Package leaflet: Information for the user

octaplasLG solution for infusion
ABO-blood group specific human plasma proteins

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What octaplasLG is and what it is used for

octaplasLG is human plasma pooled and treated for virus inactivation. Human plasma is the fluid part of human blood that carries the cells. It contains human plasma proteins which are important to maintain normal clotting characteristics and is used the same way as normal fresh-frozen plasma (FFP).

octaplasLG helps in case of complex deficiencies of coagulation factors which can be caused by severe failure of the liver or massive transfusion. octaplasLG may also be given in emergency situations when a coagulation factor concentrate (such as Factor V or Factor XI) is not available or a necessary laboratory diagnosis is not possible.

It may also be given to rapidly reverse the effects of oral anticoagulants (coumarin or indanedione type), when vitamin K is insufficient due to impaired liver function or in emergency situations.

octaplasLG can be given to patients who undergo plasma exchange in order to restore the balance of the coagulation factors.

2. What you need to know before you use octaplasLG

Do not use octaplasLG:
- if you are allergic (hypersensitive) to human plasma proteins or any of the other ingredients of this medicine (listed in section 6).
- if you know you have antibodies against the immunoglobulin called IgA.
- if you had previous reactions to any preparation of human plasma or FFP.
- if you know you have a low level of protein S (a vitamin K dependent protein in your blood).

Warnings and precautions
Talk to your doctor before using octaplasLG.
Tell your doctor if you have any other illnesses.

Take special care with octaplasLG:
- if you have a low level of immunoglobulin A.
- if you had previous reactions to plasma protein including FFP.
- if you are suffering from heart failure or fluid in the lungs (pulmonary oedema).
- if you have known risks for blood clotting (thrombotic) complications because of the potential increased risk of venous thromboembolism (clots forming in your veins).
- in case of increased inhibition of coagulation (fibrinolysis).

octaplasLG is not generally recommended for the treatment of von Willebrand's Disease.

Virus safety
When medicines are made from human blood or plasma, certain measures are put in place to prevent infections being passed on to patients. These include careful selection of the blood and plasma donors to make sure those at risk of carrying infections are excluded, and the testing of each donation and pools of plasma for signs of virus/infections. Manufacturers of these products also include steps in the processing of the blood or plasma that can inactivate or remove the viruses. Despite these measures, when medicines prepared from human blood or plasma are administered, the possibility of passing on infection cannot be totally excluded. This also applies to any unknown or emerging viruses or other types of infections.
The measures taken are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus and hepatitis C virus.
The measures taken may be of limited value against certain non-enveloped viruses such as hepatitis A virus, hepatitis E virus and Parvovirus B19.
It is strongly recommended that every time you receive a dose of octaplasLG the name and batch number of the product are recorded in order to maintain a record of the batch used.
Your doctor may recommend that you consider vaccination against hepatitis A and B viruses if you regularly/repeatedly receive human plasma-derived products.

Children
Some cases of low calcium level, possibly caused by citrate binding, have been observed during therapeutic plasma exchange in children. Monitoring of calcium is recommended during such use of octaplasLG.

Other medicines and octaplasLG
During clinical trials, octaplasLG has been administered in combination with various other medications, and no interactions have been identified.
With the administration of octaplasLG you may also get substances (e.g. pregnancy hormone) that may result in false positive test results (e.g. positive pregnancy test even though you are not pregnant).
octaplasLG may not be mixed with other intravenous fluids or medicines except red blood cells and blood platelets.
To avoid the possibility of blood clots, solutions containing calcium must not be administered by the same intravenous pathway as octaplasLG.
There are no known reactions with other drugs.
Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

octaplasLG with food and drink
No effects have been observed.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You will only be given octaplasLG if your doctor considers it important for you.

Driving and using machines
No effect has been observed upon the ability to drive or operate machinery. You alone are responsible to decide if you are in a fit condition to drive a motor vehicle or perform other tasks that demand increased concentration.

Important information about some of the ingredients of octaplasLG
For a list of ingredients please refer to section 6.
This medicine contains maximum 920 mg sodium (main component of cooking/table salt) in each bag. This is equivalent to maximum 46% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use octaplasLG

octaplasLG will be given to you by a doctor or nurse. It is given by an infusion into your veins. Your dosage depends upon your clinical situation and your body weight. Your doctor will determine the appropriate amount that you should receive.
- Before octaplasLG can be given to you by infusion an ABO-blood group compatibility test must be performed.
- In emergency cases, octaplasLG blood group AB can be given to all patients.

