**APPROVED PATIENT INFORMATION LEAFLET FOR OCTANORM®**

**SCHEDULING STATUS S4**

**OCTANORM®** (solution for injection)

Human immunoglobulin 165 mg/ml (corresponding to human protein content of which at least 95 % is IgG).

Sugar free

**Read all of this leaflet carefully before you are given OCTANORM**

- 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.
- OCTANORM 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 OCTANORM is and what it is used for
2. What you need to know before you use OCTANORM
3. How to use OCTANORM
4. Possible side effects
5. How to store OCTANORM
6. Contents of the pack and other information



15 September 2025

## 1. What OCTANORM is and what it is used for

**What OCTANORM is**

OCTANORM is a solution of human immunoglobulin G fraction from pooled human blood

**What OCTANORM is used for**

Immunoglobulins are part of normal blood. When you have an immunodeficiency disease, for example due to a genetic condition, **OCTANORM** is used to restore your immunoglobulins and the functioning of your immune system

## 2. What you need to know before you use OCTANORM

**OCTANORM should not be administered to you:**

- if you are hypersensitive (allergic) to immunoglobulin containing preparations including OCTANORM
- if you are hypersensitive (allergic) to any of the other ingredients in OCTANORM (listed in section 6)
- OCTANORM must not be injected directly into a vein (intravenously).
- OCTANORM must not be injected into a muscle (intramuscularly) if you have bleeding disorders.

**Warnings and precautions**

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

- you are on a low sodium (salt) diet - **OCTANORM** contains 4,35 mmol (or 100 mg) sodium per dose (40 ml).
- you are aware that you have an IgA deficiency with anti-IgA antibodies – hypersensitivity reaction can occur.

Special care should be taken with OCTANORM:

- If OCTANORM is accidentally administered into a vein, you could develop shock (sudden loss in blood pressure and anaphylaxis). The physician treating you must take the necessary steps to reverse the shock.
- If allergic or anaphylactic-type reactions occur, the infusion should be stopped immediately and appropriate treatment instituted. In case of shock, the current medical standards for shock treatment should be observed.
- OCTANORM does not protect against hepatitis A (viral liver disease).
- The physician treating you should not exceed the rate which is recommended for you to receive OCTANORM**.**
- You should be monitored and observed for the duration of the injection and for 20 minutes afterward for any adverse reactions. This is particularly important if:
    - You are receiving OCTANORM for the first time.
    - If it has been longer than eight weeks since you last received a human normal immunoglobulin.
- If you have pre-existing risk factors for thrombotic events (formation of blood clots) such as: advanced age, high blood pressure, diabetes mellitus and a history of vascular disease or thrombotic (clot forming) episodes, patients with acquired or inherited thrombophilic disorders, patients with prolonged periods of immobilisation, severely hypovolemic patients with diseases which increase blood viscosity.
- If you are switching from another immunoglobulin product to OCTANORM.
- The measures to prevent infections of blood borne disease may be of limited value against non-enveloped viruses such as HAV and parvovirus B19.

It is strongly recommended that, every time you receive OCTANORM the name and batch number of the product are recorded.





**Other medicines and OCTANORM**

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

In the absence of compatibility studies, OCTANORM must not be mixed with other medicinal products

- OCTANORM may decrease the effectiveness of certain vaccines containing live viruses, for example measles, rubella, mumps and chicken pox vaccine. Following treatment with OCTANORM, three months should elapse before you are vaccinated with any of these vaccines. It is therefore important that the doctor carrying out the vaccination is aware that you are having or have had treatment with OCTANORM.
- Inform your doctor that you are taking immunoglobulin when you give a blood sample, as this treatment may affect the results.

**OCTANORM with food, drink and alcohol**

Your doctor will prescribe the food and drink that you may consume.

**Pregnancy and breastfeeding and fertility**

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

The safety of OCTANORM for use in pregnancy has not been established. OCTANORM is excreted into the breast milk.

**Driving and using machinery**

OCTANORM does not impair the ability to drive and use machines.





