Proposed Patient Information Leaflet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Bioplasma FDP, 4-6 g plasma proteins/100 ml; ≥ 0,4 IU/ml coagulation factors (Powder for solution for intravenous infusion)

Descriptive name: Fresh Human Plasma

Read all of this leaflet carefully before you are given Bioplasma FDP

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or pharmacist. **Bioplasma FDP** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT BIOPLASMA FDP CONTAINS

The active substance is a solution containing plasma proteins with a normal distribution of plasma components like albumin, immunoglobulin (antibodies) and coagulation (clotting) factors. It is prepared from human plasma from healthy, unpaid donors.

After reconstitution with Water for Injection, each 100 ml contains 4 g – 6 g plasma proteins and a minimum of 0,4 IU/ml clotting factors (II, V, VIII, IX and XI). It contains no antimicrobial agent or preservative.

2. WHAT BIOPLASMA FDP IS USED FOR

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Bioplasma FDP is used in cases where plasma and/or clotting factors are needed.

3. BEFORE BIOPLASMA FDP IS ADMINISTERED

Do not administer Bioplasma FDP:

- If you have a known allergic reaction to plasma proteins and/or low levels of immunoglobulin A (IgA).
- If you have very low levels of protein S (a vitamin K-dependent protein in your blood).

Tell your doctor or healthcare professional before being given the injection:

- If you are suffering with any liver disease.
- If you have heart disease or fluid in your lungs.
- If you are pregnant.
- If your immunity is low.
- If you have a condition with an increased production of red blood cells in your body.

Your doctor will decide if you should be given this medicine in these cases.

Bioplasma FDP should not be given if it has been established that you have no deficiency of clotting factors, or if there is a specific clotting factor concentrate available to treat a specific deficiency that you may have.

Receiving Bioplasma FDP with food and drink:

Bioplasma FDP is injected directly into the vein and is not affected by food or drink.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before being given this medicine.

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Driving and using machinery:

There are no known effects of this medicine on your ability to drive or use machinery.

Important information about some of the ingredients of Bioplasma FDP:

Bioplasma FDP is prepared from human plasma. When medicinal products prepared from human plasma are given to patients, the risk of infectious diseases by certain viruses cannot be totally ruled out. This warning includes known, unknown and new viruses, as well as some other types of infections. To reduce the risk from such viruses, strict measures are applied to the selection and testing of blood donors and donations. Each unit of plasma is tested for antibodies to human immunodeficiency virus (HIV), hepatitis C virus (HCV) and hepatitis B surface antigen (HBsAg) using approved methods. Only plasma in which no evidence of these viruses is found is used in the plasma pool. In addition, the pooled plasma is also tested for these viruses and antibodies to these viruses and only processed further if no evidence of these viruses is found.

The manufacturing process also involves steps which are aimed at removing/killing viruses.

The measures taken are considered effective for lipid-enveloped viruses such as HIV, HBV and HCV. The measures taken may be of limited value against non-enveloped viruses such as hepatitis A virus (HAV) and parvovirus B19. However, only plasma pools with no evidence of HAV and < 104 IU/ml parvovirus B19, are used in the manufacture of

Bioplasma FDP.

If you are likely to receive this medicine often, it is recommended that you be vaccinated against hepatitis A and B. It is strongly recommended that, every time you receive a dose of **Bioplasma FDP**, the name and batch number of the product are recorded by the healthcare professional, in order to maintain a record of the batches used. Please speak to your doctor should you require additional information in this regard.

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Using other medicines with Bioplasma FDP:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Bioplasma FDP should not be mixed with other medicines, or administered via the same intravenous line as other medicines, as this may result in loss of efficacy of the **Bioplasma FDP** through inactivation and precipitation (settling out) of plasma proteins.

To avoid formation of clots, any solution that contains calcium should not be injected using the same intravenous line.

4. HOW TO RECEIVE BIOPLASMA FDP

Do not share medicines prescribed for you with any other person.

This product must always be given by a doctor or nurse as an injection, given very slowly, into a vein.

Your doctor will tell you how long your treatment with **Bioplasma FDP** will last.

Doses:

Your dosage depends upon your clinical situation, your body weight and results of tests done to establish your clotting factor levels. Your doctor will determine the appropriate amount that you should receive and the rate at which it should be infused. You will be continually monitored while receiving this treatment.

If you use more Bioplasma FDP than you should:

Your dosage and rate of infusion is calculated by your doctor. High dosages or infusion rates may cause increased blood volume; fluid in the lungs and/or cardiac failure. Your doctor will monitor and manage your treatment, as appropriate. If you feel unwell after being given this medicine, you should inform your doctor.

Effects when treatment with Bioplasma FDP is stopped:

Your doctor will decide when treatment with this medicine should be stopped. It is unlikely that you will experience any negative effects when treatment with this medicine is stopped.

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5. POSSIBLE SIDE EFFECTS

Bioplasma FDP can cause side effects.

These may include skin reactions, voice disorders, restlessness, vomiting, nausea, diarrhoea, abdominal or back pain, increased heart rate, tightness in the chest, fever, chills (with or without fever), chest pain, abnormal symptoms in the lung and low calcium levels. If you get any of these or just feel unwell after getting the medication, you must inform your doctor or other healthcare professional.

Some patients may have allergic type reactions due to hypersensitivity to infused plasma proteins or IgA. Rarely, the infusion of human plasma may cause anaphylactic shock (an immediate serious allergic reaction which produces a flushing of the skin, drop in blood pressure, difficulty in breathing and collapse).

Your doctor/healthcare professional will have treatment on hand while giving you this medicine to treat these allergic reactions, if they occur.

Not all side effects reported for **Bioplasma FDP** are included in this leaflet. Should your general health worsen or if you experience any untoward effects after having been given this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF BIOPLASMA FDP

Bioplasma FDP should be stored at or below 25 °C and protected from light.

Disposal:

After infusion of the correct dose, your doctor or nurse will dispose of any solution that remains, along with used syringes, needles and containers following the appropriate procedure.

7. PRESENTATION OF BIOPLASMA FDP

Pack sizes of **Bioplasma FDP:**

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200 ml: Freeze-dried powder in a 250 ml glass bottle, sealed with a rubber stopper and an aluminium cap.

This pack also contains Water for Injection and a reconstitution kit for reconstitution.

50 ml: Freeze-dried powder in a 100 ml glass bottle, sealed with a rubber stopper and an aluminium cap.

This pack also contains Water for Injection and a reconstitution kit for reconstitution.

8. IDENTIFICATION OF BIOPLASMA FDP

Bioplasma FDP is a light-yellow to yellow powder or solid brittle mass; when diluted, it is a cloudy yellow liquid.

9. REGISTRATION NUMBER

28/30.3/0405

Namibia S2
Reg.No.: 04/30.3/1043

Botswana S2
Reg. No.: BOT0200556

10. NAME AND ADDRESS OF REGISTRATION HOLDER

NATIONAL BIOPRODUCTS INSTITUTE NPC

Company Reg. No. 1994/002044/08

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158 **11. DATE OF PUBLICATION**

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