

October 11, 2024

Subject : Octaplasma Difference in Date Formatting

Dear Health Care Professional,

Octaplasma label currently has expiry date in 2 different formats. The eye readable expiry date is MM/YYYY whereas the iSBT code is in the DD/MM/YYYY.

The eye readable expiry date was changed from DD/MM/YYYY, MM being digits format to MM/YYYY based on the Health Canada Clarifax received in June 2023 to align with one of the recommended expiry date formats under section 5.5 of the Health Canada Guidance document Questions and Answers: Plain Language Labelling Regulations for Prescription Drugs (Revision date August 8, 2019).

It was determined that different expiry date format can be confusing as they show different information. A change control is opened to update the eye readable expiry date on the Octaplasma label to DD/MM/YYYY, MM being the abbreviated month that is compatible in both English and French languages to align expiry date formats on the label.

Octapharma completed assessment of the product use on the last day of the month based on the MM/YYYY expiry date and concluded that marginally exceeding the 48 Months after the actual expiry date DD/MM/YYYY is not expected to have an impact on patient safety. According to a long-term stability study 2020 reporting:

“No deviations were observed up to 60 months storage, except for borderline results of Factor X, Plasmin inhibitor, HEV Ab and ADAMTS13. All other results are within the limits of the relevant product specification.”

As an immediate corrective actions, Octapharma recommends a customer letter which states that in the case where the iSBT barcodes are not used at the hospitals, the hospital should consider the eye readable expiry date format MM/YYYY to expire on the first day of the month instead of the last day of the month temporarily. This will ensure the product use prior to its actual expiry date.

In addition, iSBT scannable barcodes have no issues and are scanning to the correct DD/MM/YYYY expiry dates.

As Octaplasma bags are frozen, they cannot be re-labelled.

Octapharma Canada Inc. is committed to provide quality products to meet customer expectations. Please do not hesitate to contact us further with any questions you may have.

Sincerely,

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