

Octim® Injection

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 get 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 Injection 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 Injection.
- If you experience unusually bad or prolonged headache, confusion, unexplained weight gain, ankle swelling, nausea or vomiting stop using Octim Injection.

In this leaflet:

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1. What Octim Injection is and what it is used for

Octim Injection is a clear, colourless solution. 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 Injection 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 Octim Injection is given

Octim Injection will not be given if you:

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

Octim Injection will not be given to increase blood clotting factors if you:

- suffer from angina
- suffer from moderate to severe type IIB von Willebrand's disease

Octim Injection will not be given to test your fibrinolytic response if you:

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

Please consult your doctor before Octim Injection is given 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

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 Injection with food or drink:

- you should avoid drinking large amounts of fluid while you are being treated with Octim Injection 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.
- when used to test 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 Injection 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 Injection.

3. How Octim Injection will be given

Depending on the condition that you are being treated for, the doctor will administer the appropriate dose by injection, either just under the skin (subcutaneous) or directly into one of your veins (intravenous).

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

The dose for adults, children and infants is 0.3 micrograms per kilogram body weight, administered just under the skin (subcutaneous) or directly into one of your veins (intravenous) over a period of 20 minutes. This dose should be given before surgery or following trauma. Further doses may be administered at 12 hourly intervals.

Fibrinolytic response test:

The dose for adults and children is 0.3 micrograms per kilogram body weight, administered just under the skin (subcutaneous) or directly into one of your veins (intravenous) over a period of 20 minutes.

If you are given more Octim Injection than you should:

As this medicine will be given to you whilst you are in hospital it is unlikely that you will be given too much, however, avoid drinking any more fluid and seek medical advice if you have any concerns.

4. Possible side effects

Like all medicines, Octim Injection can cause side effects.

STOP USING OCTIM INJECTION 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 levels 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 Injection find it causes them no problems. However, common side effects can include:

- headache
- stomach pain

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 Injection

Octim Injection should be stored in a refrigerator at 2°C to 8°C. Keep container in the outer carton.

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

This product should only be given by a doctor or qualified nurse and will be safely disposed of by them.

6. Further information

Your medicine is called Octim Injection.

- it is supplied in clear glass ampoules and each ampoule contains 1ml of a clear, sterile colourless solution.
- each 1ml of the solution contains 15 micrograms of the active ingredient Desmopressin acetate dissolved in water for injection.
- other ingredients in Octim Injection are sodium chloride and hydrochloric acid.

Marketing Authorisation Holder:

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

Manufacturer:

FERRING GmbH, Wittland 11, Kiel, Germany

Fibrinolytic Response Testing:

Besöksadress: Hojdrodergatan 16, 212 39 Malmö

Octim[®] Injection PL 03194/0055

This leaflet was last Approved in June 2015.

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Title	Leaflet OCTIM sol for inj 15mcg/ml amp 10x 1ml GB		
Item N°	5009000679	Perigord N°	290135
Item version	F-5009000679.01	Barcode N°	5009000679
Proof N°	01	F-MS N°	3005
Country	GB	Size (mm)	180 x 300
Colours	Pro Black		
FERRING PHARMACEUTICALS			
Name			
Date			
Signature			
Variable Data	Translation		
line 1:			
line 2:			
line 3:			