

December 2, 2024

**Subject: Octaplasma® Labelling Updates – Batch and Expiry Dating Formatting**

Dear Health Care Professional,

Octapharma would like to notify you of upcoming artwork changes applicable to all Octaplasma® products available. These changes will address the feedback we have received regarding the scannable bar codes that were recently implemented onto all Octaplasma® bag labels. A summary of the changes is highlighted below.

**Revised Octaplasma Labelling Information Highlights:**

- **Batch Number now available as an ISBT 128 Scannable Bar Code:** All bar codes encoded with the batch number will now scan as ISBT 128 bar codes as the appropriate ISBT 128 identifiers have been added.
- **Expiry Date Printed on Bags Changed to DD/MM/YYYY Format:** Expiry date format printed onto the bag label will now include the exact day, month and year in an alphanumeric date format.

**Changes to the product labelling will impact all batches manufactured on or after September 10<sup>th</sup>, 2024.**

Table 1 below indicates the first batches that will be received with the upcoming artwork changes:

*Table 1. first batches to be received with revised Octaplasma® label artwork.*

Description	Batch Number	Manufacturing Date	Labelled Expiry Date
Octaplasma® A	M436B9521	10/SE/2024	31/AU/2028
Octaplasma® AB	M438B9521	18/SE/2024	31/AU/2028
Octaplasma® O	M438A9521	17/SE/2024	31/AU/2028

 **Please review the summary below for details on the implemented changes.**

**Summary of Labelling Revisions:**

Below is a summary of the upcoming label artwork changes. Please refer to Appendix A for an example of the printed artwork.

### ISBT 128 Encoded Scannable Batch Numbers:

The scannable bar codes available on all Octaplasma bags now identify as ISBT 128 Bar codes when scanned. In order to allow the batch number to scan as an ISBT 128 bar code, the following symbols have been added to the beginning of each batch number: **&)0**

**Please note, these symbols are not part of the assigned batch number and are for encoding purposes only.**

These symbols have been added to allow the batch number to read as an ISBT 128 bar code when scanned.

These identifier symbols will appear only when the ISBT 128 bar code is scanned to access the batch number and are not part of the batch number printed on the actual label artwork.

For example, batch number **M436B9521** will scan as **&)0M436B9521**

### Printed Expiry Date Format Updated to DD/MM/YYYY:

The expiry date printed onto all Octaplasma bags will now be displayed in the following alphanumeric format and will include the exact day: DD/MM/YYYY

For example, November 30<sup>th</sup>, 2024 would be printed as 30/NO/2024.

Below is a list of all abbreviated forms that will be used to represent the month within the expiry date:

Abbreviated Form	Month
JA	January
FE	February
MR	March
AL	April
MA	May
JN	June
JL	July
AU	August
SE	September
OC	October
NO	November
DE	December

### **Product Information:**

Octaplasma® is a Solvent Detergent treated, pathogen inactivated standardized plasma treatment. Octaplasma® is supplied frozen in bags of 200ml containing 45-70 mg/ml of Human Plasma Proteins.

### **Indications:**

Octaplasma® is indicated for the management of complex deficiencies of coagulation factors (i.e. severe hepatic failure, patients undergoing massive transfusions or impaired liver function). Octaplasma® may be used for emergency substitution therapy in cases where coagulopathy occurs as a result of blood volume dilution or loss (i.e. cardiac surgery, liver transplants, trauma settings or intensive care).

### **Warnings and Precautions:**

This product is prepared from a large pool of human plasma employing precipitations, filtrations and chromatographic steps as well as pathogen inactivation. There remains however a possibility that it may contain the causative agents of hepatitis and other viral diseases.

High dosages or infusion rates may induce hypervolaemia, pulmonary oedema and/or cardiac failure. The volume and frequency of plasma exchanges will vary depending on the individual patient, the clinical situation, and the preferred regimen of treatment. In the event of major haemorrhage or surgery, the expert advice of a haematologist should be sought.

