LyoPlas N – w (Bag Set): Preparing for Transfusion

1. Connect transfer set to water bag Close the clamp on the transfer set. Connect the transfer set to the bag with water for injection (Aqua ad iniettabilia) using a Luer lock connector.

2. Pierce the plasma bottle Remove the protective cap from the bottle with the freeze-dried plasma. Disinfect the bottle stopper. Push the spike of the transfer set through the centre of the rubber stopper. The unit consisting of water bag, transfer set and glass bottle is now stable enough to hang freely.

3. Transfer the water Open the clamp and allow the water to completely flow from the bag into the glass bottle. (IMPORTANT: Do not press the bag as this will block the air filter!) Close the clamp.

4. Reconstitute the plasma Gently swirl the bottle to dissolve the freeze-dried plasma. Do not shake. Avoid foaming. The plasma is ready for use when all solid particles are dissolved.

You have 2 options for transfusion:

A. Transfusion from the bottle

5a. Transfusion Remove the transfer set with the bag. Suspend the bottle by its hanger label. An administration set with air vent and with a 170-230 µm standard filter is required for transfusion.

B. Transfusion from the bag

5b. Mark the bag with the service label! Keep the bag set and glass bottle together to begin with. Peel the service label off the plasma bottle and use it to mark the bag.

6. Transfer the plasma from the bottle to the bag Suspend the bag by its hanger label, open the clamp. Allow the reconstituted plasma to flow into the bag.

7. Evacuate the air Evacuate the air from the bag; this is particularly important before pressure transfusion takes place. Gently press the plasma bag so that the air above the plasma can escape via the transfer set. Then close the clamp.

8. Transfusion Check the bar code numbers to ensure correct identification. Only then should the transfer set be disconnected from the bag. An administration set with a 170-230 µm standard filter should be used for transfusion. (An air vent is not required if transfusion is made from the bag.)
**Summary of Product Characteristics LyoPlas N – w (extract)**

**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

**Designation**
LyoPlas N – w

**Composition of the medicinal product / active ingredients (qualitative and quantitative)**
Active ingredients: 0.70 to 0.85 ml/ml coagulation-promoting human plasma
Other ingredients: citrate, phosphate, glucose

**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 of 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 insufficiency
- Thrombotic thrombocytopenic purpura
- Exchange transfusion
- The use of LyoPlas N – w is not indicated as a volume, protein or albumin substitute, for immunoglobulin substitution or as parenteral nutrition.

**Contraindications**

**Absolute contraindication:**
- Plasma protein intolerance

**Relative contraindication:**
- Cardiac decompensation, hypervolaemia, hyperhydration, pulmonary oedema
- Proven IgA insufficiency

**Side Effects**
- Volume overload may lead to acute heart failure with pulmonary oedema, particularly in cardiovascular diseases.
- Risk of citrate intoxication 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 may never be ruled out with absolute certainty.
- When using medicinal products made from human blood, it is never possible to entirely rule out the risk of transmitting pathogens - including those of a previously unknown kind – which may subsequently cause infectious diseases. This applies to hepatitis, for example, and more rarely to the acquired immune deficiency syndrome (AIDS). In the United Kingdom sporadic cases have been reported of “causative organisms” (so-called prions) being found in recipients of blood transfusions from donors who later developed variant Creutzfeldt-Jakob disease (vCJD). vCJD may be acquired through the consumption of certain beef products made from cattle affected by BSE. So far, however, vCJD has not been observed in Germany.

**Warnings**
Not required

**Drug status**
Only available on prescription

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www.blutspendedienst-west.de
www.lyoplas.com

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**Deutsches Rotes Kreuz**

DRK-Blutspendedienst West