

# Octostim(R)

*Desmopressin acetate*

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Octostim. It does not contain all the information that is known about Octostim.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Octostim against the benefits they expect it will have for you.

**If you have any concerns about using this medicine ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### What Octostim is used for

**Octostim is used for the following:**

- \* to increase the levels of the blood clotting factor VIII in patients with mild and moderate haemophilia A and von Willebrand's disease (but not type IIB) prior to dental or other surgery.
- \* to treat excessive bleeding in patients with certain defects of the blood clotting cells (platelets). Octostim can reduce spontaneous bleeds or bleeding after heart or other surgery in these patients.

Octostim is a synthetic version of a natural hormone in the body called antidiuretic hormone (ADH). It has a

number of actions in the body including :

- \* increasing the amount of blood clotting factor VIII and von Willebrand's factor (vWF).
- \* helping to reduce the time it takes for bleeding to stop.

Your doctor, however, may prescribe Octostim for another purpose. Ask your doctor if you have any questions about why Octostim has been prescribed for you.

### Before you are given Octostim

#### ***When you must not be given it***

**Octostim should not be given if you have ever had an allergic reaction to Octostim or any of the ingredients listed at the end of this leaflet.**

If you have an allergic reaction you may get a skin rash, have difficulty in breathing, get symptoms of hayfever or feel faint.

**Do not use Octostim after the expiry date (EXP) printed on the ampoule and packaging.**

It may have no effect at all or not work properly if you use it after the expiry date.

**Do not use Octostim to treat any other complaints unless your doctor has instructed you to do so.**

#### ***Before it is given to you***

Your doctor must know about all the following before you are given Octostim.

**You must tell your doctor if:**

**1. you are allergic to:**

- \* anti diuretic hormone (ADH)
- \* any other medicines or any foods, dyes or preservatives.

**2. you have any medical conditions, including:**

- \* type IIB von Willebrand's disease
- \* if you are in the habit of drinking large amounts of fluid or you need to drink large amounts of fluid.
- \* have heart disease or any other disease for which you take diuretics (fluid tablets).
- \* low blood pressure
- \* cystic fibrosis
- \* any disease which causes fluid or salt imbalance which may result in too little or too much fluid in the body).

It may not be safe for you to be given Octostim if you have any medical conditions.

**3. You are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.**

Some of the medicines in common use that may interfere with Octostim include:

- \* indomethacin
- \* medicines which are known to release anti-diuretic hormone

(such as some medicines for depression or epilepsy).

These medicines may affect how well Octostim works. You may need to be given different amounts of your medicine or you may need to use different medicines. Your doctor or pharmacist has a more complete list of medicines to avoid while being given Octostim.

Your doctor or pharmacist can tell you what to do if you are taking any of these or other medicines.

#### **4. you are pregnant or plan to become pregnant.**

**Do not use Octostim if you are pregnant unless you and your doctor have discussed the risks and benefits involved.**

Octostim should only be given to a pregnant woman if it is needed.

#### **Do not breastfeed whilst receiving treatment with Octostim.**

Very small amounts of Octostim have been found in breast milk. Discuss with your doctor the risks and benefits involved if you wish to breastfeed while being given Octostim.

**If you have not told your doctor or pharmacist or nurse about any of these things, tell them before you are given Octostim.**

#### **Use in children**

Octostim will only be given to children when prescribed by a doctor. It is important that children's fluid intake is checked carefully while they are being given Octostim.

#### **Use in the elderly**

Elderly patients may be more sensitive to the effects of Octostim. If you are elderly, you should be especially careful of how much fluid you drink.

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## **How Octostim is given**

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### ***How is it given***

Octostim is not intended for self administration.

Octostim will be given by injection into a vein (intravenously). It is usually diluted in an injection fluid before it is administered by a doctor or nurse.

Octostim is never given by injection into your muscle.

### ***How much is given***

The dose of Octostim prescribed by your doctor will vary depending on the condition being treated and your response to the treatment.

The dose of Octostim you will be given will be calculated on your body weight.

### ***When it is given***

If it is used for dental or minor surgery, Octostim is usually given 30 minutes before the procedure or surgery.

If you are undergoing cardiac (heart) surgery, Octostim will be given towards the end of the operation.

