



May 12, 2014

Notice

Our file number: 14-105927-39

Prescription Drug List (PDL): Multiple additions

The purpose of this Notice of Amendment is to notify the addition of Tesamorelin and Tofacitinib to both the Human and Veterinary Prescription Drug List (PDL). These additions are effective at the time of posting.

Tesamorelin or its salts or derivatives
Tésamoréline ou ses sels ou dérivés

Tofacitinib or its salts
Tofacitinib ou ses sels

Rationale:

A scientific review of these drugs against the criteria set out in C.01.040.3 of the *Food and Drug Regulations* indicates that these drugs require prescription status.

Tesamorelin is indicated for the treatment of excess visceral adipose tissue (VAT), as assessed by waist circumference ≥ 95 centimetres (cm) for males and ≥ 94 cm for females, and confirmed by a VAT level $> 130 \text{ cm}^2$ by computed tomography (CT) scan, in treatment-experienced adult Human Immunodeficiency Virus (HIV)-infected patients. Patients receiving the drug require monitoring for adverse reactions, including impaired glucose tolerance diabetes and hypersensitivity reactions, as well as biochemical monitoring of levels of insulin-like growth factor 1 (IGF-1).

Tofacitinib is indicated for the treatment of rheumatoid arthritis (RA). Tofacitinib in combination with methotrexate is indicated for reducing the signs and symptoms of (RA) and improving physical function in adult patients with moderately to severely active RA that does not respond to methotrexate. In cases of intolerance to methotrexate, physicians may consider the use of tofacitinib as monotherapy. Tofacitinib it is not effective for all RA patients, and may cause serious adverse effects. Therefore, the therapeutic response and the safety of Tofacitinib need to be monitored.

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Additional information on how Health Canada now determines prescription status (or non-prescription status) is available in the *Guidance Document: Determining Prescription Status for Human and Veterinary Drugs* (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/pdl-ord/pdl_gd_ord_ld-eng.php).

Should you have any questions on these amendments to the Prescription Drug List please contact:

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