It is important that the infusion rate should not exceed 1 ml octaplasLG per kg of your body weight per minute. Calcium gluconate may be given into another vein to minimise the negative effects of the citrate contained in octaplasLG.
You should be observed during and at least for 20 minutes after the administration in case you develop an allergic reaction (anaphylactic reaction) or shock, in which case the infusion must be stopped immediately.

Use in children and adolescents
There is limited data in children and adolescents (0-16 years).

If you use more octaplasLG than you should
High dosages may lead to fluid overload, fluid in lungs and/or heart problems.

If you forget to use octaplasLG
Your doctor is responsible to supervise administration and to keep your laboratory values within the specified range.

If you stop using octaplasLG
Based on laboratory values your doctor decides when to stop administration of octaplasLG and will assess possible risks.

Do not use after the expiry date given on the label.

There are several options for thawing frozen octaplasLG:

- Water bath:
  Thaw in the outer wrapper for not less than 30 minutes in a circulating water bath at +30 °C to +37 °C. An overwrap bag may be used to provide further protection of contents if appropriate.

  Prevent water from contaminating the entry port. The minimum thawing time is 30 minutes at 37 °C. Temperature in the water bath must never exceed +37 °C and should not be lower than +30 °C.

  The thawing time depends on the number of bags in the water bath. If more plasma bags are thawed in parallel, the thawing time can be prolonged, but should not be longer than 60 minutes.

- Using a dry tempering system such as the SAHARA-III:
  Place the octaplasLG bags on the agitation plate according to the manufacturer instructions and thaw plasma using the fast tempering function. When a +37 °C blood component temperature is indicated on the temperature display, terminate the tempering process and remove the bags.
  During thawing of octaplasLG using a dry tempering system, it is recommended to use the protocol printer to record the course of the blood component temperature and error messages in event of failure.
- Others:
  Other thawing systems for frozen octaplasLG can be used on the condition that the methods are validated for that purpose.

Allow the content of the bag to warm to approximately +37 °C before infusion. The temperature of octaplasLG must not exceed +37 °C. Remove the outer wrapper and examine the bag for cracks or leaks.

Avoid shaking.

After thawing the solution is clear to slightly opalescent and free of solid or gelatinous particles.

Do not use solutions which are cloudy or have deposits and/or discoloration.

Thawed octaplasLG must not be refrozen. Unused product must be discarded.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Hypersensitivity reactions may rarely be observed. These are usually mild allergic type reactions consisting of localised or generalised reddening of the skin, hives or itching. More severe forms can be complicated by drop in blood pressure or swelling of the face or tongue. Severe whole-body allergic reactions may have a rapid onset and may be serious. Symptoms are drop in blood pressure, increase in heart rate, difficulty in breathing, wheezing, coughing, breathlessness, nausea, vomiting, diarrhoea, abdominal or back pain. Severe reactions may proceed to shock, unconsciousness, respiratory failure and very rarely even death.
Negative effects can be caused by the citrate contained in octaplasLG and the related low calcium level especially if the infusion rate is high, if you have liver function disorders or if you are undergoing plasma exchange procedures. You may experience symptoms like fatigue, tingling feelings (paraesthesia), tremor and low calcium levels.
octaplasLG may increase the risk of blood clots in veins of the:

- limbs, causing pain and swelling of limbs;
- lung, causing chest pain and breathlessness;
- brain, causing weakness and/or loss of sensation down one side of the body;
- heart, causing chest pain;

In all patients at risk for increased clotting of the blood special caution should be exercised and appropriate measures should be considered.
Rarely, incompatibility between antibodies in octaplasLG and antigens in your blood can result in destruction of your red blood cells (haemolytic transfusion reactions). Symptoms are chills; fever; a non-productive cough; difficulty in breathing; rash; and bleeding within the body.
Infusion of octaplasLG may give rise to specific coagulation factor antibodies.
High dosages or infusion rates may induce increased blood volume; fluid in the lungs and/or heart failure.
Acute breathing difficulties have been reported during or after the infusion of octaplasLG.

During clinical trials with octaplasLG's predecessor product, and its post-approval use, the following side effects have been identified:

System organ class	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)	Very rare (< 1/10,000)	Not known[§]
Blood system disorders				lack of red blood cells bleeding tendency	
Immune system disorders			hypersensitivity	serious allergic reaction and shock	
Psychiatric disorders				anxiety agitation restlessness	
Nervous system disorders		reduced sense of touch or sensation		dizziness tingling feelings	
Cardiac disorders				failure of the heart irregular heartbeats increase in heart rate	
Blood vessels and circulatory disorders				clot in blood vessels drop in blood pressure increase in blood pressure failure of the blood circulation reddening of the skin	
Respiratory disorders		lack of oxygen		respiratory failure bleeding in the lungs constriction of the bronchi fluid in the lungs breathlessness difficulty in breathing	acute breathing problems
Stomach and intestines disorders		vomiting nausea		abdominal pain	
Skin disorders	hives itching			rash increased sweating	
Muscular and skeletal disorders				back pain	
General disorders and administration site conditions		fever		chest pain chest discomfort chills localised swelling general discomfort application site reaction	
Investigations				antibody test positive oxygen in blood decreased	
Injury, poisoning and procedural complications				increased blood volume citrate poisoning destruction of red blood cells	

