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

3 December, 2021

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

Dear Patient,

Novartis is advising of a labelling error in the drug and dietary interaction instructions on the back of the boxes of REVOLADE®, a prescription drug used to increase platelet count.

The drug and dietary interaction instructions on the REVOLADE® boxes 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 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.

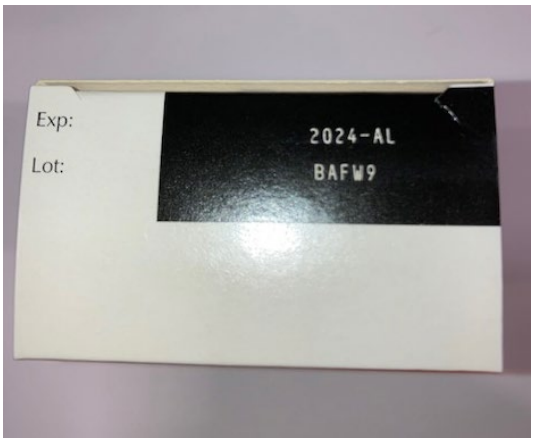
INCORRECT drug-drug and dietary interaction instructions on the back of the boxes of REVOLADE®	**CORRECT drug-drug and dietary interaction instructions on the back of the boxes of REVOLADE®**
Swallow the tablets whole, with some water. Do NOT crush tablets and then mix with food or liquids. Antacids, 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).

If you take products such as antacids, dairy or mineral supplements on a regular basis, consult your healthcare professional as soon as possible to check if your medication schedule needs to be changed or if a dose adjustment of REVOLADE® and monitoring would be needed. Do NOT change your medication schedule without consulting your healthcare professional first.

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

A list of the affected lots can be found in the table below. Refer to the side of the boxes for the lot number and expiry date (see example provided below). Additional images of REVOLADE® can be found in the Appendix below.

Example: Images of the side of a box of REVOLADE® with the lot number and expiry date



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. We hope this action reassures you of our commitment to provide you with the highest quality products and continued quality excellence for you.

If you are enrolled in the Sentia (formerly inReach) Patient Support Program (PSP) and you have questions about the drug and dietary interaction instructions, please speak to your Health Management Coach at 1-855-736-8421.

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

Sincerely yours,

Daniella Galarce, Operation Support, Manager
Quality, Canada

Galarce Jaramillo
Daniella Galarce

Firmado digitalmente por Galarce Jaramillo Daniella Galarce
Nombre de reconocimiento (DN): dc=com, dc=novartis, ou=people, ou=TQ, serialNumber=1862449, cn=Galarce Jaramillo Daniella Galarce
Motivo: I am the author of this document
Fecha: 2023.12.03 12:00:41 -05'00'

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REVOLADE is a registered trademark

Appendix

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

Images of the back of the REVOLADE® (25 mg and 50 mg strengths) box 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.