NOVARTIS PHARMACEUTICALS CANADA INC.
385 Bouchard Boulevard
Dorval, QC
H9S 1A9
www.novartis.ca

3 December, 2021

Incorrect drug and dietary interaction instructions on outer carton of REVOLADE® (eltrombopag 25 mg and 50 mg tablets for oral use)

Dear Healthcare Professional,

Novartis is advising of a labelling error in the drug-drug and dietary interaction instructions on the back panel of the outer cartons of REVOLADE®.

As per the Canadian Product Monograph, REVOLADE® is indicated:

- For the treatment of chronic immune thrombocytopenia (ITP) to increase platelet counts in adult and pediatric patients one year and older who have had an insufficient response to corticosteroids or immunoglobulins.
- To increase platelet counts in thrombocytopenic patients with chronic hepatitis C virus (HCV) infection to allow the initiation and maintenance of interferon-based therapy.
- For the treatment of adult patients with severe aplastic anemia (SAA) who have had an insufficient response to immunosuppressive therapy.

The drug-drug and dietary interaction instructions on the REVOLADE® outer cartons incorrectly state that: *Antacids, dairy products and other products (e.g. mineral supplements) should be taken at least 2 hours before or 4 hours after REVOLADE® tablets.*

The correct drug-drug and dietary interaction instructions are: ***REVOLADE® tablets should be taken at least 2 hours before or 4 hours after antacids, dairy products and/or other products (e.g. mineral supplements).*** Please refer to the table below.

INCORRECT drug-drug and dietary interaction instructions on the back panel of the outer cartons of REVOLADE®	**CORRECT drug-drug and dietary interaction instructions on the back panel of the outer cartons of REVOLADE®**
Swallow the tablets whole, with some water. Do NOT crush tablets and then mix with food or liquids. Antacids, dairy products and other products (e.g. mineral supplements) should be taken at least 2 hours before or 4 hours after REVOLADE® tablets.	Swallow the tablets whole, with some water. Do NOT crush tablets and then mix with food or liquids. REVOLADE® tablets should be taken at least 2 hours before or 4 hours after antacids, dairy products and/or other products (e.g. mineral supplements).

The use of REVOLADE® according to the incorrect drug-drug and dietary interaction instructions on the outer carton may lead to a decreased absorption of the active ingredient, eltrombopag, and reduced hematologic response. **Healthcare professionals are advised to follow up with patients taking products such as antacids, dairy, or mineral supplements on a regular basis. Patients should**

be closely monitored by physicians while correcting the drug-drug and dietary interaction instructions and dosage should be adjusted as clinically appropriate. Patients have been advised to contact their healthcare professionals to review their medication schedule and/or consider dose adjustment.

The drug-drug and dietary interaction instructions that appear in the Canadian Product Monograph and the Patient Medication Information for REVOLADE® are correct. **Healthcare professionals should refer to the Canadian Product Monograph available on the Health Canada Drug Product Database at https://health-products.canada.ca/dpd-bdpp/ and the Patient Medication Information leaflet enclosed in the REVOLADE® cartons for the directions for use.**

It is important to note that this is a labelling error affecting only the outer carton and that there are **no concerns with the product quality of REVOLADE®**. Newer lots of REVOLADE® will have the correct drug-drug and dietary interaction instructions as noted above and will be made available at the end of January 2022.

Information for Pharmacists: Prior to dispensing to patients, pharmacists are advised to place the pharmacy prescription label stickers in the centre of the back panel of the outer cartons of REVOLADE® to conceal the incorrect drug-drug and dietary instructions.

According to their clinical expertise, pharmacists are advised to refer patients to their physician should their medication schedule needs to be changed or if a dose adjustment of REVOLADE® and monitoring would be needed.

A list of the affected lots can be found in the table below. Images of REVOLADE® can be found in the Appendix below.

Affected lots:

Product Description	DIN	Lot	Expiry Date
REVOLADE® Film-coated Tablets 25 mg Blister pack of 14 tablets (2 X 7 tablets)	**02361825**	**CW6C**	**2022-JA**
		NG9U	**2022-JA**
		X73U	**2023-AU**
		XN8R	**2022-AL**
		DN5A	**2022-MA**
		286P	**2022-SE**
		R76C	**2022-NO**
		CN4F	**2023-FE**
		R75N	**2023-JA**
		GC8A	**2023-AL**
		CA8V	**2023-OC**
		2N4G	**2024-JA**

