August 11, 2020

Dear Colleagues/Customer,

Takeda Canada was made aware of an unanticipated increase in demand for Obizur 500 units [Antihemophilic Factor (Recombinant), Porcine Sequence], DIN 02447401, due to patient needs. Takeda Canada plans to import the USA lot VN22501AL, to mitigate the impending shortage of Canadian Obizur product. The USA product is similar to the Canadian product and the only difference is in the labelling. Please note that Health Canada approved the distribution of USA label product in Canada.

To ensure safe use of the product, please refer to the Obizur Canadian Product Monograph for labelling information. The Canadian Product Monograph is available in English and French here https://www.takeda.com/en-ca/obizurpm and https://www.takeda.com/fr-ca/obizurmp
If additional information is required, please contact Takeda Medical Information at +1-800-268-2772 or medinfoCA@takeda.com.

The USA Package Insert does not reflect the Canadian approved information and should not be used with the product. The Appendix provides a comparison summary of the USA and Canadian labeling (Indications, Dosing, Preparation, Administration, Dosing, Warning and Precautions) along with the pictures of the USA and Canadian product. Additionally, Canadian Blood Services will be provided with labels along with summary table of the USA and Canadian barcodes.

The current method of reporting suspected adverse drug events and to inquire about Medical Information remains unchanged. The details of reporting suspected adverse drug events is available in the Canadian Product Monograph. Additionally, the adverse drug event reporting details and the Medical Information contact details can be found online at https://www.takeda.com/en-ca/what-we-do/our-medicines/shire-products/ or suspected side effects can be reported directly by email to DrugSafety@shire.com.

Sincerely,

Jefferson Tea, PhD, MBA
Vice President/Head of Medical & Scientific Affairs

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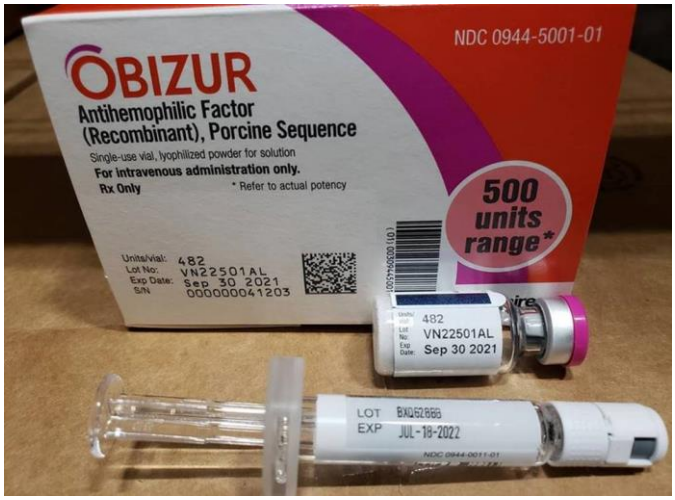
APPENDIX

Condition	USA-labelled Product	Canadian-approved Product
Indications	OBIZUR, Antihemophilic Factor (Recombinant), Porcine Sequence, is an antihemophilic factor indicated for the treatment of bleeding episodes in adults with acquired hemophilia A.	OBIZUR is indicated for: Treatment of bleeding episodes in patients with Acquired Hemophilia A (AHA)
Dosing	• Initial dose of OBIZUR is 200 units per kg. • Titrate dose and frequency of administration based on factor VIII recovery levels and individual clinical response.	- 200 units per kg initial dose - Dosage, frequency, and duration of treatment with OBIZUR depend on the severity of bleeding episode, target factor VIII levels, and the patient's clinical condition.
Preparation	Reconstitution • Use aseptic technique during the reconstitution procedure. - steps 1-12 that describe the Reconstitution procedure in detail - step 13: Use OBIZUR within 3 hours after reconstitution when stored at room temperature.	Reconstitution 1. Use aseptic technique during reconstitution procedure. - steps 1-9 that describe the Reconstitution procedure in detail under Administration: Administer OBIZUR at room temperature within 3 hours of reconstitution
Administration	For intravenous use after reconstitution only	For intravenous use after reconstitution only
Warnings and precautions	Hypersensitivity reactions can occur with OBIZUR. OBIZUR contains trace amounts of hamster proteins. Early signs of allergic reactions, which can progress to anaphylaxis, include angioedema, chest-tightness, dyspnea, hypotension, wheezing, urticaria, and pruritus. Immediately discontinue administration and initiate appropriate treatment if allergic or anaphylactic-type reactions occur.	Allergic type hypersensitivity reactions (including anaphylaxis) may occur. The product contains trace amounts of hamster proteins. Early signs of allergic reactions, which can progress to anaphylaxis, include angioedema, chest-tightness, hypotension, lethargy, nausea, vomiting, paresthesia, restlessness, wheezing, and dyspnea. Immediately discontinue administration and initiate appropriate treatment if allergic or anaphylactic-type reactions occur.

USA Image*	Canadian Image*
OBIZUR carton, OBIZUR vial and Syringe with Sterile water	OBIZUR carton, OBIZUR vial
	

Carton Label	<u>USA Obizur Product</u> NDC 0944-5001-01 (Top of Carton) (01) 00309445001 01 7 Bar code on bottom is packaging component	<u>Canadian Obizur Product</u> DIN 02447401 GTIN 00642621026887

*For comparison purposes only, each kit (USA and Canadian product) contains 1 vial of OBIZUR, syringe with sterile water and vial adapter with filter