Importation of US-labelled Vigabatrin for Oral Solution, USP due to the current shortage of Canadian-authorized Vigabatrin for Oral Solution

Dr. Reddy's Laboratories Canada Inc.
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Dear Wholesalers, Group Purchasing Organizations and Retail Pharmacies:

There is a critical shortage of Vigabatrin for Oral Solution in Canada. To help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of Dr. Reddy's Laboratories Limited's US-labelled Vigabatrin for Oral Solution, USP with English language only labels, by Dr. Reddy's Laboratories Canada Inc.

Health Canada has accepted the addition of Dr. Reddy's Laboratories Limited's 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 Canada, Vigabatrin for Oral Solution is a prescription drug product indicated for:

- Treatment of epilepsy only in those patients who respond inadequately to alternative treatment combinations or in whom other drug combinations have not been tolerated and in whom the potential benefits conferred by its use outweigh the risk of ophthalmologic abnormalities.
- Management of infantile spasms (IS or West syndrome), as monotherapy, although the benefits of its use and the risks of ophthalmologic abnormalities must be taken into account.

The US-labelled drug product has the **identical active ingredient, strength (500 mg vigabatrin), dosage form (powder for solution), route of administration (oral), and non-medicinal ingredients** as the Canadian-authorized product. The US-labelled product, however, **differs with respect to the reconstitution instructions**.

The **instructions for the US-labelled product state that the product should be reconstituted only with cold or room temperature water prior to administration** while the instructions for the Canadian-authorized product state that the product should be reconstituted with cold or room temperature water, fruit juice, milk, or infant formula prior to administration.

With the exception of the reconstitution directions, the US-labelled product can be used in the same manner as the Canadian-authorized product. The US-labelled product should only be reconstituted

with cold or room temperature water before oral administration as per the instructions in the US product labelling.

For the reconstitution instructions, healthcare professionals should refer to the United States Prescribing Information (USPI) for Dr. Reddy's Vigabatrin for Oral Solution, USP (500 mg vigabatrin) available in English at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f6be436e-46c7-e9ab-0fcf-e8d04dc12b72. **The French language reconstitution instructions of US labelled product will be available in the French translated copy of "Risk Communication Document".**

For information on the indications, contraindications, warnings and precautions, adverse reactions, drug interactions, dosage and administration (excluding reconstitution instructions), storage conditions, and handling instructions, healthcare professionals should refer to the Canadian Product Monograph for the marketed Vigabatrin for Oral Solution, 500 mg product available in English (https://health-products.canada.ca/dpd-bdpp/info?code=43682&lang=eng) on the Health Canada Drug Product Database (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html).

Information on the imported drug product

Brand name	Dosage form, strength and route of administration	Product description and packaging	Country of authorization and identifying code	Authorization holder	DEL holder/ Importer in Canada
Vigabatrin for Oral Solution, USP	**Dosage Form:** Powder for Solution **Strength:** 500 mg vigabatrin **Route of administration:** Oral	**Product Description:** Vigabatrin for oral solution, USP is available as a white to off-white powder for oral solution in packets of 500 mg. **Packaging:** supplied in packages of 50	**Country of Authorization:** United States of America **Identifying Code:** NDC 43598-697-11 (Packet), NDC 43598-697-50 (Carton)	Dr. Reddy's Laboratories, Inc. U.S. Agent for Dr. Reddy's Laboratories Limited	Dr. Reddy's Laboratories Canada Inc.

Images and tabular representation of English and French label text of US-labelled product can be found in Appendix 1.

Healthcare professionals are advised that aspects of the inner and outer labels and packaging of the US-labelled product may differ from marketed Vigabatrin for Oral Solution products in Canada. **Proper selection of the intended product must be verified to avoid confusion with other products and prevent medication errors.**

Pharmacists should advise patients about the difference in reconstitution instructions and that the

US-labelled product should be reconstituted only with cold or room temperature water prior to administration as per the instructions in the US product labelling.

