September 18, 2024

Subject: Octaplex® New Design and format for Carton and Leaflet

Dear Health Care Professional,

The purpose of this letter is to notify you of changes to the existing Octaplex® labelling artwork that have been implemented to improve ease of access to key product information for safe and effective use. The changes made will impact all Octaplex® 500IU and 1000IU labelled packaging components, including the outer carton, vial labels as well as inner leaflet.

These changes will impact all batches that are manufactured on or after April 1st, 2024.

A summary of all changes to each packaging component has been included below in **Table 1**. Revised labelling was submitted for review to Health Canada and received formal approval as of January 17th, 2024.

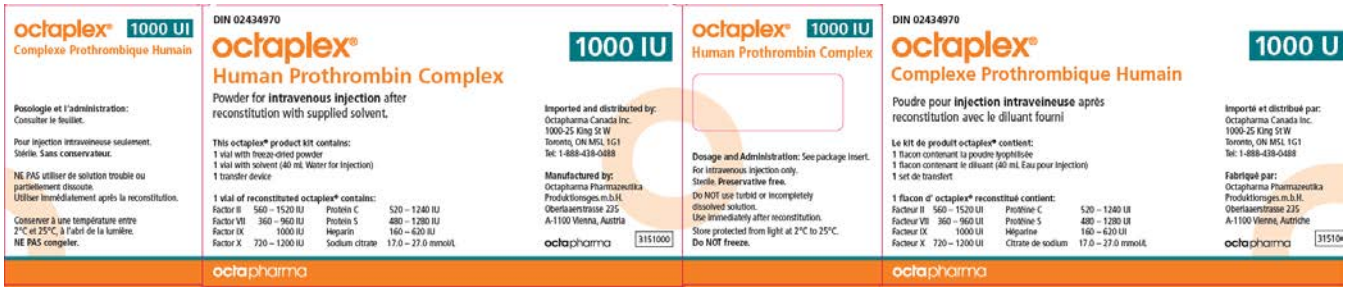
It should be noted that all product labelling continues to align with the existing product monograph and therefore any changes made at this time do not alter the way in which the product will be used or administered to patients.

Summary of Labelling Revisions:

Images below indicate all changes that apply to batches manufactured on or after April 1st, 2024.

Octaplex® 1000IU and 500IU Carton Label Summary of Changes:

1. *Key product information bolded and capitalized for enhanced visibility (e.g.* ***ne PAS congeler / do NOT freeze****)*
2. *Placement of DIN at the top left corner*
3. *Updated packaging artwork design (updated colourway and incorporated standard Octaplex circle design)*



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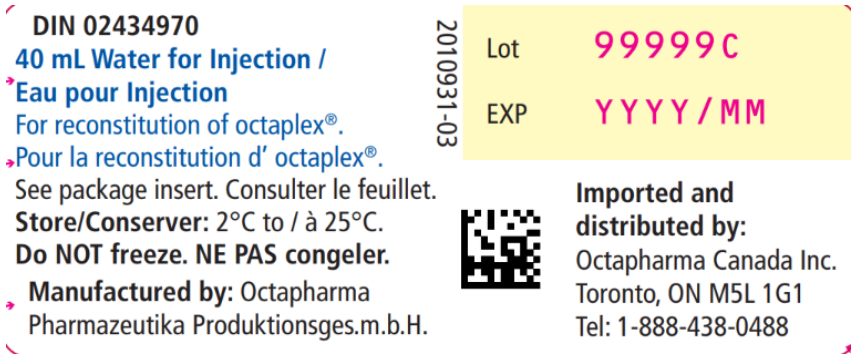
Octaplex® 1000IU and 500IU Powder for Reconstitution Vial Label Summary of Changes:

1. *Increased font size to type 6 for enhanced visibility*
2. *Rotated orientation of importer and manufacturer information*
3. *Placement of DIN at the top left corner*
4. *Revised product description from "Powder for intravenous injection after reconstitution with the supplied solvent"* to "*I.V. injection. Reconstitute with supplied solvent*"
5. *Removal of reconstituted vial ingredient composition (this information is still retained on the carton and leaflet)*
6. *Simplified wording of storage conditions and package insert statements.*
7. *Key product information has been bolded and capitalized (e.g. Do NOT freeze / NE PAS congeler and **Store/Conserver**)*

Octaplex® 1000IU and 500IU Water for Injection Vial Label Summary of Changes:

1. *Placement of DIN in top left corner*
2. *Simplified wording of storage conditions and package insert statements.*
3. *Key product information has been bolded and capitalized (e.g. **Do NOT freeze / NE PAS congeler** and **Store/Conserver**)*
4. *Rearranged layout of manufacturer and importer*



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Octaplex® 1000IU and 500IU Package Leaflet Summary of Changes:

1. *Package insert warnings section has been updated to align with the current approved Product Monograph (approved November 3, 2017). Changes between the previous package leaflet and the revised package leaflet are highlighted below for comparison.*

Previous Package Insert (B.261.006.CDN)	Revised Package Insert (2005644-09)
Side effects may include: • Headaches may rarely occur. • Allergic or allergic-type reactions: early signs include hives, increase in body temperature, generalised hives, tightness of the chest, wheezing, hypotension, and anaphylaxis. If allergic symptoms occur, discontinue the administration immediately and contact your physician. In case of shock, the current medical standards for treatment of shock are to be observed. No case of allergic or anaphylactic reaction was reported under octaplex® treatment so far; therefore the incidence is expected to be very low.	Side effects may include: • Allergic or allergic-type reactions: early signs include hives, swelling of the face or tongue, injection site reactions, chills, rapid reddening of neck/ facial region, headache, tightness of the chest, wheezing, drop in blood pressure, anxiety, nausea, vomiting, sweating, increased heart rate, and anaphylaxis. If allergic symptoms occur, discontinue the administration immediately and contact your physician. In case of shock, the current medical standards for treatment of shock are to be observed. The incidence is expected to be very low.
This is not a complete list of side effects. For any unexpected effects while taking octaplex®, contact your doctor or pharmacist.	*This is not a complete list of side effects. For any unexpected effects while taking octaplex®, contact your doctor or pharmacist.*

Product Information:

Octaplex® is a human prothrombin complex (PCC) containing the coagulation factors II, VII, IX, and X and Proteins C and S**.**

Indications:

Octaplex® is indicated for treatment of bleeding and perioperative prophylaxis of bleeding in acquired deficiency of the prothrombin complex coagulation factors, such as deficiency caused by treatment with vitamin K antagonists, or in case of overdose of vitamin K antagonists, when rapid correction of the deficiency is required.

Warnings and Precautions:

- This product is prepared from a large pool of human plasma. Octapharma employs virus reduction processes, such as the use of a solvent/detergent viral inactivation process as well as a virus removal nanofiltration step. However, as with any product prepared from human blood or plasma, the transmission of infectious agents cannot be totally excluded.

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- There is a risk of thrombosis or disseminated intravascular coagulation when patients with congenital or acquired deficiency are treated with human prothrombin complex. Patients receiving Octaplex® should be monitored for signs and symptoms of thrombosis.

Request more information or an in-service:

To request additional information or a Octaplex® in-service, please send an email with your request in the subject line to info.canada@octapharma.com or call 1-888-438-0488.

For complete prescribing information, refer to the complete Octaplex® Product Monograph, which, along with additional information, can be found on www.octapharma.ca.

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General Manager

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