REVOLADE® Film-coated Tablets 25 mg Blister pack of 28 tablets (4 X 7 tablets)	**02361825**	**NN3G**	**2022-JA**
		458P	**2022-MR**
		C92Y	**2022-MA**
		NF9X	**2022-MA**
		BP4U	**2022-OC**
		MP2T	**2022-NO**
		XV2C	**2023-JA**
		FH4J	**2023-FE**
		R75P	**2023-JA**
		LS9J	**2023-MA**
		9E4G	**2023-AU**
		9E4K	**2023-AU**
		NY8T	**2023-NO**
		BAFF5	**2024-SE**
		9L6J	**2024-JA**
REVOLADE® Film-coated Tablets 50 mg Blister pack of 14 tablets (2 X 7 tablets)	**02361833**	**JE9E**	**2022-JA**
		VR9C	**2022-MR**
		DA6H	**2022-AL**
		XA6N	**2022-SE**
		DC8W	**2022-NO**
		WJ4V	**2023-JA**
		PS4F	**2023-FE**
		SK8M	**2023-JN**
		BAFW8	**2024-AL**
		K88A	**2023-SE**
REVOLADE® Film-coated Tablets 50 mg Blister pack of 28 tablets (4 X 7 tablets)	**02361833**	**LY3F**	**2022-JA**
		TW7G	**2021-DE**
		3Y4V	**2022-MA**
		3X7B	**2022-AL**
		CH7P	**2022-AL**

NE5A	**2022-AU**
SR2G	**2022-AU**
YW5N	**2022-SE**
D89X	**2022-NO**
F27H	**2022-NO**
NS8H	**2022-NO**
V36N	**2023-JA**
YT7R	**2023-JA**
AM9M	**2023-FE**
FY8R	**2023-FE**
R75T	**2023-FE**
8D3B	**2023-MA**
WX4A	**2023-JL**
B47L	**2023-SE**
UJ4L	**2023-NO**
UJ4N	**2024-JA**
BAFW9	**2024-AL**

Reporting adverse drug reactions

Adverse drug reactions associated with the use of REVOLADE® should be reported to Novartis Pharmaceuticals Canada Inc. (see the 'Company contact point' section below) or to 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.

Company contact point

We appreciate your immediate attention and cooperation and sincerely apologize for any inconvenience that this may cause you and your patients. We hope this action reassures you of our commitment to provide you with the highest quality products and continued quality excellence for you and your patients.

Should you have any questions or concerns, please contact the **Medical Information** department at 1-800-363-8883 or medinfo.canada@novartis.com.

Sincerely yours,

Galarce Jaramillo Daniella Galarce

Firmado digitalmente por Galarce Jaramillo Daniella Galarce
Nombre de reconocimiento (DN): c=com, dc=novartis, ou=people, ou=TD, serialNumber=1862449, cn=Galarce Jaramillo Daniella Galarce
Motivo: I am the author of this document
Fecha: 2021.12.03 12:03:51 -03'00'

Daniella Galarce, Operation Support, Manager Quality, Canada

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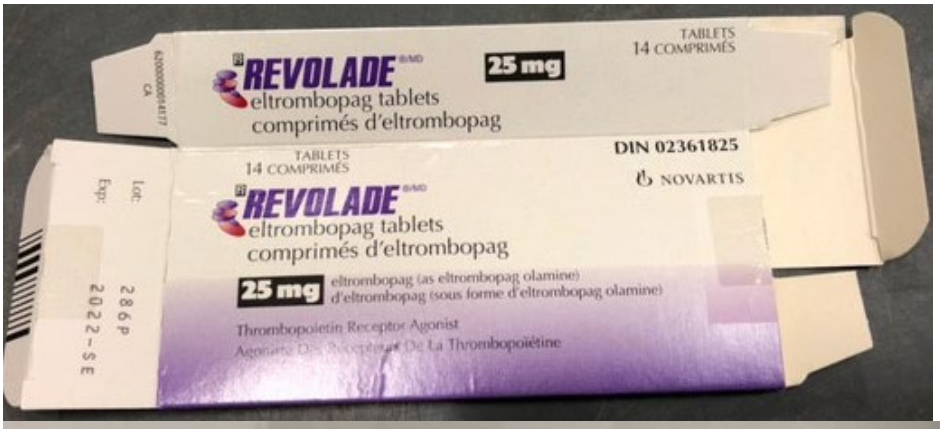
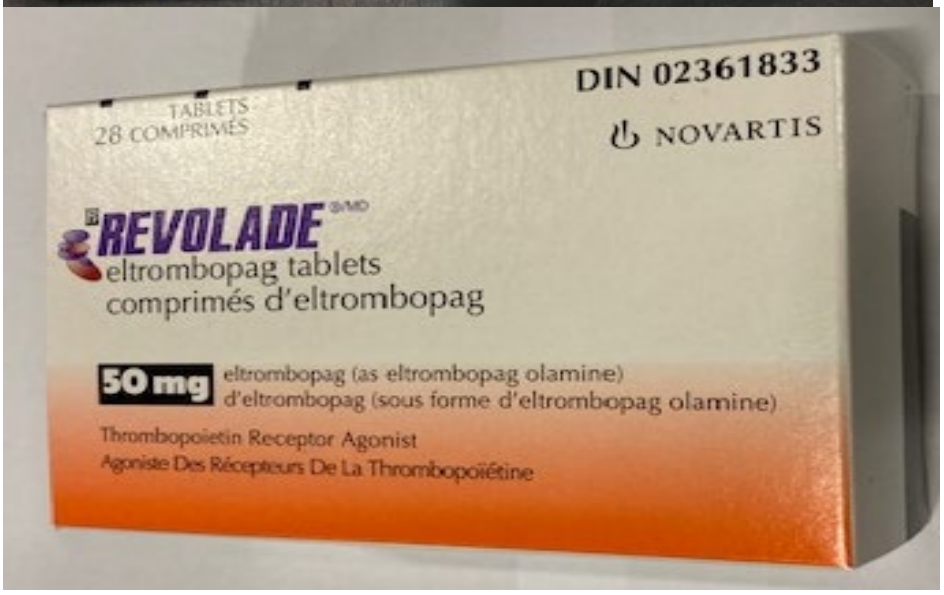
REVOLADE is a registered trademark

