DRK-Blutspendedienst West
gemeinnützige Gesellschaft mit beschränkter Haftung
der Landesverbände Nordrhein, Westfalen-Lippe, Rheinland-Pfalz und Saarland

Deutsches Rotes Kreuz

Package Leaflet and Summary of Product Characteristics (SPC)

LyoPlas N - w

1. Identification of the medicinal product

a) Designation

LyoPlas N - w

b) Substance group

Blood component, plasma for transfusion

2. Indications

- Emergency substitution in patients with clinically relevant bleeding tendencies or manifest bleeding with a complex disorder of the haemostatic system, particularly involving severe damage to the hepatic parenchyma or disseminated intravascular coagulation (DIC). Treatment of the underlying disease must take priority in all cases. As DIC always signifies a complication arising from a severe underlying disease (such as sepsis, shock, polytrauma), LyoPlas N - w should only be administered if the underlying pathological mechanisms are also treated.
- Coagulopathy due to blood thinning and/or blood loss
- Substitution in Factor V and Factor XI deficiency
- Thrombotic thrombocytopenic purpura
- Exchange transfusion

The use of LyoPlas N - w is not indicated as a volume, protein or albumin substitute, for immunoglobulin replacement or as parenteral nutrition.

3. Information for use

a) Contraindications

Absolute contraindications:

- Plasma protein intolerance

Relative contraindications:

- Cardiac decompensation, hypervolaemia, hyperhydration, pulmonary oedema
- Proven IgA deficiency

b) Precautions for use

In principle ABO-identical plasma is transfused using an administration set with a 170-230 µm pore standard filter. In exceptional cases ABO-compatible plasma may also be transfused (see haemotherapy guidelines). As a general rule, infuse rapidly and monitor the circulation in accordance with the patient's condition. If administering more than 50 ml/min to an adult, calcium must also be given.

During neonatal transfusions monitor carefully for any sign of citrate intoxication and adjust the rate of transfusion to the clinical condition.

c) Interactions with other medicinal products, as far as they may affect the action of the medicinal product, and main incompatibilities

Interactions with other medicinal products are not known. Due to the potential activation of coagulation factors, solutions containing calcium must not be administered concurrently through the same line. Medicinal products must not be added to the plasma.

d) Special patient groups

Pregnancy and lactation: No objections if used as directed.

Effects on the ability to drive or operate machinery: The recipient should rest for at least half an hour following the plasma transfusion.

e) Warnings

Not applicable.

4. Instructions for proper use

a) Dosage

- The dosage depends on the clinical picture and the results of blood coagulation tests. As a guideline, the rule of thumb for the initial dose is: 1 ml plasma per kg of body weight should increase the factor contents by up to 1%. An adult initially requires at least 3 or 4 units of plasma to achieve a haemostatic effect.

b) Method of administration

For intravenous infusion after reconstitution in water for injection

c) Frequency of administration

Depending on the indication

d) Duration of treatment

Depending on the indication

e) Overdose

A high dose carries the risk of cardiovascular overload.

f) Emergency measures

If incompatibilities occur, stop the transfusion immediately but keep the venous access port open and, depending on the severity of the symptoms, initiate treatment in accordance with current emergency treatment guidelines. In the case of hypervolaemia a reduction in volume may be indicated.

5. Side effects

- In case of rapid transfusion and/or larger volumes a volume overload may lead to acute heart failure with pulmonary oedema, particularly in cardiovascular diseases.
- Citrate intoxication is possible in case of rapid transfusion and/or larger volumes, particularly in hepatic dysfunction, shock, acidosis, hypothermia and in neonates.
- Transfusion related acute lung injury (TRALI)
- Anaphylactoid reactions have been observed in rare cases.
- Coagulation factor inhibitors may develop.
- The risk of bacterial contamination can never be ruled out with absolute certainty.
- When using medicinal products made from human blood the possibility of passing on infection cannot be totally excluded. This also applies to any unknown or emerging viruses or other types of infections. This applies to hepatitis, for example, and less commonly to the acquired immune deficiency syndrome (AIDS). This risk of transmission can be minimised by the appropriate selection of donors and testing of donated blood.
- In the United Kingdom isolated cases have been reported of "causative agents" (called prions) being found in recipients of blood from donors who later developed variant Creutzfeldt-Jakob disease (vCJD). vCJD may be acquired through the consumption of certain beef products derived from cattle affected by BSE. So far, however, vCJD has not been observed in Germany.

Reporting suspected side effects: It is of importance to notify if there is a suspected case of side effects. Notifications enable to monitor the risk-benefit balance continuously. Members of health organizations should notify every putative side effect to their national competent authority. Patients should be informed to consult their doctor or medicinal specialist if side effects occur. This also applies for side effects not described in this SPC. Reporting of side effects will enhance knowledge on drug safety.

6. Pharmacological properties

LyoPlas N - w does not only contain proenzymes of coagulation and fibrinolysis, but also their inhibitors. The protein concentration varies with the protein level of the donations. The activity of components is subject to individual variations and has to be at least 70% of their original activity. LyoPlas N - w contains neither foreign substances nor endogenous substances in unphysiological concentrations.

Because it is cell-free, LyoPlas N - w may be transfused for the purposes of preventing a graft-versus-host reaction.

7. Further instructions

a) Details of storage and shelf life

- LyoPlas N - w has a shelf life of 15 months at + 2°C to + 25°C. The expiry date is given on the label.
- Plasma may not be used after its expiry date.
- LyoPlas N - w is supplied together with water for injection in plastic bags. Appropriate transfer sets are enclosed.
- Reconstituted LyoPlas N - w may not be frozen for transfusion.

