APPROVED PATIENT INFORMATION LEAFLET FOR OCTAPLEX® 500 IU

SCHEDULING STATUS S4

OCTAPLEX® 500 IU (Powder and solvent for solution for infusion)

Per vial:

Human coagulation factor II	280 – 760 IU
Human coagulation factor VII	180 – 480 IU
Human coagulation factor IX	500 IU
Human coagulation factor X	360 – 600 IU
Protein C	260 – 620 IU
Protein S	240 – 640 IU

The total protein content per vial is 260 - 820 mg. The specific activity of the product is ≥ 0,6 IU/mg proteins, expressed as factor IX activity.

Sugar free

Read all of this leaflet carefully before you are given OCTAPLEX.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- OCTAPLEX 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.

What is in this leaflet

1. What OCTAPLEXis and what it is used for
2. What you need to know before you use OCTAPLEX
3. How to use OCTAPLEX

4. Possible side effects
5. How to store OCTAPLEX
6. Contents of the pack and other information

1. What OCTAPLEX is and what it is used for

OCTAPLEX belongs to a group of medicines called clotting factors. It contains the human vitamin K dependent blood coagulation factors II, VII, IX and X.

OCTAPLEX is used to treat and prevent bleeding:

- caused by medicines called vitamin K antagonists (such as warfarin). These medicines block the effect of vitamin K and cause a shortage of the vitamin K dependent clotting factors in your body. OCTAPLEX is used when rapid correction of the shortage is required.
- in people born with a shortage of the vitamin K dependent clotting factors II and X. It is used when purified specific clotting factor product is not available.

2. What you need to know before you use OCTAPLEX

OCTAPLEX should not be administered to you:

- if you are allergic (hypersensitive) to any of the actives in OCTAPLEX or any of the other ingredients of OCTAPLEX (listed in section 6).
- if you are allergic to heparin or if heparin has ever caused a reduction in the level of platelets in your blood.
- if you have a deficiency of immunoglobulin A (IgA deficiency) with known antibodies against IgA.

Warnings and precautions

The advice of a specialist experienced in the management of coagulation disorders should be sought.

If an allergic or anaphylactic-type reaction occurs, your doctor will stop the infusion immediately and give appropriate treatment.

Viral safety

When medicines are made from human blood or plasma, standard measures are put in place to prevent infections being passed on to patients.

The standard measures are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus and hepatitis C virus and may be of limited value against certain non-enveloped viruses such as hepatitis A virus and Parvovirus B19.

Your doctor may recommend that you consider vaccination against hepatitis A and B viruses if you regularly/repeatedly receive human plasma-derived products.

It is strongly recommended that every time you receive a dose of OCTAPLEX the name and batch number of the product are recorded in order to maintain a record of the batch used.

There is a risk of thrombosis or disseminated intravascular coagulation (serious illness, with clots forming all over the body) when you receive OCTAPLEX (particularly if you receive it regularly). Your doctor will observe you closely for signs or symptoms of intravascular coagulation or thrombosis. This is especially important if you have a history of coronary heart disease, liver disease, if you are going to have an operation.

Children and adolescents

There are no data available regarding the use of OCTAPLEX **i**n children or newborn.

Other medicines and OCTAPLEX

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

OCTAPLEX must not be mixed with other medicinal products.

OCTAPLEX stops the effect of vitamin K antagonist medicines (like Warfarin), but no interactions with other medicines are known. OCTAPLEX may affect the results of clotting tests which are sensitive to heparin.

OCTAPLEX with food and drink

No effects have been observed, but your doctor will prescribe the food and drink that you may consume if necessary.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving OCTAPLEX**.**

The safety of OCTAPLEX for use in pregnancy and breastfeeding has not been established.

Driving and using machines

It is not known how OCTAPLEX affects your ability to drive and use machines.

OCTAPLEX contains sodium and heparin

OCTAPLEX contains 75 -125 mg sodium per vial. Please tell your doctor or other healthcare specialist if you are on a controlled sodium diet.

OCTAPLEX contains heparin may cause allergic reactions and reduced blood cell counts which may affect the blood clotting system.(see **"4. Possible side effects"). ** Patients with a history of allergic reactions caused by heparin should not use heparin-containing medicines (see "**OCTAPLEX should not be administered to you "**)

3 How to use OCTAPLEX

Treatment with OCTAPLEX will be started under the supervision of a doctor who is specialised in clotting disorders and will be given to you by a doctor or nurse. It is given by an infusion into your veins.

