

Mitomycin Omegapharm

Powder for injection, 2 mg/vial, 10 mg/vial and 20 mg/vial

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about Mitomycin Omegapharm but it does not contain all the available information. 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 treating you with Mitomycin Omegapharm against the benefits they expect it will have for you.

If you have any concerns about being treated with Mitomycin Omegapharm ask your doctor or pharmacist.

Keep this leaflet, because you may need to read it again.

What Mitomycin Omegapharm is used for

Mitomycin Omegapharm contains mitomycin, which is an anti-cancer agent. It is used to treat cancer of the stomach, pancreas, colon, lung (non-small cell), breast, cervix, head and neck, liver and bladder.

Mitomycin Omegapharm works by stopping cancer cells from growing.

Ask your doctor if you have any question about why Mitomycin Omegapharm was prescribed for you.

Before you are given Mitomycin Omegapharm

When you must not be given Mitomycin Omegapharm

- You must not take Mitomycin Omegapharm if you have a history of severe allergic reactions to mitomycin or to any of the ingredients listed at the end of this leaflet.

Symptoms of a severe allergic reaction may include; chills, fever, fast heart beat, wheezing or coughing, difficulty breathing, dizziness, flushing, sweating and swelling of the face, tongue or other parts of the body. You must not take Mitomycin Omegapharm if you have any condition or any blood disorder which causes you to bleed very easily.

Before you are given Mitomycin Omegapharm

You must tell your doctor if;

- you have ever had an allergic reaction to any medicine, or other substances such as food, preservatives or dyes.
- you have ever had a condition which caused you to bleed very easily.
- you have an infection now or had one recently.
- you have ever had a problem with your kidneys.
- you are pregnant or likely to become pregnant you are breast-feeding.

Taking other medicines

You must tell your doctor if you are taking any medicines,

Including the ones you buy without a prescription from a pharmacy, supermarket or health food shop. The medicines you take may be affected by Mitomycin Omegapharm, or may affect how well it works. You may need different amounts of your medicine, or you may need to take or use different medicines. Your doctor will advise you, they may have more information on medicines to be careful with or avoid while you are being given Mitomycin Omegapharm.

How Mitomycin Omegapharm is given

Mitomycin Omegapharm is given to you in hospital. It will always be given to you by a doctor or by a nurse.

Mitomycin Omegapharm may be given alone or with other anti-cancer medicines.

How much is given

The amount (dose) you will be given is worked out by your doctor. It is based on your size and on the type of cancer. The dose worked out for you may be different to the dose for another patient.

How it is given

Mitomycin Omegapharm is mixed with an intravenous fluid and given as an infusion (drip) into a vein. It may be given as a single dose, or

divided into 10 daily doses given each day for five days then after 2 treatment-free days, given for another 5 five days.

This may all be repeated at intervals of 6 to 8 weeks.

Mitomycin Omegapharm may also be given directly into the bladder via a small tube and retained in the bladder for as long as possible, until you urinate.

Overdose

Mitomycin Omegapharm will be given to you under the supervision of a doctor so it is most unlikely that you will receive too much.

However if you experience severe side effects you must tell your doctor or a nurse immediately.

You may need urgent medical attention.

While you are being given Mitomycin Omegapharm

Things you must do

Be sure to keep all your doctor's appointments so your progress can be checked. You will require blood tests to see how Mitomycin Omegapharm is affecting your blood, particularly your white cell count, or if it is affecting any other organs such as your kidneys or liver. If the numbers of white cells in your blood are significantly reduced, your doctor may reduce the amount of Mitomycin Omegapharm you are given or may stop treatment until the numbers of white cells increase.

Mitomycin Omegapharm can affect your white cell count for up to 8 weeks after you received your Mitomycin Omegapharm.

Due to the effect on your blood cells, the following precautions should be taken to reduce your risk if infection or bleeding:

Avoid people who have infections. Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or find it painful or difficult to urinate.

Be careful when using a toothbrush, toothpick or dental floss. Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work.

Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters.

Avoid contact sports or other situations where you may bruise or get injured.

Tell your doctor or nurse if you have any concerns before during or after your treatment with Mitomycin Omegapharm.

Tell any other doctors, dentists or pharmacists who are treating you that you are being given Mitomycin Omegapharm.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given Mitomycin Omegapharm.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given Mitomycin Omegapharm, or have been given Mitomycin Omegapharm within the last 12 months.

If you become pregnant while being treated with Mitomycin Omegapharm, tell your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how being treated Mitomycin Omegapharm affects you.

As with other medicines used to treat cancer Mitomycin Omegapharm may cause tiredness, drowsiness and blurring of vision in some people.

Make sure you know how you react to Mitomycin Omegapharm before you drive a car, operate machinery, or do anything else that could be dangerous if you are tired or drowsy. If this occurs do not drive.

Side effects

Tell your doctor or a nurse as soon as possible if you do not feel well while you are being given Mitomycin Omegapharm.

Like other cancer medicines, Mitomycin Omegapharm helps most people who have cancer, but it may have unwanted side effects. Some of these side effects may be prevented or treated by therapy with other medicines. If side effects do occur, their severity usually depends on the dose of Mitomycin Omegapharm you have received.

Ask your doctor to answer any questions you may have.

Tell your doctor or nurse if you notice any of the following and they worry you.

- fever, loss of appetite, nausea, vomiting, diarrhoea
- headache, blurred vision, confusion, tiredness,
- irregular heart beat (palpitations), fatigue
- oedema, pain, swelling
- When administered into the bladder, side effects may include irritation of the bladder, change in the frequency of urination, itchy rash on the hands and genital area, bladder damage, skin damage to the genital area.

Tell your doctor or nurse as soon as possible if you notice any of the following;

- tiredness, headaches, shortness of breath when exercising, dizziness, looking pale, fast heart rate
- infection; fever, chills, sore throat, bruising easily, bleeding

longer than usual after minor cuts or scrapes, bleeding gums or nose bleeds, rash of small reddish-purple spots on your skin, blood in your stool, urine or vomit

- passing little or no urine, drowsiness, nausea, vomiting, poor appetite, headache, weakness, fever, diarrhoea, irritable
- nausea, vomiting, diarrhoea, abdominal pain, loss of appetite with yellowing of the skin and eyes, bleeding, fatigue, weakness, or confusion
- burning, stinging, pain, redness or swelling at the injection site
- Fatigue, fluid on the ankles or abdomen, shortness of breath, dry or moist cough

These are serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately, or go to accident and emergency at your nearest hospital if you notice any of the following signs of a sudden life-threatening allergic reaction:

- chills, fever, fast heart beat, wheezing or coughing, difficulty breathing, dizziness, flushing, sweating and swelling of the face, tongue or other parts of the body.

Tell your doctor if you notice any of these effects, or if you experience any other effects while being given Mitomycin Omegapharm.

Before being given to you Mitomycin Omegapharm will be dissolved in sterile water and added to an intravenous fluid. For intravesical administration, Mitomycin Omegapharm will also be dissolved in sterile water.

Sponsored by:

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AUSTRALIA

Registration Numbers:

Mitomycin Omegapharm 2 mg
AUST R 243552

Mitomycin Omegapharm 10 mg
AUST R 243553

Mitomycin Omegapharm 20 mg
AUST R 243554

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What is in Mitomycin Omegapharm

The active ingredient in Mitomycin Omegapharm is mitomycin.

Each vial contains 2 mg, 10 mg, or 20 mg mitomycin.

The In-active ingredient in Mitomycin Omegapharm is mannitol.