or decrements of 5 mg/day if IGF-I levels have decreased below normal range) in order to maintain the serum IGF-I concentration within the age-adjusted normal range and alleviate the signs and symptoms of acromegaly. The maximum dose should not exceed 30 mg/day. Further dosing guidelines are available in the Product Monograph.

Somavert is contraindicated for patients with a history of hypersensitivity to any of its components. The stopper on the vial of Somavert contains latex. Detailed conditions for the use of Somavert are described in the Product Monograph.

Based on the Health Canada review of data on quality, safety, and effectiveness, Health Canada considers that the benefit/risk profile of Somavert is favourable for the treatment of acromegaly in patients who have had an inadequate response to surgery, and/or radiation therapy, and other medical therapies, or for whom these therapies are not appropriate.

Notices of Decision (NDs) are produced in accordance with the Summary Basis of Decision (SBD) initiative. All NDs will be reproduced within the corresponding SBD, normally available within 5 months of product authorization.