



14 JUNE 2023

Importation of US-labelled Sabril® (vigabatrin) Tablets Due to Shortage of Canadian-authorized Sabril®

Subject: Drug stockout for Sabril® (vigabatrin) tablets, 500 mg and potential drug shortage for Sabril® powder for oral solution, 500 mg

Intended Audience: Healthcare Professionals and Pharmacies

Lundbeck Pharmaceuticals LLC (Lundbeck) is experiencing low levels of inventory of Sabril® (vigabatrin) powder for oral solution, 500 mg due to drug manufacturing and supply chain disruptions. The tablet formulation of Sabril® is presently out of stock. Stock for both presentations is anticipated to normalize in August 2023.

KEY MESSAGES

- There is a stockout of Sabril® (vigabatrin) tablets, 500 mg and a low level of inventory of Sabril® powder for oral solution, 500 mg in Canada. To help mitigate the shortage situation, Health Canada has permitted the exceptional, temporary importation and sale of US-labelled Sabril® Tablets, with English only labels, by Lundbeck Canada Inc. and has added this product to the List of Drugs for Exceptional Importation and Sale (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages/list.html>).
- **In order to preserve the supply of Sabril® powder for oral solution for patients not able to take the tablet formulation, we ask that pharmacists order the US-labelled tablets for patients presently using Sabril® tablets.**
- In Canada, Sabril® is indicated as second line adjunctive treatment of partial epilepsies and the management of infantile spasms (West syndrome).
- The US-labelled product has the **same strength (500 mg vigabatrin), route of administration, and dosage form** as the Canadian-authorized product, but **differs with respect to the debossing on the tablet (US tablets are imprinted with "OV 111" while Canadian tablets are imprinted with "SABRIL") and product packaging (US bottles have an outer carton while the Canadian bottles do not have an outer carton).**
- **Pharmacists should advise patients on the differences in appearances of the US and Canadian Sabril® tablets.**
- **The US-labelled product can be used and administered in the same manner as the Canadian-authorized product. For appropriate use of the US-labelled product, healthcare professionals should refer to the Canadian Product Monograph for Sabril® (vigabatrin tablets, 500 mg) available in English and French on the Health Canada Drug Product Database (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>).**



INFORMATION ON THE IMPORTED PRODUCT

Product Name	Sabril® Tablets
Product Description	500 mg Vigabatrin, Tablet. For Oral Administration. Lactose-free. Available in bottles of 100 tablets. The tablet is white, film-coated, oval, biconvex, scored on one side, and debossed with "OV 111" on the other side.
Foreign Identifying Code	NDC 67386-111-01
Lot Number and Expiry Date	Lot Number: Lot# 3197373 Expiry Date: MAR / 2024
US Market Authorization Holder	Lundbeck Pharmaceuticals LLC, Six Parkway North, Deerfield, IL, 60015, United States
Importer/Distributor in Canada	Lundbeck Canada Inc. 2600 Alfred-Nobel Blvd., Suite 400, Saint-Laurent, Quebec, Canada H4S 0A9

It is anticipated that a resupply of Canadian-authorized Sabril® powder for oral solution, 500 mg (DIN 02068036) will be available approximately August 2023 and the Canadian-authorized Sabril® tablets, 500 mg (DIN 02065819) may be available as early as August 2023.

INFORMATION FOR HEALTHCARE PROFESSIONALS

Healthcare professionals can locate the Canadian Patient Medication Information for Sabril® (vigabatrin tablets, 500 mg) on the Lundbeck Canada website:

English:([Sabril Patient Information CAN English \(lundbeck.com\)](http://lundbeck.com/Sabril_Patient_Information_CAN_English))

French:([Sabril Informations aux patients Francais.pdf \(lundbeck.com\)](http://lundbeck.com/Sabril_Informations_aux_patients_Francais.pdf))

Information about the US-labelled Sabril® Tablets for healthcare professionals is available for reference in English only at the following link:

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a88ac1b4-e2c9-45c0-b321-4785902172e3>.

Images of the US-labelled and Canadian-authorized products can be found in the Appendix below.

The US product labels are in English only while the Canadian product labels are in English and French.

The US-labelled product does not have a Drug Identification Number or a barcode that scans in medication management systems in Canada. A facility-generated sticker may be required to enable barcode scanning and allow proper identification of the product being dispensed and administered.

Lundbeck LLC

Six Parkway North
Deerfield, IL 60015

Tel 847-282-1000
Fax 847-282-1001



Proper selection of the intended product must be confirmed to avoid confusion with other products and prevent medication errors.

