

## Thawing frozen octaplasLG® bags with: Plasmatherm® Barkey GmbH & Co



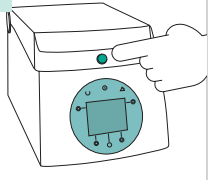
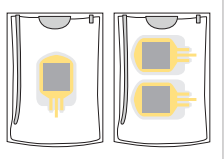
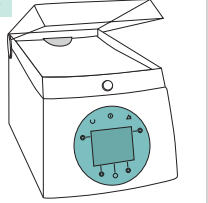
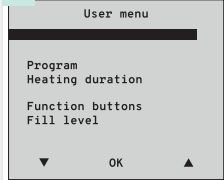


### Instructions

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

### 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:<sup>2</sup>

|  |  |   |  |
|--|--|---|--|
| <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 10px;"> <b>1</b>  </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 10px;"> <b>2</b>  </div> <div style="border: 1px solid #ccc; padding: 5px;"> <b>3</b>  </div> | <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 10px;"> <p>Press the green button on the front of the device above the operating panel to open the heating chamber.</p> </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 10px;"> <p>Lift the upper heating cushion by the grip and place a <b>maximum of 2 octaplasLG® bags</b> between the heating cushions. Avoid overlapping of the plasma bags.</p> </div> <div style="border: 1px solid #ccc; padding: 5px;"> <p>Place the upper heating cushion back over the octaplasLG® bags without any folds. Close the heating chamber cover until the cover button engages.</p> </div> | <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 10px;"> <b>4</b>  </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 10px;"> <b>5</b>  </div> <div style="border: 1px solid #ccc; padding: 5px;"> <b>6</b>  </div> | <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 10px;"> <p>Press the menu button (lower central button) to enter the user menu. Go down to "Program", press the "OK" button to enter the submenu and chose the "octaplas" program each time to confirm your choice.</p> </div> <div style="border: 1px solid #ccc; padding: 5px;"> <p>When the program was started, the display will show the program name, the current water temperature and the current remaining time (<b>thawing time for 2 bags is 30 min</b>).</p> </div> <div style="border: 1px solid #ccc; padding: 5px;"> <p>Once finalized, a flashing message "Program complete" appears and an acoustic signal sounds. Open the heating chamber cover or acknowledge the end of the program with the confirm button (OK), and remove the plasma bags.</p> </div> |
|--|--|---|--|

Important: In case of need, 3 till 4 **octaplasLG®** bags can be thawed using the "octaplas program" for 45 min.<sup>2</sup> To set the octaplas program as a permanent function button, please see the user manual.

### After finalization of the thawing cycle:<sup>3</sup>

- 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.<sup>3</sup>**

Any unused product or waste material should be disposed of in accordance with local requirements.<sup>3</sup>



**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  $\leq 0.020$ - $0.025$  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  $\geq 20$  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  $\alpha 2$ -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](mailto:safetyreporting@octapharma.com)  
Octapharma AG, Seidenstrasse 2, 8853 Lachen, Switzerland, [www.octapharma.com](http://www.octapharma.com)

#### Reference:

1. Instructions for use Barkey plasmatherm. Version 1 EN. Issued 2009-12-22 for SN 1107500 onwards
2. Heger A et al. Thawing of pooled, Solvent/Detergent-treated plasma octaplasLG®: Validation studies using different thawing devices. Transfus Med Hemother 2017;44:94-98
3. octaplasLG summary of product characteristics

In case of questions about your Plasmatherm® device, please contact your local Barkey distributor.  
Date of preparation: April 2017

Octapharma AG, Seidenstrasse 2  
8853 Lachen, Switzerland  
[www.octapharma.com](http://www.octapharma.com)

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