Date: 11th May 2023

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

OctaplasLG infusion 200ml bags (Blood Group A and AB) (Human plasma proteins 57.5mg per ml): Interim Supply of Belgium and Czech Republic Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Octapharma Limited is currently experiencing supply disruption with OctaplasLG infusion 200ml bags (Blood Group A and Blood Group AB) (Human plasma proteins 57.5mg per ml) in the UK (Great Britain).

To ensure continuity in supply, Octapharma Limited has obtained approval from the MHRA to supply Belgium product (Blood Group A: M313B9521; 2000 bags and Blood Group AB: M308A9521; 1200 bags) and Czech Republic product (Blood Group A: M220A9521; 1000 bags and Blood Group AB: M222B9521; 1200 bags) which is expected to be on the UK (Great Britain) market from 15th May 2023 to 30th June 2023.

Please note the following:

- This product is considered licensed in the UK (Great Britain).
- The product from Belgium/Czech Republic has the same formulation as the UK (Great Britain) product.
- The product from Belgium/Czech Republic is manufactured according to the same manufacturing process and quality controls as the UK (Great Britain) product.
- There are minor differences between the Belgian/Czech Republic and UK product information (languages). Please ensure the UK Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) are followed.
- Please refer to the UK approved SmPC and PIL supplied electronically with the Belgium/Czech Republic packs. Discard the Belgium/Czech Republic leaflet in the pack.
- For additional copies of the leaflet, please refer to https://www.medicines.org.uk/emc/product/4171 or contact the company contact point (see below).
- The MHRA has agreed to an exemption granted in accordance with regulation 266(4)(a) and (b) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of octaplasLG and that the information must be given in English .

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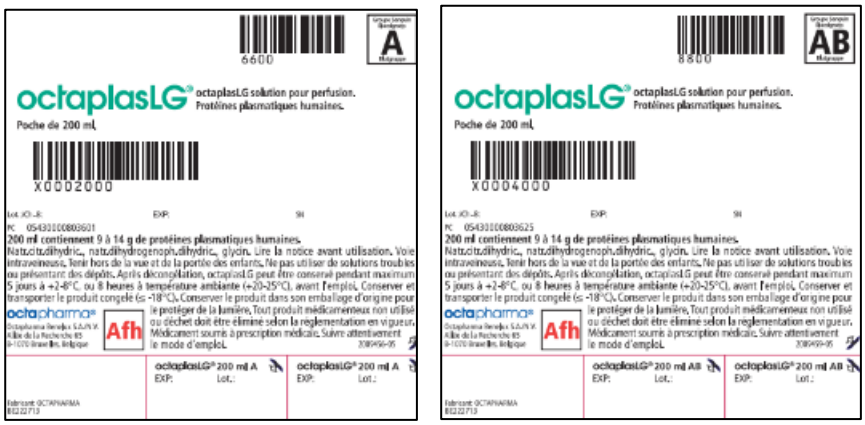
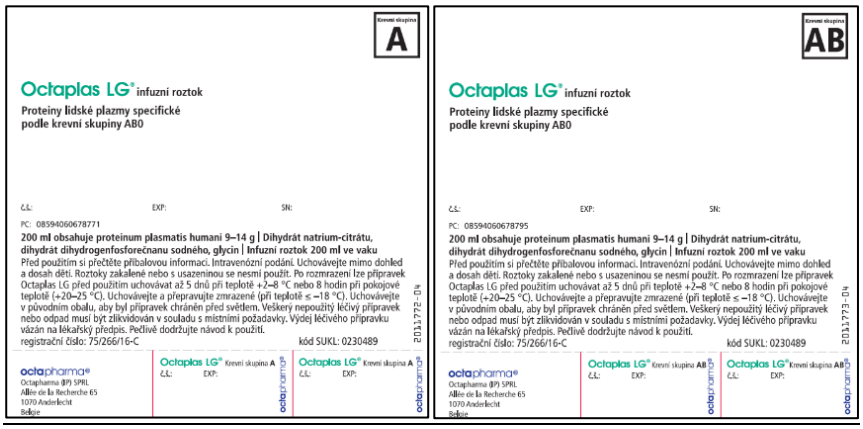
Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

Please continue to order via the usual process. Customer services will provide further information on orders when placed.

Images of Belgium product labels:



Images of Czech Republic product labels:



Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store

- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as blood products, antibodies and advanced therapies [such as gene and tissue therapy]) or vaccine, please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch-number.

Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to more accurately report suspected ADRs to the Yellow Card scheme.

Company contact point

If you have any questions about this letter or require more information about octaplasLG, please contact Octapharma Limited medical information at uk.medinfo@octapharma.com or telephone 0161 837 3782 or visit https://www.octapharma.co.uk/contact-us/contact-information.

Yours faithfully,

Clare Worden
General Manager
Octapharma Limited