

Package Leaflet: Information for the User

Octostim[®] 1.5 mg/ml Nasal Spray

Desmopressin acetate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Octostim Nasal Spray is and what it is used for

Octostim Nasal Spray is a solution for nasal use only. It contains Desmopressin acetate, an antidiuretic (reduces urine production).

It is used for:

- 1) To test for Fibrinolytic response
- 2) Shortening or normalisation of prolonged bleeding time prior to an invasive therapeutic or diagnostic operation, or for therapeutic control of bleeding in patients with prolonged bleeding time as a consequence of congenital or drug-induced thrombocyte dysfunction, uremia, cirrhosis of the liver or in patients with prolonged bleeding time of unknown etiology.
- 3) For the therapeutic control of bleeding and bleeding prophylaxis in connection with minor surgical procedures in patients with mild haemophilia A and von Willebrand's disease who respond positively to the test dose. Even moderate forms of the disease can be treated.
- 4) Factor VIII-release in plasma donors.

2. What you need to know before you use Octostim Nasal Spray

Do not use Octostim Nasal Spray:

- if you are allergic to desmopressin or any of the other ingredients of this medicine (listed in section 6)
- if you drink unusually large quantities of fluids, or if you experience excessive thirst
- if you are taking diuretics (water tablets)
- if you have heart problems
- if you have type IIB von Willebrand's disease
- For fibrinolytic response testing: if you have high blood pressure, heart problems or are taking diuretics (water tablets)

Warnings and Precautions

Talk to your doctor or pharmacist before using Octostim Nasal Spray.

Use with caution in very young or elderly patients.

Please consult your doctor before Octostim Nasal Spray is given:

- if you have an illness causing fluid and/or electrolyte imbalance e.g. vomiting, diarrhoea, infections or fever
- if you have a medical condition that could be made worse by fluid and/or electrolyte disturbance (conditions where your blood sodium levels are too low or you are likely to build up too much water in your body, e.g. hyponatraemia)
- if you have been warned that you are at risk of increased intracranial pressure

Other medicines and Octostim Nasal Spray:

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Please inform your doctor or pharmacist:

- if you are on medication for depression (e.g. tricyclic antidepressants or selective serotonin reuptake inhibitors), psychosis (e.g. chlorpromazine) or epilepsy (e.g. carbamazepine), as these medicines may increase the risk of water retention.
- if you are taking a medicine for pain and/or inflammation containing non-steroidal anti-inflammatory drugs (also known as NSAIDs) e.g. indomethacin or ibuprofen, as these medicines may increase the risk of water retention.

Octostim Nasal Spray with food or drink:

You should avoid drinking a large amount of fluid while you are being treated with Octostim Nasal Spray as this could lead to build up of water which dilutes the salt in the body. This is a serious problem and may lead to convulsions. You should only drink enough fluid to satisfy your thirst.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Octostim nasal spray has no or negligible effects on the ability to drive and/or use machines.

Octostim Nasal Spray contains Benzalkonium Chloride

Octostim Nasal Spray contains benzalkonium chloride, which is an irritant and may cause skin reactions.

3. How to use Octostim Nasal Spray

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

- **Fibrinolytic response test:**
Adults: One spray into each nostril.
- **During surgery or following trauma in patients with mild to moderate haemophilia and von Willebrand's disease to increase blood clotting factors:**
Adults: One spray into each nostril half an hour before surgery or at bleeding.

Under direct medical supervision, further doses may be administered at 12 hourly intervals for a maximum of 2-3 days.

PATIENT INSTRUCTIONS

It is important to use your medicine as directed by your doctor.

The pharmacy label on the bottle will tell you when to use your medicine and how much to use. If it does not, or you are not sure, ask your doctor or pharmacist.

How to use Octostim Nasal Spray:

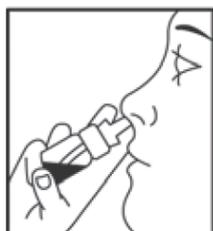
1. Remove the protective cap.



2. When first used, press the spray several times until a consistent, fine spray is seen.



3. Ensure that the dip-tube is in the liquid when using Octostim Nasal Spray. With your head tilted slightly back, place the nozzle just inside your nostril.



4. Hold your breath (DO NOT SNIFF) and press the spray once.
5. Repeat this procedure in the other nostril (until the prescribed dose has been given).
6. Replace the protective cap after use.
7. Do not store above 25°C. Keep vial in the outer carton. Do not freeze.
8. If the spray is not used within 7 days of the previous dose, press the spray at least once, until a consistent, fine spray is seen.

If you use more Octostim Nasal Spray than you should:

If you use more Octostim Nasal Spray than you should, talk to your doctor or pharmacist immediately.

If you forget to use Octostim Nasal Spray

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You should avoid drinking large amounts of fluid while you are being treated with Octostim Nasal Spray as this could lead to a build up of water which dilutes the salt in the body. This is a serious problem and may lead to convulsions.

STOP USING OCTOSTIM NASAL SPRAY if you experience:

- allergic reactions including; itching, skin rashes, swelling of the face, lips or throat, difficulty in breathing, wheeziness, chest tightness or coughing
- unusually bad or prolonged headache, confusion, unexplained weight gain, ankle swelling, nausea or vomiting (signs and symptoms of water retention which can occur if too much fluid is consumed)

If you experience any of the above side effects, you should contact your doctor or go to the nearest casualty department immediately.

Most people using Octostim Nasal Spray find it causes them no problems.

Other side effects associated with Octostim Nasal Spray are listed below, starting with the most common.

The following common side effects may affect more than 1 in 10 people:

- headache
- nausea
- an increase in the rate of heart beats
- facial flushing
- stomach pain
- blocked or runny nose
- nose bleeds
- eye redness

The following very rare side effects may affect up to 1 in 10,000 people:

- allergic reaction
- swelling due to a build up of fluid
- confusion
- vomiting
- rash
- muscle spasms
- fatigue

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Octostim Nasal Spray

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Keep vial in the outer carton. Store in an upright position. Do not freeze.

Do not use Octostim Nasal Spray after the expiry date which is stated on the carton and vial label after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening: Dispose of any unused medicine 6 months after you first open the nasal spray

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Octostim Nasal Spray contains

The active substance is desmopressin acetate. Each spray contains 150 micrograms of the active ingredient, desmopressin acetate.

The other ingredients are sodium chloride, citric acid monohydrate, disodium phosphate dihydrate, benzalkonium chloride solution and purified water.

What Octostim Nasal Spray looks like and contents of the pack

Octostim 1.5 mg/ml Nasal Spray is presented in a glass vial with a pump spray device. Each vial contains a volume of 2.5 ml to allow the delivery of 25 sprays. Octostim Nasal Spray is a clear colourless solution for nasal use only.

Marketing Authorisation Holder

Ferring Ireland Ltd., United Drug House, Magna Drive, Magna Business Park, Citywest Road, Dublin 24

Manufacturer

Ferring GmbH, Wittland 11, D-24109, Kiel, Germany.

This leaflet was last revised in October 2014.