Please also note that an oral syringe is required for product administration and is to be provided separately to patients by the pharmacy.

The US-labelled product does not have a drug identification number (DIN) or a barcode that scans in medication management systems in Canada. A facility-generated sticker may be required to enable barcode scanning and allow the product being dispensed and administered to be properly identified.

Reporting adverse drug reactions

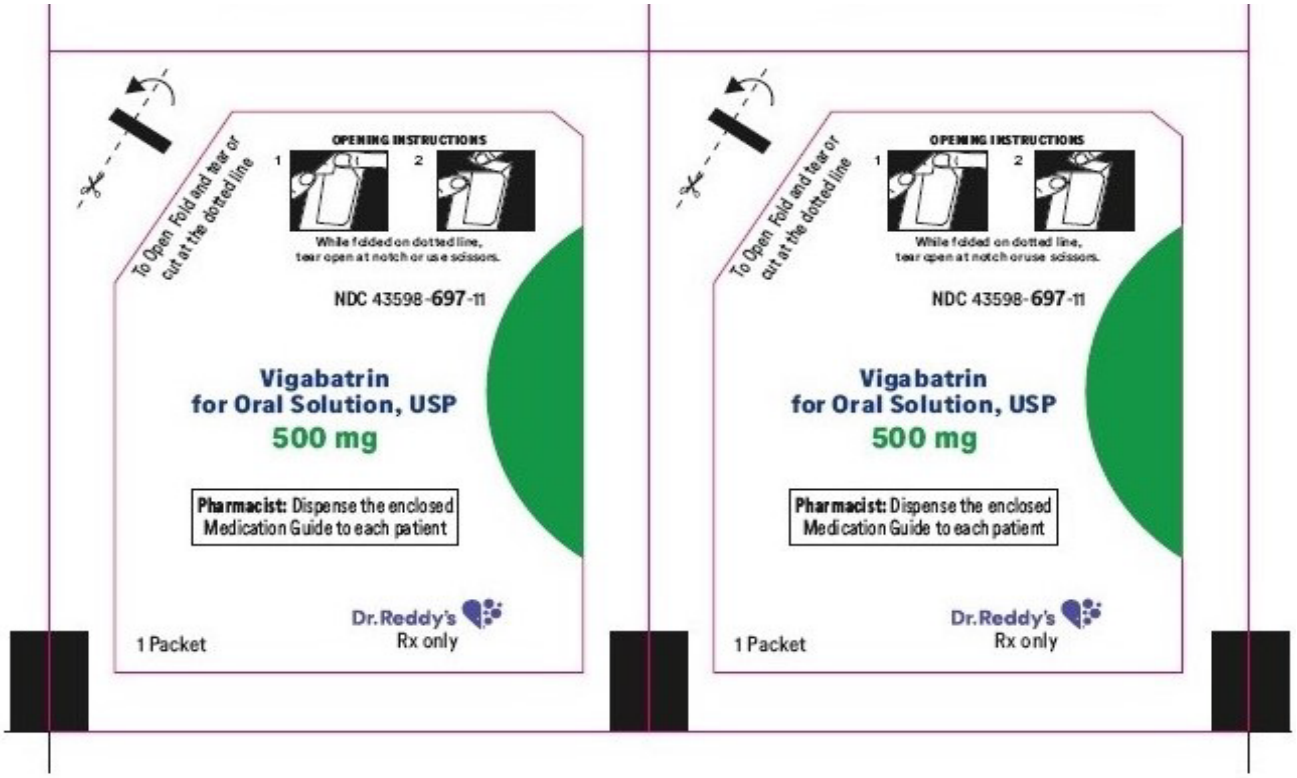
Adverse drug reactions associated with the use of Vigabatrin for Oral Solution, USP should be reported to Dr. Reddy's Laboratories Canada Inc., by calling 1-855-845-1739 or to Health Canada's Adverse Reaction Reporting Web Page (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) or by calling toll-free at 1-866-234-2345.

