

Osmitrol Intravenous Infusion

Consumer Medicine Information (CMI) summary

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

1. Why am I receiving Osmitrol?

Osmitrol Intravenous Infusion contains mannitol. It is used to help the body make more urine to prevent or treat early kidney failure before it becomes permanent. It is also used to lower high pressure inside the eye (when other treatments don't work), reduce pressure inside the head and swelling of the brain or help the body get rid of harmful substances through the urine.

For more information, see Section [1. Why am I receiving Osmitrol?](#) in the full CMI.

2. What should I know before I receive Osmitrol?

Do not use if you have ever had an allergic reaction to any of the ingredients listed at the end of the 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 I receive Osmitrol?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Osmitrol 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 is Osmitrol given?

- Your doctor or trained nurse will give Osmitrol by an infusion (drip) into a vein (intravenously).
- Your doctor will decide how much Osmitrol to give. The amount depends on your need and condition.

More instructions can be found in Section [4. How is Osmitrol given?](#) in the full CMI.

5. What should I know while receiving Osmitrol?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, nurse, dentist or pharmacist you visit that you are using Osmitrol.
Things you should not do	<ul style="list-style-type: none">• Osmitrol has been prescribed for you and should not be used by anyone else.• Do not use Osmitrol to treat any other condition unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Osmitrol affects you.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• This medicine will be stored in the pharmacy or the hospital ward, below 30°C.

For more information, see Section [5. What should I know while receiving Osmitrol?](#) in the full CMI.

6. Are there any side effects?

Serious side effects, such as allergic reactions, cardiac failure and kidney failure, are possible.

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.

Osmitrol Intravenous Infusion

Active ingredient: *mannitol*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Osmitrol Intravenous Infusion (Osmitrol). **You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about using Osmitrol.**

Where to find information in this leaflet:

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

1. Why am I receiving Osmitrol?

Osmitrol contains the active ingredient mannitol.

Mannitol is a type of sugar alcohol that is used as a medicine to help remove extra water from the body. It works by making your kidneys produce more urine.

Osmitrol is used to:

- Help the body make more urine to prevent or treat early kidney failure before it becomes permanent.
- Lower high pressure inside the eye when other treatments don't work.
- Reduce pressure inside the head and swelling of the brain.
- Help the body get rid of harmful substances through the urine.

2. What should I know before I receive Osmitrol?

Warnings

Do not use Osmitrol if:

- you are allergic to mannitol or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have higher-than-normal amounts of salts, sugars or other substances in your blood.
- you have severe heart failure, or heart or lung issues following the start of Osmitrol therapy.
- you have severe kidney problems where you are passing little to no urine, or kidney damage following the start of Osmitrol therapy.
- you did not respond to the Osmitrol test dose.

- you have fluid in your lungs, causing severe breathing difficulties.
- you have active bleeding on the brain, or a condition that allows harmful substances to cross from your bloodstream into your brain.
- you are very dehydrated.

Check with your doctor if you:

- have kidney problems
- have heart problems
- are in shock (a medical condition where your body doesn't have enough blood to keep your organs working properly)
- have recently had an operation
- drink water compulsively
- have a condition that affects your central nervous system
- have any other medical conditions
- 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.

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

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 and Osmitrol may interfere with each other and put your health at risk. These include:

- diuretics (a group of medicines used to remove fluid from the body)
- lithium (a medicine used to treat bipolar disorder)
- methotrexate (a medicine used to treat some autoimmune conditions and cancers)
- Cyclosporin (a medicine used to prevent rejection of organ transplants)
- certain types of antibiotic medicines (aminoglycosides)
- some medicines used to relax muscles
- some medicines used to prevent blood clots
- digoxin (a medicine used to treat heart problems)

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

4. How is Osmitrol given?

How it is given

- Your doctor or trained nurse will give Osmitrol by an infusion (drip) into a vein (intravenously).
- It is usually given in the hospital, clinic or nursing home.

How much is given

- Your doctor will decide how much Osmitrol to give. The amount depends on your need and condition.

If you are given too much Osmitrol

The doctor or nurse giving you Osmitrol is trained and experienced in the use of this sort of medicine, so it is unlikely that you will be given an overdose.

If you think that you have been given too much, you may need urgent medical attention.

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.

5. What should I know while receiving Osmitrol?

Things you should do

During and after treatment, discuss your progress with your doctor. Tell them if you've had any side effects or concerns, especially during the first few days of therapy.

Your doctor and nurse will closely monitor you during treatment, and may use laboratory tests to make sure you are safely receiving the right amount of medicine.

Remind any doctor, nurse, dentist or pharmacist you visit that you have used Osmitrol.

Things you should not do

- Osmitrol has been prescribed for you and should not be used by anyone else.
- Do not use Osmitrol to treat any other condition unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Osmitrol affects you.

The effects of Osmitrol on driving and using machines or tools have not been studied.

Drinking alcohol

Tell your doctor if you drink alcohol.

Osmitrol may cause dizziness or tiredness in some people.

Looking after your medicine

Osmitrol will be stored in the pharmacy or the hospital ward, below 30°C.

Getting rid of any unwanted medicine

Osmitrol is for single use, and for one person only. Your doctor or nurse will discard any unused medicine. They will not save unused portions for later, either for you or anyone else.

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.

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

Less serious side effects

Less serious side effects	What to do
Infusion site-related: <ul style="list-style-type: none">• local pain, irritation, inflammation, swelling, itchiness or abnormal clotting at the site of infusion• pain, swelling, or damage caused by fluid leaking from the infusion into the tissues around the vein Others: <ul style="list-style-type: none">• dehydration, thirst, dry mouth• cramps• needing to urinate a lot	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Infusion site-related: <ul style="list-style-type: none">• pain, redness or swelling of the infusion vein• skin turning black, dark purple or grey• skin becoming swollen, shiny or blistering Kidney related: <ul style="list-style-type: none">• decreased urine output• swelling of the hands or feet or other parts of the body• weight gain• tiredness, lethargy	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.

<ul style="list-style-type: none"> • trouble concentrating • confusion • changes in your breathing • blood in the urine (pink coloured urine) <p>Allergic reaction-related:</p> <ul style="list-style-type: none"> • dizziness or light-headedness due to low blood pressure • shortness of breath, wheezing, cough or trouble breathing • swelling of the mouth, lips, tongue or around the eyes • rash, itching or hives on the skin • fever, chills or sweating • runny nose • generalised pain • muscle and joint stiffness • nausea • vomiting • headache <p>Heart related:</p> <ul style="list-style-type: none"> • chest pain • changes in heart rate <p>Nerve and brain related:</p> <ul style="list-style-type: none"> • seizures • blurred vision • loss of consciousness • unresponsive to surroundings and pain 	
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. Some side effects, such as imbalances in body salt levels, can only be detected using laboratory tests.

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 Osmitrol contains

Active ingredients (main ingredients)	Mannitol
Other ingredients (inactive ingredients)	Hydrochloric acid/Sodium hydroxide (for pH adjustment)

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

What Osmitrol looks like

Osmitrol is a clear, colourless solution in VIAFLEX plastic bags. It is available as:

- 10% Osmitrol (Mannitol) IV Infusion, 1000 mL – Aust R 19479
- 20% Osmitrol (Mannitol) IV Infusion, 500 mL – Aust R 19496

Who distributes Osmitrol

Baxter Healthcare Pty Ltd
 1 Baxter Drive
 Old Toongabbie
 NSW 2146
 Australia

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