High infusion rates may cause cardiovascular effects as a result of citrate toxicity (fall in ionised calcium), especially in patients with liver function disorders. Due to the risk of citrate toxicity, the infusion rate should not exceed 0.020-0.025 mmol citrate/kg body weight/min, which equals to 1 mL OCTAPLASMA/kg body weight/min. Toxic effects of citrate can be minimised by giving calcium gluconate i.v. into another vein. Patients should be observed for at least 20 minutes after the administration.

### **Request more information or an in-service:**

To request additional information or an Octaplasma® in-service, please send an email with your request in the subject line to [info.canada@octapharma.com](mailto:info.canada@octapharma.com) or call 1-888-438-0488.

For complete prescribing information, refer to the complete Octaplasma® Product Monograph, which, along with additional information, can be found on [www.octaplasma.ca](http://www.octaplasma.ca).

**Sri Adapa**

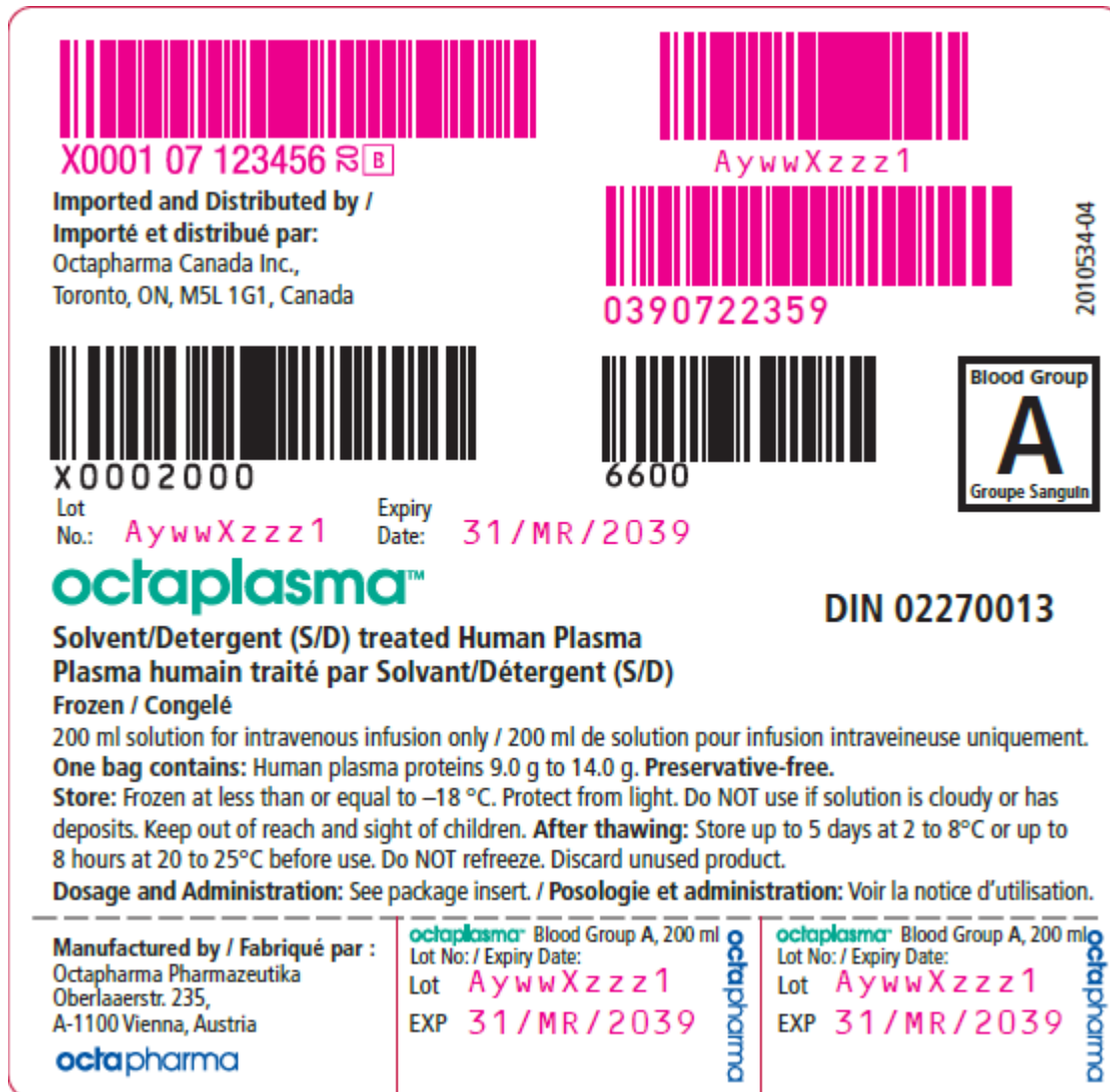
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**Octaplasma® Labelling Updates – Appendix A**

