

Date: 01/Feb/2021

Dear Valued Customer,

This letter is to notify you of an additional repackaging activity for WinRho® SDF following modifications to the WinRho® SDF labelling.

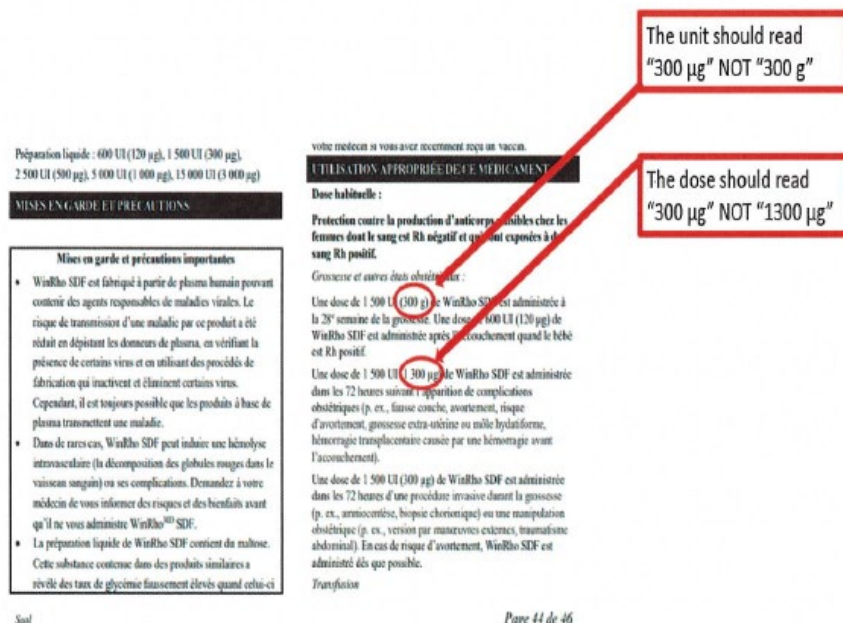
1. Product Monograph

As previously communicated, a labelling error was identified on the WinRho® SDF product monograph (PM) and product insert. This is applicable to all marketed strengths of WinRho® SDF.

The correction was specific to the French language PART III - PATIENT MEDICATION INFORMATION section of the PM and the French language product insert. Under the section PROPER USE OF THIS MEDICATION, the unit "g" for grams is present instead of the correct unit "µg" for micrograms. The dosage in the paragraph which followed was also modified, with "1300 µg" instead of the required dose of "300 µg". All other product information and dosing guidelines are correct throughout. Please see Figure 1 herein for more information.

The modifications to the Patient Information section of the French Product Monograph (PM) were authorized by Health Canada, and subsequently put into effect.

Figure 1: Incorrect section on French Canadian Product Monograph and insert – PART III



2. Further Product Monograph and Patient Insert Revisions:

- Replaced abbreviations with clearer text information to include:
 - μg = mcg
 - IU = international units
 - $<$ = less than
 - $>$ = greater than
 - \leq = less than or equal to
 - \geq = greater than or equal to
 - \pm = plus or minus
- Replaced 'Immune globulin' with 'Immunoglobulin'
- Updated contact number for AE reporting from 877-443-0224 to 833-644-4216
- Corrected minor punctuation, typos and translation errors
- PART II of the package insert was removed from the insert, in line with Health Canada Guidance Document: "Labelling of Pharmaceutical Drugs for Human Use", to provide for a better fit of the insert into the product carton. PART II will remain in the Product Monograph.

3. Lot Number

A repackaging activity occurred for the following WinRho[®] SDF lot incorporating the revised product insert as described above. As a result of the repackaging, an additional digit (a '1') was added to the lot number sequence as it appears on the product carton. As the change was simply a replacement of the revised insert, the original vial lot number remained the same.

The affected lot and the corresponding lot identifiers are provided in the table that follows.

Drug Product	Vial label lot number	Carton lot number
WinRho SDF 1000 mcg (5000 IU)	23002957	230029571

Please note that any required communication related to this lot, will reference both the unit carton and vial lot numbers to avoid any opportunity for confusion.

The revised Product Monographs can be found on the product website (www.winrho.com) or through the links below:

[WinRho English Product Monograph](#)

[WinRho French Product Monograph](#)

Thank you for supporting the use of WinRho[®] SDF Rho(D) Immunoglobulin (Human).

Saol Customer Service

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