

Mitocin

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 have I been given Mitocin?

Mitocin contains the active ingredient mitomycin. Mitocin is used to treat advanced cancers. Mitocin is used to prevent recurrent bladder cancer. For more information, see Section [1. Why have I been given Mitocin?](#) in the full CMI.

2. What should I know before I am given Mitocin?

Do not receive Mitocin if you have ever had an allergic reaction to mitomycin or any of the ingredients listed at the end of the CMI. Do not receive Mitocin if you have an acute infection, low white or red blood cell counts or platelet counts, any condition or any blood disorder which causes you to bleed very easily, or you are breastfeeding. Do not receive Mitocin in the bladder if you have a perforated bladder.

Talk to your doctor if you have any other medical conditions, take any other medicines, you are pregnant or plan to become pregnant or are breastfeeding, you are a woman of childbearing potential or a man capable of fathering children, or you are elderly.

For more information, see Section [2. What should I know before I am given Mitocin?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Mitocin and affect how it works. See Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How Mitocin is given?

- Mitocin is given to you in hospital as an injection into your vein or directly into the bladder. It will always be given by a doctor or a nurse.
- The amount (dose) you will be given depends on a variety of factors including your size, the type of cancer and any other chemotherapy you are receiving. Your doctor will work out the right dose for you and how often you should be given Mitocin.

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

5. What should I know while being given Mitocin?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you have been given Mitocin.• Be sure to keep all your doctor's appointments.• Tell your doctor if you become pregnant or intend to become pregnant while being treated with Mitocin.• Talk to your doctor if you intend to father a child during treatment or 6 months after treatment.• Take precautions to reduce your risk of infection or bleeding.
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For more information, see Section [5. What should I know while being given Mitocin?](#) in the full CMI.

6. Are there any side effects?

Common side effects include, nausea, vomiting, rash, cough, difficulty breathing, shortness of breath. Serious side effects include allergic reactions with symptoms such as, swelling of the face, tongue or other parts of the body, problems with breathing, coughing, dizziness, flushing and sweating. Other serious side effects include problems with bleeding such as, bruising easily and bleeding longer than usual; fever, confusion, fast heartbeat, and rapid breathing associated with infection. 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.

Mitocin

Active ingredient: *mitomycin*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why have I been given Mitocin?

Mitocin contains the active ingredient mitomycin.

Mitomycin is an anticancer agent.

Mitocin is used to treat cancer of the stomach, pancreas, colon, lung (non-small cell), breast, cervix, head and neck, liver and bladder. It works by stopping cancer cells from growing.

2. What should I know before I am given Mitocin?

Warnings

Do not receive Mitocin if:

- you are allergic to mitomycin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Do not receive Mitocin intravenously if:

- you are breastfeeding.
- you have low red or white blood cell counts.
- you have low platelet counts.
- you have an acute infection.
- you have any condition or any blood disorder which causes you to bleed very easily.

Do not receive Mitocin in the bladder (intravesically) if:

- you have perforation (hole) of the bladder.

Check with your doctor if you:

- have any other medical conditions including those listed below:
 - 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 a problem with your kidneys.
 - you have a problem with your liver.
 - you have a problem with your lungs.
 - your general state of health is poor.
 - you have inflammation of the bladder, and you are receiving Mitocin in the bladder.
 - you are undergoing radiotherapy.
- take any medicines for any other condition.

Before you start treatment, your doctor may arrange kidney, liver, lung, and blood tests. Be sure to keep your appointments.

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. Mitocin should not be used during breastfeeding. Breast-feeding must be discontinued before you start to use Mitocin.

3. What if I am taking other medicines?

Tell your doctor 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.

Check with your doctor if you are not sure about what medicines, vitamins or supplements you are taking and if these affects or are affected by Mitocin.

4. How Mitocin is given?

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

How much is given

- The amount (dose) you will be given is worked out by your doctor. It is based on a variety of factors including, your size, the type of cancer, and any other chemotherapy you are receiving. The dose worked out for you may be different to the dose for another patient.

How it is given

- Mitocin 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.
- Mitocin 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.

If you are given too much Mitocin

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

If you think that you have been given too much Mitocin, 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 being given Mitocin?

Things you should do

- Be sure to keep all your doctor's appointments so your progress can be checked. You will require blood tests to see how Mitocin is affecting your blood, particularly your white blood cell and platelet counts, or if it is affecting any organs such as your kidneys. If the numbers of white cells or platelets in your blood are significantly reduced, your doctor may reduce the amount of Mitocin you are given or may stop treatment until the numbers of white cells and/or platelets increase. Mitocin can affect your white cell count for up to 8 weeks after you received your Mitocin.
- Due to the effect on your blood cells, the following precautions should be taken to reduce your risk of 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.
- If you intend to breastfeed while being treated with Mitocin, tell your doctor.
 - If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given Mitocin.

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

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

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

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

If you become pregnant or intend to become pregnant while being treated with Mitocin, tell your doctor.

Remind any doctor, dentist or pharmacist you visit that you have been given Mitocin.

Driving or using machines

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

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

Make sure you know how you react to Mitocin 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.

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 nurse if you have any further questions about 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 Mitocin you have received.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • Nausea and vomiting • Fever • