

OCTOSTIM[®] Injection

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about being given this medicine, speak to your doctor or pharmacist.

1. Why am I being given OCTOSTIM Injection?

OCTOSTIM Injection contains the active ingredient desmopressin acetate, which is a synthetic version of a naturally occurring substance produced in the brain called vasopressin. It is used for several different conditions including **to increase the blood clotting factor VIII levels in patients with mild and moderate haemophilia A and von Willebrand's disease (but not type IIB) prior to dental or other surgery and to treat excessive bleeding in patients with certain defects of the blood clotting cells (platelets).**

For more information, see Section [1. Why am I being given OCTOSTIM Injection?](#) in the full CMI.

2. What should I know before being given OCTOSTIM Injection?

Do not use OCTOSTIM Injection if you have ever had an allergic reaction to desmopressin acetate or to any of the ingredients listed at the end of the CMI. (see Section [7. Product details](#) in the full CMI.)

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before being given OCTOSTIM Injection?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with OCTOSTIM Injection and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How will I be given OCTOSTIM Injection?

OCTOSTIM Injection is given by injection into a vein (intravenously). It is never given by injection into your muscle (intramuscularly) and is not intended for self-administration.

- **For use prior to dental or other surgery of patients with mild and moderate haemophilia A and von**

Willebrand's disease (but not type IIB) - it is usually given 30 minutes before the procedure or surgery. For cardiac (heart) surgery, it will be given towards the end of the operation.

More instructions can be found in Section [4. How will I be given OCTOSTIM Injection?](#) in the full CMI.

5. What should I know while being given OCTOSTIM Injection?

<p>Things you should do</p>	<ul style="list-style-type: none"> ● Remind any doctor, dentist or pharmacist you visit that you are being given OCTOSTIM Injection. ● If you are going to have surgery, tell the surgeon or anaesthetist that you are being given this medicine.
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● OCTOSTIM Injection should not be given to you to treat any other complaints unless your doctor tells you to do so.
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> ● Keep OCTOSTIM Injection in a refrigerator at a temperature between 2°C and 8 °C. Do not freeze. Keep it

in its original packaging and protect it from light.

- Store it in a cool dry place away from moisture, heat or sunlight.

For more information, see Section [5. What should I know while being given OCTOSTIM Injection?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. Most of them are minor and temporary but some may need medical attention. **Tell your doctor if you experience any side effects, including headache, stomach pain, nausea or vomiting, rapid weight gain, confusion or drowsiness. These are signs and symptoms of hyponatraemia (low sodium levels in the blood), a rare, but serious possible side effect of OCTOSTIM Injection.** For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

OCTOSTIM[®] Injection

Active ingredient(s): *desmopressin acetate*

Consumer Medicine Information (CMI)

This leaflet provides important information about being given OCTOSTIM Injection. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about being given OCTOSTIM Injection.**

Where to find information in this leaflet:

- [1. Why am I being given OCTOSTIM Injection?](#)
- [2. What should I know before being given OCTOSTIM Injection?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given OCTOSTIM Injection?](#)
- [5. What should I know while being given OCTOSTIM Injection?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given OCTOSTIM Injection?

OCTOSTIM Injection contains the active ingredient desmopressin acetate. OCTOSTIM Injection is a synthetic version of a naturally occurring substance produced in the brain called vasopressin.

OCTOSTIM Injection has several different actions on the body including:

- 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.

2. What should I know before being given OCTOSTIM Injection?

Warnings

OCTOSTIM Injection should not be used if:

- you are allergic to desmopressin, or any of the ingredients listed at the end of this leaflet.
- you suffer from polydipsia (have excessive thirst and requiring increased fluid intake) or psychogenic

polydipsia (psychologically-caused are in the habit of drinking large amounts of fluid

- you have cardiac insufficiency (heart failure in which the heart is not able to pump enough blood throughout the body resulting in shortness of breath, swelling of feet or legs due to fluid build-up)
- you have low levels of sodium in your bloodstream
- you have SIADH (hormone secretion disorder where there is an overproduction of a hormone causing fluid retention, resulting in weakness, tiredness or confusion)
- you have a history of a condition marked by severe pain in the chest, often also spreading to the shoulders, arms and neck, owing to an inadequate supply to the heart (angina pectoris).
- you have von Willebrand's disease type IIB (a Bleeding disorder)
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions especially the following:
 - a known allergy to anti-diuretic hormone (ADH)
 - too little or too much fluid in the body
 - heart or blood vessel disease or any other disease for which you take diuretics (fluid tablets)

- low blood pressure
- cystic fibrosis or any other disease which causes fluid or salt imbalance
- any disease of the blood clotting cells (platelets)
- serious problems with bladder function or with passing urine
- raised pressure within your head (increased intracranial pressure)
- moderate to severe renal insufficiency
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

OCTOSTIM Injection should only be given to a pregnant woman if it is needed. Your doctor can discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

OCTOSTIM Injection is not recommended while you are breast-feeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with OCTOSTIM Injection and affect how it works.

