

OCTOSTIM®

Injection

desmopressin acetate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about OCTOSTIM Injection.

It does not contain all the available information. It does not replace talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you been given OCTOSTIM Injection against the benefits they expect it will have for you.

If you have any concerns about this medicine you will be given ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What OCTOSTIM is given for

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

It has a number of different actions in the body. This means that OCTOSTIM Injection can be used for several different conditions 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

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

Before you are given OCTOSTIM

When you must not be given it

OCTOSTIM Injection must not be given if you have an allergy to:

- any medicine containing desmopressin or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- 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.

You must not be given OCTOSTIM Injection if 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)
- 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)
- have low levels of sodium in your bloodstream
- have von Willebrand's disease type IIB (a Bleeding disorder)
- have SIADH (hormone secretion disorder where there is an overproduction of a hormone causing fluid retention, resulting in weakness, tiredness or confusion)
- 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).

Do not breast-feed if you are taking this medicine.

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

Do not give this medicine to a child under the age of 6 years.

Safety and effectiveness in children younger than 6 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before it is given to you

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- a known allergy to anti-diuretic hormone (ADH)
- 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
- moderate to severe renal insufficiency.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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.

It is recommended that you do not breastfeed while given OCTOSTIM Injection.

If you have not told your doctor about any of the above, tell him/her before you will be given OCTOSTIM Injection.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from

your pharmacy, supermarket or health food shop.

Some medicines and OCTOSTIM Injection may interfere with each other. These include:

- tricyclic antidepressants, which are medicines used to treat e.g. depression (such as clomipramine, imipramine, desipramine)
- selective serotonin reuptake inhibitors (SSRIs), which are medicines used to treat e.g. depression or anxiety (such as citalopram, paroxetine, sertraline)
- chlorpromazine, which is an anti-psychotic medicinal product used to treat e.g. schizophrenia
- carbamazepine, which is used to treat e.g. bipolar disorder and epilepsy
- antidiabetic medicinal products used for type II diabetes (medicines in the sulfonylurea group), particularly chlorpropamide
- medicines used to treat high blood pressure and some other conditions (ACE inhibitors or angiotensin receptor blockers e.g. enalapril, perindopril, irbesartan etc.)
- non-steroidal anti-inflammatory drugs (NSAIDs), which are medicinal products used for the treatment of pain and inflammation (e.g. aspirin and ibuprofen).

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while you have been given this medicine.

How OCTOSTIM is given

OCTOSTIM Injection 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 Injection is never given by injection into your muscle.

OCTOSTIM Injection is not intended for self-administration.

How much OCTOSTIM you will be 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 on your body weight.

When OCTOSTIM is given

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 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. This could range from several hours to a number of days.

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 receive too much (Overdose)

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

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much OCTOSTIM Injection. 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.

While you are being given OCTOSTIM

Things you must do

If you are about to be started on any new medicine, remind your

doctor and pharmacist that you are being given OCTOSTIM Injection.

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

Tell your doctor immediately if you become pregnant while being given OCTOSTIM Injection.

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

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 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 must not do

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

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or change the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen.

Side Effects

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

This medicine helps most people who are given it, but it may have unwanted side effects in a few 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.

If you are over 60 years of age you may have an increased chance of getting side effects.

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

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

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

- facial pressure or pain
- increased body temperature (fever)
- inflammation of the stomach and intestines
- stomach pain or nausea
- fatigue or tiredness.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- emotional, behavioural or visual disturbances
- fast heart rate
- low blood pressure, feeling dizzy or lightheaded
- allergic reactions including skin rash or more general reactions.

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

If you notice any of the following, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- confusion or drowsiness
- continuing headache
- nausea or vomiting

- rapid weight gain, which may be due to a build-up of water in the body
- convulsions, fitting and blackouts.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

After OCTOSTIM is given

Storage

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.

Do not store OCTOSTIM Injection, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

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

Product Description

What it looks like

OCTOSTIM ampoule contains 15 micrograms of the active ingredient, desmopressin acetate, in 1 mL solution. Is a clear colourless solution for injection, packed in 1 mL ampoules. The ampoules are available in boxes of 10.

Ingredients

OCTOSTIM Injection also contains the inactive ingredients:

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

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

OCTOSTIM Injection is supplied in Australia by:

Ferring Pharmaceuticals Pty Ltd
Suite 2, Level 1, Building 1
20 Bridge Street
Pymble, NSW 2073
Australia.

AUST R 46758 - OCTOSTIM desmopressin acetate 15 micrograms/1mL injection, ampoule.

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