Questions or concerns

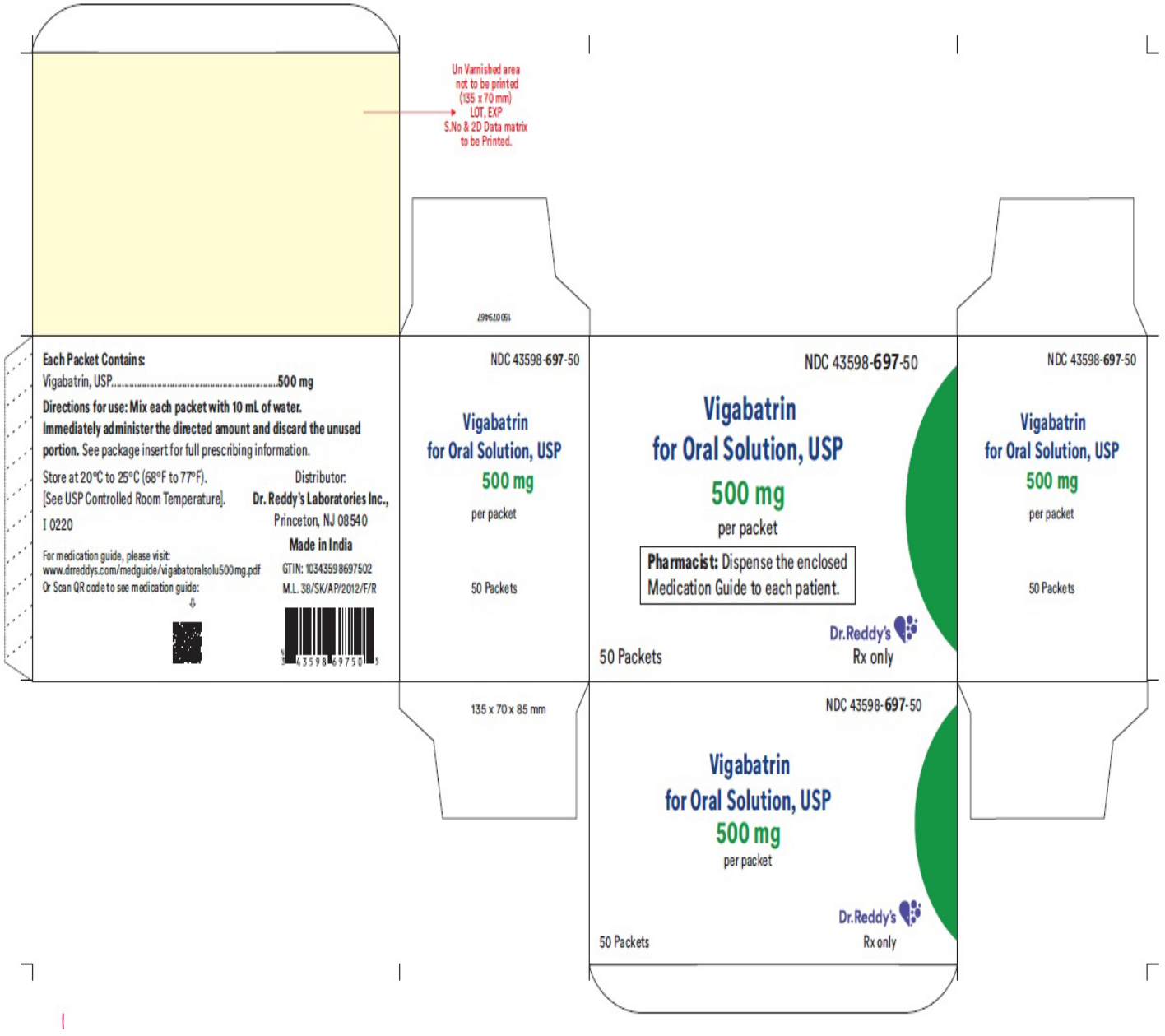
For questions or concerns about US-labelled Vigabatrin for Oral Solution, USP, please contact Dr. Reddy's Laboratories Canada Inc., by calling 1-855-845-1739.