If you have responded to treatment with Octostim and require more doses, further doses may be given every 12 hours for as long as it is needed.

### ***How long Octostim is given***

This will depend on your condition and on your response to treatment with Octostim.

If you are being treated with Octostim to prevent or control bleeding, it will be given for as long as necessary to stop excessive bleeding. This could range from several hours to a number of days.

Your doctor will decide when treatment with Octostim should be stopped.

## ***What to expect***

Individuals will vary greatly in their response to Octostim and you may not feel any effect. You will receive regular monitoring to check on your body's response to Octostim.

If you have a defect in your blood clotting cells (platelets), your skin bleeding time will be monitored before surgery to determine whether you are at high risk of blood loss.

### ***If you receive too much (Overdose)***

It is unlikely that you will be given too much Octostim. However, should any of the following signs or symptoms occur, you should tell your doctor or nurse immediately.

Possible signs of overdose may include confusion, lethargy, continuing headache, problems with passing urine and rapid weight gain due to build up of fluid in the body.

The signs of overdosage can be treated by restoring your body's fluid balance, lowering the dose or giving Octostim less often, or it may be stopped completely.

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## **While you are being given Octostim**

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### ***Things you must do***

**Avoid excessive fluid intake. You should discuss how much fluid you can drink with your doctor.**

You should restrict your fluid intake as much as possible while you are being given Octostim as a build up of fluid in the body can occur leading to side effects.

**Tell your doctor immediately if you become pregnant while being given Octostim.**

Your doctor can discuss with you the risks of using it while you are pregnant.

**Tell all doctors, dentists and pharmacists who are treating you that you are being given Octostim, especially if you are being started on any new medicines.**

### **Things to be aware of**

Octostim does not cause drowsiness and does not appear to affect your ability to drive or to operate machinery.

Octostim has not been shown to increase the effects of alcohol.

However, as with any new medicines you should take care when driving, operating machinery or drinking alcohol until you know how Octostim affects you.

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## **Side Effects**

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**Tell your doctor or pharmacist or nurse as soon as possible if you do not feel well while you are being given Octostim.**

Octostim helps most people who are given it, but it may have unwanted side effects in some people.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you :**

- \* a fast heart rate, dizziness and faintness upon getting up quickly (these are signs of low blood pressure).
- \* headache
- \* nausea or vomiting
- \* flushing of the face
- \* mild stomach cramps

These are all uncommon side effects and tend to occur with larger doses of Octostim.

**Tell your doctor or nurse immediately if you notice any of the following :**

- \* weight gain
- \* lethargy
- \* confusion
- \* blackouts
- \* convulsion or fitting

These are all serious side effects and are the results of too much water in your body. You may need urgent medical attention.

Your doctor will be monitoring for the more severe side effects of low blood pressure, fluid and salt imbalance and water retention.

**Tell your doctor if you notice anything else that is making you feel unwell.**

Some people may get other side effects while using Octostim.

There is no evidence that Octostim is addictive.

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## **After using Octostim**

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### **Storage**

Octostim is usually stored in the hospital pharmacy or in the ward. It should be protected from light and stored in a refrigerator at a temperature between 2 - 8 degrees C.

### **Disposal**

Any Octostim which is left over, not used or has passed its expiry date will be disposed of by hospital staff.

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## **Product Description**

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### **What it looks like**

Octostim is a clear colourless solution for injection. It is packed in 1 mL ampoules. The ampoules are available in boxes of 10.

### **Ingredients**

Each Octostim 15mcg/mL ampoule contains the active ingredient desmopressin acetate (DDAVP) 15 micrograms in 1mL of solution.

### **Additives**

Octostim also contains :

- \* water for injections
- \* sodium chloride
- \* hydrochloric acid (to adjust the pH)

### **Manufacturer**

Octostim is made overseas by Ferring AB, Sweden and supplied in Australia by:

Ferring Pharmaceuticals Pty Ltd  
Suite 2B, Level 2, 802 Pacific Highway, Gordon, NSW 2072  
Australia

This leaflet was prepared in December 2000.

Australian Registration Number:  
AUST R 46758 15mcg/mL

Octostim is the registered trade mark of Ferring AB, Sweden