[§]Spontaneous reporting data

Depending on type and severity of adverse reactions, the infusion rate must be reduced or the administration must be stopped. Appropriate action will be taken by your doctor.
If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Additional side effects in children
In the course of plasma exchange procedures low calcium level may be observed in children especially in patients with liver function disorders or in case of high infusion rates. Monitoring of calcium is recommended during such use of octaplasLG.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store octaplasLG

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the label after the abbreviation EXP.
Store and transport frozen (at ≤ -18 °C).
Store in the original package in order to protect from light.
After thawing, chemical and physical in-use stability has been demonstrated for 5 days at 2 – 8 °C or 8 hours at room temperature (20 – 25 °C).
From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.
Do not use this medicine if you notice that the solution is cloudy or contains deposits and/or discoloration.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What octaplasLG contains
- The active substances are ABO-blood group specific human plasma proteins. A 200 ml bag contains 9 – 14 g (45 – 70 mg/ml).
- The other ingredients are:
  Sodium citrate dihydrate, Sodium dihydrogenphosphate dihydrate and Glycine.

What octaplasLG looks like and contents of the pack
octaplasLG is presented as a solution for infusion.
200 ml in bag.
Pack size of 1 and 10.
The frozen solution is (slightly) yellow.

Marketing Authorisation Holder:
Octapharma Limited
Glassworks House
32 Shudehill
Manchester M4 1EZ
United Kingdom
Tel: 01618373770
Fax: 01618373799

Manufacturers:
Octapharma AB
SE-112 75 Stockholm
Sweden

This leaflet was last revised in 11/2024.

The following information is intended for healthcare professionals only:

Dosage and administration

Dosage

The dosage depends upon the clinical situation and underlying disorder, but 12 – 15 ml octaplasLG/kg body weight is a generally accepted starting dose. This should increase the patient's plasma coagulation factor levels by approximately 25%.
It is important to monitor the response, both clinically and with measurement of e.g. activated partial thromboplastin time (aPTT), prothrombin time (PT), and/or specific coagulation factor assays.

Dosage for coagulation factor deficiencies:
An adequate haemostatic effect in minor and moderate haemorrhages or surgery in coagulation factor deficient patients is normally achieved after the infusion of 5 – 20 ml octaplasLG/kg body weight. This should increase the patient's plasma coagulation factor levels by approximately 10 - 33 %. In the event of major haemorrhage or surgery, the expert advice of a haematologist should be sought.

Dosage for TTP and haemorrhages in intensive plasma exchange:
For therapeutic plasma exchange procedures, the expert advice of a haematologist should be sought. In TTP patients the whole plasma volume exchanged should be replaced with octaplasLG.

Method of administration

Administration of octaplasLG is to be performed blood-group specifically. In emergency cases, octaplasLG blood group AB can be regarded as universal plasma since it can be given to all patients regardless of blood group.
After thawing, octaplasLG is to be infused intravenously using infusion equipment with filters. An aseptic technique must be used throughout the infusion.

Citrate toxicity can occur when more than 0.020 – 0.025 mmol citrate per kg per minute is administered. Therefore, the infusion rate should not exceed 1 ml of octaplasLG per kg per minute. Toxic effects of citrate can be minimised by giving calcium gluconate intravenously into another vein.

Warnings and precautionary measures for the administration:
In case of anaphylactic reaction or shock, the infusion must be stopped immediately. Treatment should follow the guidelines for shock therapy.
Patients should be observed for at least 20 minutes after the administration.

Incompatibilities:

- octaplasLG product can be mixed with red blood cells and platelets if ABO compatibility of both preparations is respected.
- octaplasLG must not be mixed with other medicinal products, as inactivation and precipitation may occur.
- To avoid the possibility of clot formation, solutions containing calcium must not be administered by the same intravenous line as octaplasLG.

Interference with serological testing:
Passive transmission of plasma components from octaplasLG (e.g. β-human chorionic gonadotropin; β-HCG) may result in misleading laboratory results in the recipient. For example, a false-positive pregnancy test result has been reported following passive transmission of β-HCG.