

## Package Leaflet: Information for the User

### Octostim<sup>®</sup> 15 micrograms/ml Solution for Injection

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 any 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.

#### **What is in this leaflet:**

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

## **1. What Octostim Injection is and what it is used for**

Octostim 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: Octostim 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. What you need to know before Octostim Injection is given**

#### **Octostim Injection will not be given:**

- if you are allergic to desmopressin or any of the ingredients 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 suffer from angina or have heart problems
- if you have type IIB von Willebrand's disease
- if you have low blood salt levels known as hyponatraemia
- 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 before Octostim Injection is given to you.

Use with caution in very young or elderly patients.

Please consult your doctor before Octostim Injection 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 Injection:**

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

#### **Octostim Injection with food or drink:**

You should avoid drinking a large amount of fluid while you are being treated with Octostim 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.

#### **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.

#### **Octostim Injection contains sodium**

This medicinal product contains less than 1 mmol sodium (23 mg) per 1 ml vial, i.e. essentially 'sodium-free'.

### **3. How Octostim 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 and children is 0.3 micrograms per kilogram body weight, administered just under the skin (subcutaneous) or directly into one of your veins (intravenous). For intravenous administration, the dose should be diluted in 50ml to 100ml of 0.9% sodium chloride for injection and given over a period of 15 to 30 minutes. This dose should be given before surgery or following trauma. Further doses may be administered at 6-12 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). For intravenous administration, the dose should be diluted in 50ml to 100ml of 0.9% sodium chloride for injection and given over a period of 15 to 30 minutes.

**If you given more Octostim that you need**

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, 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 Injection 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 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 (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 Injection find it causes them no problems.

**Other side effects associated with Octostim Injection are listed below, starting with the most common.**

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

- headache
- nausea
- fatigue
- a decrease in blood pressure
- an increase in the rate of heart beats
- facial flushing
- stomach pain

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

- dizziness

**Reporting of side effects**

If you get any 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 directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: +353 1 6764971; Fax: +353 1 6762517; Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Octostim Injection**

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

Octostim Injection should be stored in a refrigerator at 2°C to 8°C.

For single use only. Discard any unused contents.

Do not use Octostim Injection 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.

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 Injection contains**

The active substance is desmopressin acetate. Each 1ml of solution contains 15 micrograms of desmopressin acetate.

The other ingredients are sodium chloride, hydrochloric acid, and water.

### **What Octostim Injection looks like and contents of the pack**

Octostim 15 micrograms/ml Solution for Injection is presented in clear glass, single use ampoules containing 1 ml of a clear, colourless solution. It is supplied in packs of 10 ampoules.

### **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 04/2015.