Lundbeck LLCSix Parkway North
Deerfield, IL 60015Tel 847-282-1000
Fax 847-282-1001**REPORTING ADVERSE DRUG REACTIONS**

Adverse drug reactions associated with the use of US-labelled Sabril® Tablets should be reported to either Lundbeck Canada Medical Information or Health Canada:

Lundbeck Canada Medical Information	Health Canada
<ul style="list-style-type: none"> • by calling 1-866-880-4636 or • via email to canadamedicalinformation@lundbeck.com or • at https://www.lundbeck.com/ca/en/report-adverse-drug-reaction 	<ul style="list-style-type: none"> • 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

ORDERING IMPORTED US PRODUCT

Orders for the US-labelled Sabril® Tablets can be placed through Ashfield Healthcare. Pharmacies can register with Ashfield Healthcare by emailing jennifer.santangelo@ashfieldhealthcare.com or calling 1-514-630-7484 and referencing the Lundbeck Sabril® Program. The pharmacy will be required to provide their full address and license number. Once registered, Ashfield will send out a weekly solicitation to all pharmacies in network with instructions on how to order the product.

QUESTIONS OR CONCERNS

Should you have any questions or concerns about US-labelled Sabril® Tablets, contact Lundbeck Canada Medical Information at 1-866-880-4636 or canadamedicalinformation@lundbeck.com.

Sincerely,

Marija Simin Geertsen, MD, MBA, Vice President, Lundbeck US Medical Affairs
Martine Hubert, MD, Senior Director, Medical and Regulatory Affairs, Lundbeck Canada

Lundbeck LLC

Six Parkway North
Deerfield, IL 60015

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APPENDIX

Images of US-labelled Sabril® Tablets (500 mg vigabatrin, Tablet):



The US-labelled product is available in bottles containing 100 tablets and comes packaged in an outer carton.

US Tablet:



The US tablet is white, film-coated, oval, biconvex, scored on one side, and debossed with “OV 111” on the other side.

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US Container Label:

<p>Each Tablet Contains: vigabatrin 500 mg</p> <p>See package insert for full prescribing information. Store at controlled room temperature, 20-25°C (68-77°F). Dispense in a USP tight container.</p> <p>Manufactured by: Patheon Cincinnati, OH 45237, U.S.A. For: Lundbeck Deerfield, IL 60015, U.S.A. Sabril is a registered trademark of Lundbeck</p>	<p>NDC 67386-111-01 100 Tablets</p> <p>Sabril[®] (vigabatrin) Tablets</p> <p>500 mg</p> <p>DISPENSE THE ENCLOSED MEDICATION GUIDE WITH EACH PRESCRIPTION.</p> <p>Rx only</p> <p></p>	<p>LOT: [redacted] EXP: [redacted]</p> <p>70032407</p>	<p>FFO</p>
	<p>LOT: [redacted] EXP: [redacted]</p> <p>70032407</p>		

US Carton Label:

<p>Store at controlled room temperature, 20-25°C (68-77°F).</p> <p>Dispense in a USP tight container.</p>	<p>NDC 67386-111-01 100 Tablets</p> <p>Sabril[®] (vigabatrin) Tablets</p> <p>500 mg</p> <p>DISPENSE THE ENCLOSED MEDICATION GUIDE WITH EACH PRESCRIPTION.</p> <p>Rx only</p> <p></p>	<p>Each Tablet Contains: vigabatrin 500 mg</p> <p>Recommended Dosage: See package insert for dosage information.</p> <p>Manufactured by: Patheon Cincinnati, OH 45237, U.S.A.</p> <p>For: Lundbeck Deerfield, IL 60015, U.S.A.</p> <p>Sabril is a registered trademark of Lundbeck</p> <p>Rx only</p> <p></p>
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Images of Canadian-authorized Sabril® (500 mg vigabatrin, Tablet):



The Canadian product is available in bottles containing 100 tablets. The Canadian product does **not** have an outer carton.

Canadian Tablet:



The Canadian tablet is white to off-white, film-coated, oval biconvex, scored on one side, and imprinted with "SABRIL" on the other side.

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Canadian Container Label:

Daily dosage: As directed by your healthcare professional. Total daily dose may be taken in one or two doses. **Store:** 15° - 30°C. Protect from moisture. Keep out of reach and sight of children.

Posologie quotidienne : Selon les directives de votre professionnel de la santé. La dose quotidienne totale peut être prise en une ou deux doses. **Conserver :** 15° - 30°C. Protéger de l'humidité. Garder hors de la portée et de la vue des enfants.

DIN 02065819

100 tablets/
comprimés

Sabril®
Vigabatrin Tablets/
Vigabatrine Comprimés

500 mg

Antiepileptic/
Antiépileptique



Pharmacist: Dispense with Patient Medication Information. **Au pharmacien :** Remettre avec les renseignements sur le médicament pour le patient.

Manufactured for/
Fabriqué pour :
Lundbeck, Deerfield, IL
60015, U.S.A.
Imported and distributed
by:/Importé et distribué
par :
Lundbeck Canada Inc.,
Saint-Laurent (Québec)
Canada H4S 0A9
Questions or concerns/
Product Monograph; Des
questions ou problème?/
Monographie de produit:
1-866-880-4636
® Trademark of Lundbeck/
® Marque déposée de Lundbeck



LOT: YYY-MM
EPO

70036106