Abbreviated Prescribing Information for LG-octaplas™ (human plasma proteins):

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

**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. Substitution therapy in coagulation factor deficiencies, when a specific coagulation factor concentrate (e.g. factor V or factor XI) is not available for use or in emergency situations when a precise laboratory diagnosis is not possible. Rapid reversal of the effects of oral anticoagulants when a prothrombin complex concentrate is not available for use or administration of vitamin K is insufficient due to impaired liver function or in emergency situations. Potentially dangerous haemorrhages during fibrinolytic therapy, using e.g. tissue plasminogen activators, in patients who fail to respond to conventional measures. Therapeutic plasma exchange procedures, including those in Thrombotic Thrombocytopenic Purpura (TTP).

**Dosage and Administration:** The dosage depends upon the clinical situation and underlying disorder, but 12-15mL LG-octaplas™/kg body weight is a generally accepted starting dose.

- **Coagulation factor deficiencies:** Adequate haemostatic effect in minor/moderate haemorrhages or surgery normally achieved after infusion of 5-20 mL/kg. This should increase plasma coagulation factor levels by 10-33%. For major haemorrhage or surgery, seek advice of a haematologist. **TTP** and haemorrhages in intensive plasma exchange: For therapeutic plasma exchange procedures seek advice of a Haematologist. In patients with TTP the whole plasma volume exchanged should be replaced with LG-octaplas™. Monitor response clinically and with measurements of aPTT, PT and/or specific coagulation factor 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 ≤ mL LG-octaplas™/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. After ambulant infusion, the patient should rest for 1 hour. Should not use as volume expander or in bleeding caused by coagulation factor deficiencies where a specific factor concentrate is available or 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 LG-octaplas™, manifest or latent cardiac decompensation and pulmonary oedema. LG-octaplas™ has reduced protein S activity – exercise caution in patients at risk for thrombotic complications. In plasma exchange, LG-octaplas™ should only be used to correct coagulopathy with abnormal haemorrhage. In case of anaphylactic reaction/shock stop infusion and administer appropriate treatment. LG-octaplas™ must not be mixed with other drugs. Do not administer solutions containing calcium by the i.v. line as LG-octaplas™. Consider Hepatitis B and A vaccination. Infection prevention measures include donor selection, screening donations and plasma pool with effective manufacturing steps to inactivate/remove viruses and prions. The possibility of transmitting infective agents (including unknown and emerging viruses) cannot be totally excluded. Record name and batch number at each administration.

**Pregnancy and lactation:** Should be administered to pregnant or lactating women only if alternative therapies are inappropriate.

**Undesirable effects:** Anaphylactic/anaphylactoid reaction/shock. Hypersensitivity. Nausea, vomiting, abdominal or back pain, rash pruritus, urticaria, hyperhidrosis, chills, pyrexia, agitation. Respiratory disorder, bronchospasm, dyspnoea, pulmonary oedema/haemorrhage, cardiovascular effects (with high infusion rates), tachycardia, arrhythmia, chest pain, cardiac arrest, circulatory collapse, hypotension, hypertension, flushing, haemorrhagic diathesis, thromboembolism, application site reactions. Immediate or delayed type of haemolytic transfusion reactions may occur with ABO incompatibility. See SmPC for further details of adverse reactions.

**Packaging quantities:** 200mL bag.

**Legal Category:** POM. **Marketing Authorisation Number:** PA 521/4/2. **Marketing Authorisation Holder:** Octapharma Ltd. The Zenith Building, 26 Spring Gardens, Manchester, M2 1AB, United Kingdom. **Date of Preparation of Prescribing Information:** December 2013. **OPL/13/10E**

**Adverse events should be reported.** Reporting forms and information can be found at [www.imb.ie](http://www.imb.ie) Adverse events should also be reported to Octapharma on +44 (0)1748 828855.