Important Safety Information on NARDIL (phenelzine sulfate) Shortage

ERFA Canada 2012 Inc.

2020/06/24

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

Key messages

- **Due to a global shortage of NARDIL (phenelzine sulfate), a potent monoamine oxidase inhibitor (MAOI) indicated for the treatment of certain types of depressed patients, intermittent shortages of the product will be experienced in Canada.**
- **Healthcare professionals are advised to:**
    - **Ensure no new patients are started on NARDIL.**
    - **Consider switching patients taking NARDIL to an alternative treatment.**
    - **Avoid abrupt discontinuation of NARDIL treatment to prevent withdrawal syndrome, which can be serious. Treatment discontinuation should be gradual, and a `wash out` period of at least 10 days is necessary after discontinuation of NARDIL and before the start of the new treatment.**
    - **Monitor patients closely when taking patients off NARDIL.**
- **Health Canada, in partnership with health care system stakeholders, is working with ERFA Canada 2012 Inc. to help minimize the impact of this shortage on Canadians.**

What is the issue?
Due to a global shortage, availability of NARDIL (phenelzine sulfate) in Canada, manufactured by ERFA Canada 2012 Inc., is expected to be intermittent and a steady supply of the product in the future cannot be guaranteed based on current available information. Phenelzine is currently listed on the **Tier 3 list** of shortages. Tier 3 shortages are those with the greatest impact on supply and drugs on this list

are in high demand or currently in shortage. Health Canada works in collaboration with the provinces and territories, industry and stakeholders to mitigate the impact of Tier 3 shortages on patients and the health care system. Additional information and the latest updates regarding the shortage of NARDIL are available at: **drugshortagescanada.ca**.

Products affected

NARDIL, Phenelzine Sulfate Tablets USP, 15 mg DIN 00476552.

Background information

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

Due to a global shortage, NARDIL has been on backorder since March 2020. In March 2020, ERFA Canada 2012 Inc. sent a backorder notification to Health Canada, and a letter to all Canadian pharmacies outlining the importance of informing NARDIL patients and their physicians about the actual shortage and advising them to consider switching to alternative treatments. Supply conditions are expected to remain intermittent and access may not be available. Current shortage information is available at **www.drugshortagescanada.ca**.

Information for consumers

NARDIL (phenelzine sulfate) is used to treat depression where anxiety or fear is the main symptom and treatment with other drugs has failed.

There is a global shortage of NARDIL and based on current available information, the Canadian product manufacturer cannot guarantee a steady supply in the future. All patients who are treated with NARDIL should consult their healthcare professional as soon as possible in order to discuss alternative treatment options.

Before patients stop taking NARDIL, they need to talk to their healthcare professional. Patients should discuss with their healthcare professional how to safely discontinue NARDIL to minimize discontinuation symptoms and understand what symptoms require medical attention. Patients who suddenly stop taking NARDIL can experience serious side effects within one to three days including nightmares, agitation, psychosis (seeing or hearing things that are not there, or believing things which are not true) and convulsions.

Patients are advised to contact their health care professional and seek medical advice should they experience these side effects or an exacerbation of their underlying disease as soon as possible. Patients should also discuss any questions or concerns with their healthcare professional.

Information for healthcare professionals

Abrupt withdrawal of NARDIL can be associated with an uncommon withdrawal syndrome. Signs and symptoms of this syndrome generally commence 24 to 72

hours after drug discontinuation and may range from vivid nightmares with agitation to frank psychosis and convulsions. This syndrome generally responds to reinstitution of low-dose NARDIL therapy followed by cautious downward titration and discontinuation.

Currently in Canada, there are two other MAOIs available for the treatment of major depressive disorder: Parnate (tranylcypromine) and Manerix (moclobemide). Tranylcypromine is the most similar antidepressant to NARDIL. They both are irreversible old generation MAOIs. Moclobemide is a newer generation and a reversible MAOI. Compared to NARDIL and tranylcypromine, moclobemide treatment has no diet restrictions.

Healthcare professionals are advised to:

- Ensure no new patients are started on NARDIL.
- Consider switching patients taking NARDIL to an alternative treatment.
- Avoid abrupt discontinuation of NARDIL treatment to prevent withdrawal syndrome, which can be serious. NARDIL dose should be tapered off gradually for 3 to 5 weeks, and a 'wash out' period of at least 10 days is necessary after discontinuation of NARDIL and before the start of the new treatment.
- Monitor patients closely when taking patients off NARDIL.

Action taken by Health Canada

Health Canada and health care system stakeholders are working with ERFA Canada 2012 Inc. to manage the supply disruption of NARDIL. Health Canada is communicating this important safety information to healthcare professionals and Canadians via the Recalls and Safety Alerts Database on the Healthy Canadians Web Site. This communication will be further distributed through the MedEffect™ e-Notice email notification system as well as social media channels including LinkedIn and Twitter.

Report health or safety concerns

Managing marketed health product-related side effects depends on healthcare professionals and consumers reporting them. Any serious or unexpected side effects in patients receiving NARDIL should be reported to Health Canada.

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You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax.

For other health product inquiries related to this communication, contact Health Canada at:

Marketed Health Products Directorate
E-mail: mailto:mhpd_dpsc.public@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

Original signed by

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