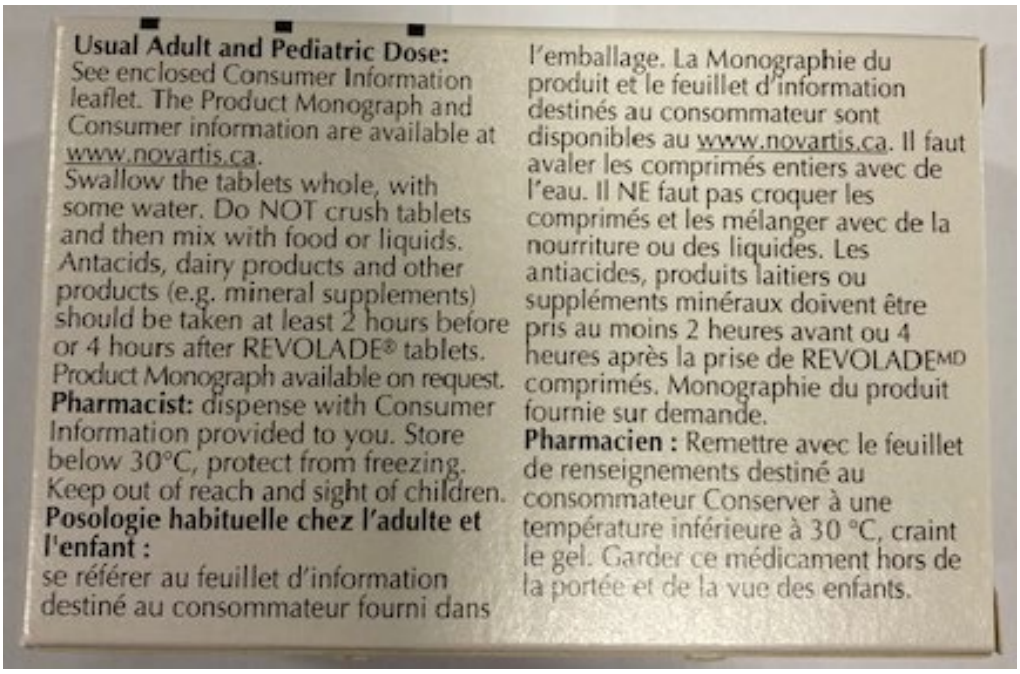
Appendix

Images of the REVOLADE® (25 mg and 50 mg strengths) outer cartons with the <u>INCORRECT</u> drug-drug and dietary interaction instructions





Images of the back panel of the REVOLADE® (25 mg and 50 mg strengths) outer carton with the <u>INCORRECT</u> drug-drug and dietary interaction instructions



Usual Adult and Pediatric Dose:
See enclosed Consumer Information leaflet. The Product Monograph and Consumer information are available at www.novartis.ca.
Swallow the tablets whole, with some water. Do NOT crush tablets and then mix with food or liquids. Antacids, dairy products and other products (e.g. mineral supplements) should be taken at least 2 hours before or 4 hours after REVOLADE® tablets. Product Monograph available on request.
Pharmacist: dispense with Consumer Information provided to you. Store below 30°C, protect from freezing. Keep out of reach and sight of children.
Posologie habituelle chez l'adulte et l'enfant :
se référer au feuillet d'information destiné au consommateur fourni dans l'emballage. La Monographie du produit et le feuillet d'information destinés au consommateur sont disponibles au www.novartis.ca. Il faut avaler les comprimés entiers avec de l'eau. Il NE faut pas croquer les comprimés et les mélanger avec de la nourriture ou des liquides. Les antiacides, produits laitiers ou suppléments minéraux doivent être pris au moins 2 heures avant ou 4 heures après la prise de REVOLADE[MD] comprimés. Monographie du produit fournie sur demande.
Pharmacien : Remettre avec le feuillet de renseignements destiné au consommateur Conserver à une température inférieure à 30 °C, craint le gel. Garder ce médicament hors de la portée et de la vue des enfants.