For reconstitution, always proceed as follows:

First remove the flip-off cap and disinfect the stopper. Close the clamp and connect the transfer set to the water bag. Then pierce through the centre of the stopper of the plasma bottle and allow all of the water to flow into the bottle. Suspend the bag by its hanger when adding the water. Do not press the bag and keep the bottle upright, otherwise the air vent of the transfer set may become blocked. As soon as the water has been completely transferred, close the clamp and dissolve the freeze-dried plasma. Gently swirl to aid the reconstitution process (do not shake!) The reconstitution is completed when all particles have been solved. Store plasma at room temperature until transfusion.

Instructions for transfusion:

- The dissolved plasma can be transfused from the glass bottle using a vented administration set with a 170 to 230 µm pore standard filter.
- For transfusion from the bag the plasma can be transferred to the bag. To do so suspend the bottle by its hanger label, open the clamp and allow the plasma to flow into the bag. To mark the bag peel the large service label off the bottle and attach it to the bag. Please check the bar code numbers to ensure correct identification. Before a pressure transfusion, the bag has to be vented via the transfer set. To do so gently press the plasma bag so that the air above the plasma can escape via the transfer set. Then close the clamp of the transfer set. For transfusion an administration set with standard filter 170 to 230 µm and without air vent should be used.

Discard any dissolved plasma that has not been used.

Avoid any risk of contamination.

Reconstituted plasma should be used immediately at the latest within 6 hours.

b) Visual inspection

Inspect the containers for damage before transfusion. Never transfuse the contents of damaged containers.

c) Composition of the medicinal product/ active substances (qualitative and quantitative)

Active ingredients:

0.70 to 0.85 ml/ml coagulable human plasma

Excipients:

Citrate, phosphate, glucose

d) Pharmaceutical form and contents, container

One packaged unit with:

1 glass bottle with 200 ml freeze-dried human plasma

1 plastic bag containing 200 ml water for injection

1 transfer set for transferring the water

e) Details of the pharmaceutical company/marketing authorisation holder

DRK-Blutspendedienst West gemeinnützige Gesellschaft mit beschränkter Haftung der Landesverbände Nordrhein, Westfalen-Lippe, Rheinland-Pfalz und Saarland
Feithstr. 182, 58097 Hagen

f) Details of the manufacturer releasing the finished product for circulation

DRK-Blutspendedienst West gemeinnützige Gesellschaft mit beschränkter Haftung der Landesverbände Nordrhein, Westfalen-Lippe, Rheinland-Pfalz und Saarland
Zentralbereich Plasma
Feithstrasse 180 – 186, 58097 Hagen

g) Marketing Authorisation Number

PEI.H.03075.01.1

h) Date of first authorisation or renewal of authorisation

24. May 2004

i) Drug Status

Prescription only

8. Additional Information

Measures for reducing the risk of transmitting infectious agents:

When using medicinal products made from human blood, it is never possible to entirely rule out the risk of transmitting infectious diseases; measures are therefore taken to minimise the risk of transmission of infectious materials:

Only donations from healthy donors who test negative for human immunodeficieny virus (anti-HIV-1/2 antibodies, HIV-1 genome), hepatitis B virus (HBsAg, anti-HBc antibodies), hepatitis C virus (anti-HCV antibodies, HCV genome) and Treponema pallidum (anti-Treponema pallidum antibodies) are used in the manufacture of LyoPlas N - w. An exception applies to testing for hepatitis B virus in that the result of the above-mentioned test for anti-HBc antibodies may also be reactive in certain cases. In such cases further tests (HBV genome, quantitative anti-HBs antibodies) are performed to be absolutely sure that the donor is not infectious. The plasma is stored in quarantine for 4 months. After these 4 months the plasma donor is retested for all the infection markers examined at the time of donation and the LyoPlas N - w unit is only released and put into circulation if the test results again prove negative. As this is a cell-free preparation, the risk of transmitting leukocyte-associated viruses (CMV, HTLV-1/2, EBV etc) and bacteria (Yersinia enterocolitica) can be greatly reduced.

Quality assurance:

In order to be able to carry out transfusions of plasma, health care establishments have to take quality assurance measures in accordance with national medicinal law. Amongst others these include detailed instructions on both diagnosis and dosage subject to the underlying condition and clinical picture (such as coagulopathy due to blood loss and/or blood thinning, substitution in Factor V and Factor XI deficiency, thrombotic thrombocytopenic purpura, exchange transfusions), preventive measures to maintain the integrity of the blood preparation before transfusion, and instructions on patient follow-up to establish the success of transfusion, the potential formation of coagulation factor antibodies and inhibitors, and prophylactic measures to be taken etc.

Special precautions for disposal:

Partially used preparations or products that are no longer usable must be disposed of as specified by the health care establishment.

The national guidelines concerning blood components and transfusion therapy have to be considered.

The German "Guidelines for collecting blood and blood components and for the use of blood products (haemotherapy)" applicable at the time and any additional publications from the German Medical Association (Bundesärztekammer) and the Paul-Ehrlich-Institut have to be taken into consideration. Attention should also be paid to the 'New cross-sectional guidelines of the German Medical Association for hemotherapy with fresh frozen plasma. Evidence-based recommendations for risk-benefit assessment' issued by the German Medical Association (Bundesärztekammer).

9. Date of the last revision

15 July 2016

This SPC has not been legalized by the German competent authority.