Thawing frozen octaplasLG® bags with:
Transfusio-therm® 2000*
EIC Umwelt- und Medizintechnik Ltd

Instructions
Before starting the thawing of frozen octaplasLG® bags, prepare the plasma-thawing device according to the manual provided by the manufacturer.¹

Precaution:
• Do not store frozen octaplasLG® bags at room temperature before thawing.
• Remove octaplasLG® bags from the freezer immediately before the thawing process starts.
• octaplasLG® bags are delivered sealed in a secondary outer wrapper. Thaw octaplasLG® bags in the outer wrapper.

The following thawing procedure has been validated for frozen octaplasLG® bags using the Transfusio-therm® 2000:²

1. Insert octaplasLG® bags (up to 3 bags) in the middle of the holder, with contact to silver plate (yellow flashing control light).

2. Confirm the occupation of the stored plasma intake by the “confirmation key” (yellow continuous control light).

3. If the start release has been activated (yellow flashing start control light), start the thawing process by using the “start” key, with the door closed (yellow continuous light).

4. Once reaching the set temperature +30°C (takes approx. 5 min for 1 bag, 10 min for 3 bags), the warming process will switch off automatically (green flashing control light, intermittent sound).
   Confirm the set temperature by the “confirmation key” (green continuous light, no sound) and the display will show “withdraw conserve”.
   Remove the particular bag(s). Confirm the removal of the bag(s) on the “confirmation key”. Continue thawing until all bags are thawed and removed.

After finalization of the thawing cycle:³
• Remove the outer wrapper just before infusion and examine the bag for cracks or leaks.
• Avoid shaking.
• Do not use solutions which are cloudy or have deposits.

Thawed octaplasLG® must not be refrozen. Unused product must be discarded.³
Any unused product or waste material should be disposed of in accordance with local requirements.³

*: Universal and plasma fast-thawing models
Name of the medicinal product: octaplasLG®, solution for infusion. Presentation: solution for infusion containing 45-70 mg human plasma proteins/mL. Indications: Complex deficiencies of coagulation factors such as coagulopathy due to severe hepatic failure or massive transfusion. Coagulation factor deficiencies, when a specific coagulation factor concentrate is not available or in emergency situations when a precise laboratory diagnosis is not possible. Rapid reversal of oral anticoagulants effects when a prothrombin complex concentrate is not available or administration of vitamin K is insufficient. Potentially dangerous haemorrhages during fibrinolytic therapy, in patients who fail to respond to conventional measures. Therapeutic plasma exchange procedures.

Dosage and Administration: The dosage depends upon the clinical situation and underlying disorder. 12-15 mL octaplasLG®/kg body weight is a generally accepted starting dose.

Coagulation factor deficiencies: adequate haemostatic effect in minor/moderate haemorrhages or surgery is normally achieved after the infusion of 5-20 mL/kg. For major haemorrhage, surgery, TTP and haemorrhages in intensive plasma exchange seek advice of a haematologist. Monitor response clinically and with measurements of aPTT, PT and/or specific coagulation factors assays. Administer by intravenous infusion after thawing using infusion set with a filter. Due to risk of citrate toxicity, infuse at a rate ≤ 0.020-0.025 mmol citrate/kg /min. – equal to 1 mL octaplasLG® /kg /min.

Contraindications: IgA deficiency with documented antibodies against IgA. Hypersensitivity to the active substance, excipients or residues from the manufacturing process. Severe protein S deficiency.

Special Warnings and Precautions: Observe patient for ≥20 mins after infusion. Should not use: as volume expander, in case of bleeding caused by coagulation factor deficiencies when a specific factor concentrate is available, to correct hyperfibrinolysis in liver transplantation or other complex conditions with disturbances of haemostasis caused by α2-antiplasmin deficiency. Use with caution in IgA deficiency, plasma protein allergy, previous reactions to FFP or octaplasLG®, manifest or latent cardiac decompensation and pulmonary oedema. octaplasLG® has reduced protein S activity – caution in patients at risk for thrombotic complications. In plasma exchange, should only be used to correct coagulopathy with abnormal hemorrhage. Stop infusion in case of anaphylactic reaction/shock. Do not mix with other drugs. Do not administer solutions containing calcium by the same i.v. line. Despite measures to prevent infection, possibility of transmitting infective agents cannot be totally excluded – record name and batch number. Consider Hepatitis B and A vaccination.

Pregnancy and lactation: Use only if alternative therapies are regarded inappropriate.

Undesirable effects: Anaphylactic/anaphylactoid reactions, nausea, vomiting, abdominal or back pain, rash pruritus, chills, pyrexia, cardiovascular effects (with high infusion rates). Immediate or delayed type of haemolytic transfusion reactions may occur with ABO incompatibility. Overdose: High dosages or infusion rates may induce hypervolaemia, pulmonary oedema and/or cardiac failure. Especially in patients with liver function disorders, high infusion rate may cause cardiovascular effects as a result of citrate toxicity. Issue information: February 2015. Octapharma AG, Lachen, Switzerland.

Registered Product Information may differ in your country. For further information and before prescribing please refer to the nationally approved SmPC.

Adverse events should be reported to octapharma®: safetyreporting@octapharma.com Octapharma AG, Seidenstrasse 2, 8853 Lachen, Switzerland, www.octapharma.com

Reference:
1. Transfusio-therm® 2000 – Operating Instructions – Status: May 2016 MS
3. octaplasG summary of product characteristics

In case of questions about your Transfusio-therm® 2000 device, please contact your local BIC Umwelt- und Medizintechnik Ltd distributor.

Date of preparation: April 2017

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