Medicines that may increase the effect of OCTOSTIM Injection include:

- medications which are known to release antidiuretic hormone, which can increase the risk of fluid buildup in the body such as:
 - tricyclic antidepressants
 - selective serotonin reuptake inhibitors (SSRIs) (antidepressants)
 - chlorpromazine (anti-psychotic)
 - carbamazepine (bipolar disorder and epilepsy medication)
 - opioids (pain relief medications)
 - medications which are known to treat high blood sugar (diabetes) (e.g. medicines in the sulfonylurea group)
 - non-steroidal anti-inflammatory drugs (NSAIDs), which are medicinal products used for the treatment of pain and inflammation (e.g. aspirin and ibuprofen).
 - NSAIDs may induce water retention/low sodium levels in the blood (hyponatraemia).

These medicines may affect how well OCTOSTIM Injection works. You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect OCTOSTIM Injection.

4. How will I be given OCTOSTIM Injection?

OCTOSTIM Injection is given by injection into a vein (intravenously). It is never given by injection into your muscle (intramuscularly).

OCTOSTIM Injection is not intended for self-administration.

How much OCTOSTIM Injection is given

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

The dose of OCTOSTIM Injection you will be given will be calculated based on your body weight.

When OCTOSTIM Injection is given

Patients with mild and moderate haemophilia A and von Willebrand's disease (but not type IIB) prior to dental or other surgery

- if it is used for dental or minor surgery, OCTOSTIM Injection is usually given 30 minutes before the procedure or surgery
- if you are undergoing cardiac (heart) surgery, OCTOSTIM Injection will be given towards the end of the operation
- if you have responded to treatment with OCTOSTIM Injection and require more doses, further doses may be given every 12 hours for as long as it is needed.

How long OCTOSTIM Injection is given

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

If you are being treated with OCTOSTIM Injection to prevent or control bleeding, it will be given for as long as necessary to stop excessive bleeding.

You doctor will decide when treatment with OCTOSTIM Injection should be stopped.

What to expect

Individuals will vary greatly in their response to OCTOSTIM Injection 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, your skin bleeding time will be monitored before surgery to determine whether you are at high risk of blood loss.

If you are given too much OCTOSTIM Injection

It is unlikely that you will be given too much OCTOSTIM Injection.

If you think that you or anyone else have been given too much OCTOSTIM Injection, you should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include confusion, drowsiness, continuing headache, nausea or vomiting, rapid weight gain due to a build-up of water in the body, or, in severe cases, convulsions.

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

5. What should I know while being given OCTOSTIM Injection?

Things you should do

If you are about to be started on any new medicine, remind your doctor, dentist, or pharmacist you visit that you are being given OCTOSTIM Injection.

If you are going to have surgery, tell the surgeon or anaesthetist that you are being given this medicine.

It may affect other medicines used during surgery.

If you become pregnant while being given OCTOSTIM Injection, tell your doctor immediately.

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

If you are about to have any blood tests, tell your doctor that you are being given this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you should not do

OCTOSTIM Injection should not be given to you to treat any other complaints unless your doctor tells you to do so.

Driving or using machines

This medicine is not expected to affect your ability to drive a car or operate machinery.

Looking after your medicine

OCTOSTIM Injection is usually stored in the hospital pharmacy or in the ward.

Keep OCTOSTIM Injection in a refrigerator at a temperature between 2°C and 8 °C. Do not freeze. Keep it in its original packaging and protect it from light.

If you store the medicine out of its original packaging it may not keep well.

Store it away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date. The expiry date refers to the last day of that month.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

The elderly may be at an increased risk of some side effects.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Side effects

Side effects	What to do
Hyponatraemia or low sodium levels in the blood may have the	These side effects are not usually serious but can become serious.

Side effects	What to do
<p>following signs or symptoms:</p> <ul style="list-style-type: none"> • headache • stomach pain • nausea. <p>Hyponatraemia can potentially become a serious side effect, see below.</p> <p>Common side effects (affects between 1 to 10 in 100 users):</p> <ul style="list-style-type: none"> • fatigue (tiredness) <p>Rare side effects (affect less than 1 in 1000 users):</p> <ul style="list-style-type: none"> • dizziness (feeling lightheaded) <p>Side effects (unknown frequency):</p> <ul style="list-style-type: none"> • generalised or local swelling (limbs, face) • chills 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">● high or low blood pressure● fast heart rate● emotional or behavioural disturbances <p>*Hypersensitivity or allergic reactions (unknown frequency):</p> <ul style="list-style-type: none">● shortness of breath, wheezing or difficulty breathing● swelling of the face, lips, tongue or other parts of the body● rash, itching or hives on the skin. <p>*Hyponatraemia or low sodium levels in the blood may have the following serious signs or symptoms:</p> <ul style="list-style-type: none">● confusion or drowsiness● continuing headache● nausea or vomiting	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● rapid weight gain, which may be due to a build-up of water in the body ● convulsions, fitting and blackouts (including coma) <p>*These side effects are rare</p>	

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given OCTOSTIM Injection.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What OCTOSTIM Injection contains

Active ingredient (main ingredient)	desmopressin acetate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• sodium chloride• hydrochloric acid (to adjust the pH)• water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What OCTOSTIM Injection looks like

OCTOSTIM Injection are supplied in 1 mL ampoules and are available in boxes of 10.

OCTOSTIM desmopressin acetate 15 micrograms/1 mL injection ampoule is a clear colourless solution for injection packed in 1 mL ampoules (AUST R 46758).

Who distributes OCTOSTIM Injection

Ferring Pharmaceuticals Pty Ltd

Suite 2, Level 1, Building 1

20 Bridge Street

Pymble, NSW 2073

Toll free: 1800 337 746

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