

OCTIM[®] Nasal Spray

Desmopressin acetate

PATIENT INFORMATION

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet, you may need to read it again
- If you have further questions, please ask your doctor or pharmacist
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Important things that you need to know:

- Octim Nasal Spray is used
 - during surgery or following trauma in patients with mild to moderate haemophilia (blood condition) or von Willebrand's disease (blood clotting condition)
 - to test for fibrinolytic response
- You should avoid drinking large amounts of fluid while you are being treated with Octim Nasal Spray.
- If you experience unusually bad or prolonged headache, confusion, unexplained weight gain, ankle swelling, nausea or vomiting stop using Octim Nasal Spray.

In this leaflet:

1. What Octim Nasal Spray is and what it is used for
2. Before you use Octim Nasal Spray
3. How to use Octim Nasal Spray
4. Possible side effects
5. Storing Octim Nasal Spray
6. Further information

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

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

- during surgery or following trauma in patients with mild to moderate haemophilia (blood condition) or von Willebrand's disease (blood clotting condition) to increase blood clotting factors (*Note: Octim Nasal Spray is not suitable for every patient or for the treatment of all types of haemophilia or von Willebrand's disease.*)
- to test for fibrinolytic response (a test to measure the capacity of the body to dissolve blood clots once they have formed)

2. Before you use Octim Nasal Spray

Do not use Octim Nasal Spray if you:

- are allergic to any of the ingredients listed in section 6 of this leaflet
- drink unusually large quantities of fluids including alcohol, or if you experience excessive thirst

To be used during surgery or following trauma in patients with mild to moderate haemophilia or von Willebrand's disease:

Do not use Octim Nasal Spray if you:

- suffer from angina
- suffer from Type IIB (classed as moderate to severe) von Willebrand's disease

To test for fibrinolytic response:

Do not use Octim Nasal Spray if you:

- have high blood pressure or heart problems
- are taking diuretics (water tablets)

Please consult your doctor before using Octim Nasal Spray if you:

- have an illness causing fluid and/or electrolyte imbalance e.g. vomiting, diarrhoea, infections or fever
- 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. Hyponatremia.
- suffer from serious heart or kidney disease
- have cystic fibrosis

Taking/using other medicines:

Please inform your doctor or pharmacist if you:

- are taking or have recently taken or used any other medicines - even those not prescribed.
- are on medication for depression or epilepsy
- are taking a medicine for pain and/or inflammation containing non-steroidal anti-inflammatory drugs (also known as NSAIDs) e.g. indomethacin or ibuprofen

Taking Octim Nasal Spray with food or drink:

- you should avoid drinking large amount of fluid while you are being treated with Octim 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 fluids to satisfy your thirst.
- when used to test for fibrinolytic response, limit fluid intake to no more than 500ml, from 1 hour before until 8 hours after the dose

Pregnancy:

If you are pregnant or planning a pregnancy, please inform your doctor before you use Octim Nasal Spray as blood pressure monitoring is recommended due to the increased risk of pre-eclampsia (a condition in pregnant women that can cause serious complications). Symptoms of pre-eclampsia include high blood pressure, oedema (swelling due to the build up of fluid) and proteinuria (protein in the urine).

Breast-feeding:

If you are breast-feeding ask your doctor or pharmacist for advice before using Octim Nasal Spray.

Important information about some of the ingredients in Octim Nasal Spray:

Octim Nasal Spray contains Benzalkonium Chloride which may cause bronchospasm (when your breathing airway suddenly narrows, causing coughing and difficulty in breathing).

3. How to use Octim Nasal Spray

For details on use of this product see the patient instructions section at the end of this leaflet.

Do NOT use more than the prescribed dose in any 24 hour period.

If you have the impression that the effect of Octim Nasal Spray is too strong or too weak, talk to your doctor or pharmacist.

The usual doses are:

During surgery or following trauma in patients with mild to moderate haemophilia and von Willebrand's disease to increase blood clotting factors:

Adults (including the elderly): 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.

If you have been given Octim Nasal Spray to use occasionally as the need arises, there should be an interval of at least 3 days between doses unless your doctor has specifically instructed you otherwise.

Fibrinolytic response test:

Adults (including the elderly): One spray into each nostril.

If you used more Octim Nasal Spray than you should:

If you have used more Octim Nasal Spray than you should, talk to your doctor or pharmacist immediately.

If you forget to use Octim Nasal Spray:

Please consult your doctor or pharmacist for advice.

4. Possible side effects

Like all medicines, Octim Nasal Spray can cause side effects.

STOP USING OCTIM 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

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

Low level of sodium in your blood can lead to fits. This is more likely to happen if you drink large amounts of fluid while receiving this medication.

Most people using Octim Nasal Spray find it causes them no problems. However, common side effects can include:

- headache
- stomach pain
- blocked or runny nose, nose bleeds

Very rare cases of emotional disorders including aggression in children have also been reported.

If you experience one or more of these side effects or any other undesirable effects, please inform your doctor or pharmacist.

5. Storing Octim Nasal Spray

Keep Octim Nasal Spray out of the reach and sight of children. Do not store above 25°C. Keep vial in the outer carton in order to protect it from light. Do not freeze.

Use by date: Do NOT use Octim Nasal Spray past the expiry date on the packaging. The expiry date refers to the last day of that month.

If you are unsure about the storage, ask your pharmacist. It is best to return all old and unused medication to your pharmacist for safe disposal.

6. Further information

Your medicine is called Octim Nasal Spray. It is a solution for nasal use only.

- it is presented in a glass vial with a pump spray device. Each vial contains a volume of 2.5ml to allow the delivery of 25 sprays
- each spray contains 150 micrograms of the active ingredient, Desmopressin acetate
- other ingredients in Octim Nasal Spray are citric acid monohydrate, disodium phosphate dihydrate, sodium chloride, benzalkonium chloride solution 50% and purified water.

Marketing Authorisation Holder: Ferring Pharmaceuticals Ltd., Drayton Hall, Church Road, West Drayton, UB7 7PS, (UK)

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

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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 OCTIM 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 Octim 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 using alternate nostrils 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 in order to protect it from light. 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.