Appendix 1 - English US Inner and Outer Label of US labelled Vigabatrin for Oral Solution, USP

US Packet Label



US Carton Label



Tabular representation of English and French Label text of US-labelled **Vigabatrin for Oral Solution, USP**

Packet Label	**Étiquette des sachets**
English	**Français**
Front Panel	**Avant**
Vigabatrin for Oral Solution, USP 500 mg	Vigabatrine pour solution buvable, USP 500 mg
Pharmacist: Dispense the enclosed Medication Guide to each Patient	Pharmacien : Remettre à chaque patient accompagné du Guide sur le médicament ci-inclus
1 Packet	1 sachet
Rx Only	Produit d'ordonnance seulement
Opening Instructions While folded on dotted line, tear open at notch or use scissors. To Open Fold and tear or cut at the dotted line	Instructions d'ouverture Plier le long des pointillés, puis déchirer à l'encoche ou utiliser des ciseaux Pour ouvrir, plier et déchirer ou couper en suivant les pointillés
Back Panel	**Arrière**
Each Packet Contains: Vigabatrin USP 500 mg	Chaque sachet contient: Vigabatrine USP 500 mg
Directions for use: Mix each packet with 10 mL of water. Immediately administer the directed amount and discard the unused portion. See package insert for full prescribing information. Store at 20°C to 25°C (68°F to 77°F). (See USP Controlled Room Temperature). Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540 Made in India Opening Instructions on Front	Mode d'emploi : Mélanger le contenu du sachet avec 10 mL d'eau. Administrer la dose prescrite immédiatement et jeter la partie inutilisée. Consulter la notice d'emballage pour obtenir les renseignements thérapeutiques complets. Conserver entre 20 et 25°C (68 et 77°F). (Voir Température ambiante contrôlée, USP). Distribué par : Dr. Reddy's Laboratories Inc. Princeton, NJ 08540 Fabriqué en Inde Instructions d'ouverture sur le devant

Carton label	**Étiquette des cartons**
English	**Français**
Vigabatrin for Oral Solution, USP 500 mg per packet	Vigabatrine pour solution buvable, USP 500 mg par sachet
Pharmacist: Dispense the enclosed Medication Guide to each Patient	Pharmacien : Remettre à chaque patient accompagné du Guide sur le médicament ci-inclus
50 Packets	50 sachets
Rx Only	Produit d'ordonnance seulement
Each Packet Contains: Vigabatrin USP 500 mg	Chaque sachet contient: Vigabatrine USP 500 mg
Directions for use: Mix each packet with 10 mL of water. Immediately administer the directed amount and discard the unused portion. See package insert for full prescribing information. Store at 20°C to 25°C (68°F to 77°F). (See USP Controlled Room Temperature). Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ, 08540 Made in India For medication guide, please visit: www.drreddys.com/medguide/vigabatoralsolu500mg.pdf or Scan the QR code to see medication guide	Mode d'emploi : Mélanger le contenu du sachet avec 10 mL d'eau. Administrer la dose prescrite immédiatement et jeter la partie inutilisée. Consulter la notice d'emballage pour obtenir les renseignements thérapeutiques complets. Conserver entre 20 et 25 °C (68 et 77 °F). (Voir Température ambiante contrôlée, USP). Distribué par : Dr. Reddy's Laboratories Inc. Princeton, NJ 08540 Fabriqué en Inde Pour consulter le Guide sur le médicament, veuillez vous rendre à la page www.drreddys.com/medguide/vigabatoralsolu500mg.pdf ou numériser le code QR