**1. Octaplasma Bag Label**



The image shows a template for an Octaplasma bag label. It features several barcode areas and text fields. At the top left is a large barcode with the alphanumeric string 'X0001 07 123456' and a small 'B' in a square. To its right is another large barcode with the string 'AywwXzzz1'. Below these are two smaller barcodes: one with '0390722359' and another with '6600'. A vertical barcode on the right side is labeled '2010534-04'. In the center-left, there is a barcode with 'X0002000' below it, and text for 'Lot No.: AywwXzzz1' and 'Expiry Date: 31/MR/2039'. To the right of this is a 'Blood Group A' logo. The product name 'octaplasma™' is prominently displayed in green, followed by 'Solvent/Detergent (S/D) treated Human Plasma' and its French equivalent. The DIN number 'DIN 02270013' is also present. At the bottom, there are two columns of manufacturing information, each with a vertical 'octapharma' logo. The left column lists the manufacturer 'Octapharma Pharmazeutika' in Austria, and the right column lists 'octaplasma® Blood Group A, 200 ml' with lot and expiry details.

**X0001 07 123456** **B**

**AywwXzzz1**

**0390722359**

**2010534-04**

**X0002000**

**6600**

**Blood Group A**  
**Groupe Sanguin**

**Lot No.: AywwXzzz1**      **Expiry Date: 31/MR/2039**

**octaplasma™**

**DIN 02270013**

**Solvent/Detergent (S/D) treated Human Plasma**  
**Plasma humain traité par Solvant/Détergent (S/D)**  
**Frozen / Congelé**

200 ml solution for intravenous infusion only / 200 ml de solution pour infusion intraveineuse uniquement.  
**One bag contains:** Human plasma proteins 9.0 g to 14.0 g. **Preservative-free.**  
**Store:** Frozen at less than or equal to -18 °C. Protect from light. Do NOT use if solution is cloudy or has deposits. Keep out of reach and sight of children. **After thawing:** Store up to 5 days at 2 to 8°C or up to 8 hours at 20 to 25°C before use. Do NOT refreeze. Discard unused product.  
**Dosage and Administration:** See package insert. / **Posologie et administration:** Voir la notice d'utilisation.

**Manufactured by / Fabriqué par :**  
Octapharma Pharmazeutika  
Oberlaaerstr. 235,  
A-1100 Vienna, Austria  
**octapharma**




**octaplasma®** Blood Group A, 200 ml  
Lot No. / Expiry Date:  
Lot **AywwXzzz1**  
EXP **31/MR/2039**  
**octapharma**

**octaplasma®** Blood Group A, 200 ml  
Lot No. / Expiry Date:  
Lot **AywwXzzz1**  
EXP **31/MR/2039**  
**octapharma**

**Octaplasma® Labelling Updates – Appendix A**

**2. Label Artwork Legend – Individual Elements Defined**

**Variable data printed (see above specimen for placing and number of prints):**

	ISBT Code 128 Bag number
	ISBT Code 128 expiry date in format &> Julian date+time (&>0390722359)
AywwXzzz1	Batch number
31 / MR / 2039	Expiry Date =date of production + 48 months (last day of previous month), months abbreviations to be used: JA, FE, MR, AL, MA, JN, JL, AU, SE, OC, NO, DE
	ISBT Code 128 Batch-Number (&)0AywwXzzz1)