LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

octaplasLG, Powder and solvent for infusion (plasma protein, human,)

SE/H/1866/02/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

Summary Public Assessment Report

octaplasLG
plasma protein, human, Octapharma EMEA/H/PMF/000008/05

Powder and solvent for solution for infusion,

This is a summary of the public assessment report (PAR) for octaplasLG. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is octaplasLG and what is it used for?

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.

How does octaplasLG work?

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).

How is octaplasLG used?

The pharmaceutical form is powder and solvent for solution for infusion for.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of octaplasLG have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that the product is effective in treating:

- 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 (coumarin or indanedione type) 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).

What are the possible side effects from octaplasLG?
For the full list of side effects, see section 4 of the package leaflet.
For the full list of restrictions, see the package leaflet.

Why is octaplasLG approved?

The Swedish Medical Products Agency decided that the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of octaplasLG?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about octaplasLG

The full PAR for octaplasLG can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with octaplasLG, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2023-04.