If you got more OCTAPLEX than you should

Since a healthcare professional will administer OCTAPLEX, he/she will control the dosage. However, in the event of overdosage the risk is higher of developing clotting complications (such as heart attack

and clots in your veins or lungs), disseminated intravascular coagulation (a serious illness where clots form all over the body). Your doctor will manage the overdosage.

If you forget to use OCTAPLEX

It is unlikely that the dose will be missed since your doctor is responsible to supervise administration of OCTAPLEX and to keep your laboratory values within the specified range.

If you stop using OCTAPLEX

Based on laboratory values your doctor decides when to stop administration of OCTAPLEX and will assess possible risks.

4. Possible side effects:

OCTAPLEX can have side effects.

If you experience severe reactions, the infusion will be stopped by your doctor and correct treatment will be started.

Not all side effects reported for OCTAPLEX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking OCTAPLEX, please consult your health care provider for advice.

Tell your doctor if you notice any of the following:

- allergic type of reactions [including swelling of the hands, feet, face, lips, mouth or throat which may cause difficulty in breathing, bronchospasm (constriction of the muscles in the walls of the bronchioles), injection site reactions, chills, flushing, urticaria, headache, changes in blood pressure, anxiety, nausea, vomiting, sweating, tachycardia (rapid heartbeat), fever (increase in body temperature)]. These reactions may progress to severe anaphylaxis (allergic shock).

The following side effects have also been reported:

- developing of neutralizing antibodies (inhibitors) against any of the contained clotting factors. If such inhibitors occur, the replacement therapy will not be very effective
- thromboembolic episodes (blood clotting) including myocardial infarction, cerebral infarction, ischemic stroke, pulmonary embolism, deep vein thrombosis, peripheral thrombosis or ischemia
- circulatory collapse
- tremor
- cardiac arrest
- respiratory failure
- a temporary increase in liver test results (transaminases)
- allergic reaction where a sudden fall in the number of platelets in the blood occur (heparin-induced thrombocytopenia type II). The treatment with OCTAPLEX will be stopped immediately if you show this allergic reaction. You must not receive heparin containing medicinal products in the future.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of OCTAPLEX.

5 How to store OCTAPLEX

Store all medicines out of reach of children.

***Powder and solvent*:**

- Store at or below 25 °C.
- Do not freeze.
- Store in the original package in order to protect from light.
- Do not use OCTAPLEX after the expiry date which is stated on the label.

Reconstituted solution:

- stability of the solution has been demonstrated for up to 8 hours at or below 25 °C. To prevent contamination, the solution should be used immediately and on one occasion only.

Do not use solutions that are cloudy or have deposits.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and information

What OCTAPLEX contains:

The active substances are

Name of ingredient	**OCTAPLEX Quantity per vial (IU)**	**OCTAPLEX Quantity after reconstitution with 20 ml of Water for Injections (IU/ml)**
Active substances:		
Human coagulation factor II	280 - 760	14 - 38
Human coagulation factor VII	180 - 480	9 - 24
Human coagulation factor IX	500	25
Human coagulation factor X	360 - 600	18 - 30
Further active ingredients:		
Protein C	260 - 620	13 - 31
Protein S	240 - 640	12 - 32

The total protein content per vial is 260 - 820 mg. The specific activity of the product is ≥ 0,6 IU/mg proteins, expressed as factor IX activity.

Other ingredients:

Powder: tri-sodium citrate dehydrate, heparin

Solvent: Water for Injection

What OCTAPLEX looks like and contents of the pack

OCTAPLEX consists of a bluish-white lyophylised powder and a clear, colourless solvent (water for injection) for reconstitution for infusion.

The reconstituted product is a colourless to slightly blue solution and free form visible particles.

One package of OCTAPLEX contains:

- Powder in a clear and colourless 30 ml vial (type I glass) with a grey stopper (halobutyl rubber) and a blue flip off cap (aluminium)
- Solvent (water for injection) in a colourless 20 ml vial (type I or type II glass) with a grey stopper (halobutyl rubber) and a blue flip off cap (aluminium)
- 1 Transfer set

Holder of Certificate of Registration

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Access to the corresponding Professional Information

If you are a healthcare professional and require the Professional Information Leaflet electronically, please contact us on za-enquiries@octapharma.com