

IMPORTATION OF US-LABELLED PHENELZINE SULFATE TABLETS USP 15mg DUE TO SHORTAGE OF CANADIAN LABELLED PHENELZINE SULFATE PRODUCT

AUDIENCE

Healthcare professionals including psychiatrists, general practitioners, pharmacists, and nurses.

KEY MESSAGES

- Phenelzine sulfate is a potent monoamine oxidase inhibitor (MAOI) indicated for the treatment of certain types of depressed patients.
- There is currently a shortage of phenelzine sulfate tablets in the Canadian market.
- Due to global shortage and given the medical necessity of this product for patients in Canada, Health Canada has added Lupin's product from the United States (US), Phenelzine Sulfate Tablets USP, to the List of Drugs for Exceptional Importation and Sale.
Link: <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods/information-provisions-related-drugs-biocides/list.html>
- The US product is labelled in English only and the label will be available on Lupin Pharma Canada's website. (Link: <http://www.lupinpharma.ca/generic-product> ; see below for outer label image). Additionally, the Product Information and Consumer Medicine Information for Lupin's US-labelled Phenelzine Sulfate Tablets USP will also be available online (<http://www.lupinpharma.ca/generic-product>).
- The US-labelled Phenelzine Sulfate Tablets USP is similar to Canadian authorized phenelzine sulfate tablets in terms of indications, recommended dosage, strength and presentation. It is recommended that healthcare professionals follow instructions included in the Canadian authorized phenelzine sulfate product labelling. (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>)
- The differences between the US-labelled Phenelzine Sulfate Tablets USP and Canadian authorized phenelzine sulfate tablets include:
 - Storage instructions.
 - Non-medicinal (inactive) ingredients.

ISSUE

There is currently a shortage of phenelzine sulfate 15 mg tablets in the Canadian market. Given the medical necessity of this product for patients in Canada, Health Canada has added US-labelled Phenelzine Sulfate Tablets USP, 15mg (manufactured by Novel Laboratories, a division of Lupin Ltd.) to the List of Drugs for Exceptional Importation and Sale, as an interim measure to help mitigate the shortage.



Link: <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods/information-provisions-related-drugs-biocides/list.html>

BACKGROUND INFORMATION

Phenelzine sulfate is a potent monoamine oxidase inhibitor (MAOI) indicated for the treatment of depressed patients clinically characterized as "atypical", "nonendogenous" or "neurotic". In Canada, Phenelzine sulfate, is indicated for patients who have failed to respond to other drugs more commonly used for these conditions.

INFORMATION FOR HEALTHCARE PROFESSIONALS

Healthcare professionals are advised of the following:

- US-labelled Phenelzine Sulfate Tablets USP (15 mg) contain the same amount of active ingredient compared to Canadian authorized and marketed phenelzine sulfate tablets (15 mg).
- The key formulation and labelling characteristics of Phenelzine Sulfate Tablets USP are indicated in the table below.

Product Name	Phenelzine Sulfate Tablets USP
Active Substance	Phenelzine sulfate
Concentration	15 mg per tablet
Other ingredients (inactive):	mannitol, USP; colloidal silicon dioxide, NF; povidone, USP; edetate disodium, USP; magnesium stearate, NF; purified water, USP; polyvinyl alcohol part-hydrolyzed USP, polyethylene glycol-3350 NF, FD&C yellow # 6, talc USP and titanium dioxide USP.
Fill Volume	60 tablets / bottle

- When switching between various antidepressants and phenelzine sulfate, the directions – specifically the duration of initiation and discontinuation regimens – are different between the US-labelled product and Canadian approved phenelzine. Healthcare professionals should read and carefully follow the instructions in the Canadian Product Monograph (CPM) for the phenelzine sulfate product at <https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>
- US-labelled Phenelzine Sulfate Tablets USP (15 mg) should be stored at 20°C-25°C.
- The non-medicinal (inactive) ingredients in the US-labelled Phenelzine Sulfate Tablets (15 mg) are different from the Canadian product (see listing in the table above).
- The US product does not have a Drug Identification Number (DIN) or a barcode that scans in medication management systems in Canada. A facility-generated sticker or



over-label may be required to enable barcode scanning and allow proper identification of the product being dispensed and administered.

In addition to the information found in the CPM referenced above, if needed, information for patients, physicians, pharmacists and other healthcare professionals about Phenzelzine Sulfate Tablets USP is available at <http://www.lupinpharma.ca/generic-product>

REPORT HEALTH OR SAFETY CONCERNS

Adverse reactions associated with the use of Phenzelzine Sulfate Tablets USP can be reported to Lupin Pharma Canada (by phone at 1- 844-587-4623 or by email at drugsafety@lupin.com), or Health Canada at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html> or by calling toll-free at 1-866-234-2345.

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IMAGES

US Label image