**OCTANORM contains sodium**

OCTANORM contains small amounts of sodium chloride (salt). Please inform your doctor or other healthcare professional if you are on a low salt diet. (see "**Special care should be taken with OCTANORM**")

## 3 How to use OCTANORM

You will not be expected to give yourself **OCTANORM.** It will be given to you by a person who is qualified to do so.

Your doctor will decide if you need **OCTANORM** and at what dose. **OCTANORM** is administered under the skin (subcutaneous) and should be at room or body temperature prior to use.

If you qualify for home treatment using **OCTANORM**, you will be instructed by your physician in the use of the application device, infusion techniques, the keeping of a treatment diary and measures to be taken in case of severe adverse events

**If you receive more OCTANORM than you should**

Since a healthcare professional will administer this medicine, he/she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

**If you missed a dose of OCTANORM**

Receive the missed dose as soon as you remember it. However, if it is almost time for your next dose, do not receive your missed dose. If you miss two or more doses, consult your doctor.

Do not receive a double dose to make up for forgotten individual doses.





## 4. Possible side effects:

OCTANORM can have side effects.

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

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

These side effects occur less frequently with OCTANORM**.**

If any of the following happens, tell your doctor immediately, or seek medical assistance immediately:

- anaphylactic shock (swelling of the hands, feet, ankles, face, lips or throat that may cause difficulty in swallowing or breathing).
- rash or itchiness.

These are all very serious side effects. If you have them, you may have had a serious reaction to OCTANORM**.** You may need urgent medical attention - your healthcare practitioner should take appropriate steps to treat you.

Tell your doctor if you notice any of the following:

These side effects occur less frequently with **OCTANORM.**

- hypersensitivity (allergic reaction)
- dizziness
- headache
- hypotension (low blood pressure)
- thromboembolic event (formation of blood clots)
- nausea (feeling sick) or vomiting
- back pain





- arthralgia (pain in the joints)
- fever
- stiffness or muscle cramps
- tiredness

Tell your doctor if you notice a local reaction at the place on your body where you were injected, such as swelling, tenderness, pain, redness or itchiness. These side effects occur frequently with OCTANORM.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Adverse drug reaction and product quality reporting form, found online under SAHPRA's E-Services: https://www.sahpra.org.za/ e-Library/GLF-CEM PV-06A. By reporting side effects, you can help provide more information on the safety of OCTANORM**.**

## 5 How to store OCTANORM

Store all medicines out of reach of children.

Store and transport at 2 ºC to 8 ºC. Protect from light.

DO NOT FREEZE.

Store in the original container. Keep the vial in the outer carton.

Once the vial has been opened use the content immediately and return any unused part to your pharmacist.

Do not use after the expiry date stated on the vial.

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





Within its shelf-life, the unopen vial may be stored at or below 25 °C for up to 6 months, without being refrigerated again during this period, and must be discarded if not used after the storage at or below 25 °C for the six months period. Any unused product should be disposed of in accordance with local requirements, without being refrigerated again during this period, and must be discarded if not used after this.

Any unused product should be disposed of in accordance with local requirements.

## 6. Contents of the pack and information

### What OCTANORM contains

The active substance is human immunoglobulin 165 mg/ml (at least 95 % is immunoglobulin G).

The other ingredients are glycine, sodium chloride, sodium acetate, polysorbate 80, water for injections

### What OCTANORM looks like and contents of the pack

OCTANORM is a clear or slightly opalescent and colourless or pale yellow or light-brown solution.

Free of visible particles.

OCTANORM is a solution for injection and is available in:

6 ml and 12 ml of solution filled in a 20 ml clear glass vial (type I) with a bromobutyl rubber stopper with a flip-off cap.

Pack of 1 and packs of 10 or 20.

24 ml or 48 ml of solution in a 50 ml clear glass vial (type I) with a bromobutyl rubber stopper with a flip-off cap.

Pack of 1 and packs of 10 or 20

Not all pack sizes may be marketed

**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 za1-enquiries@octapharma.com



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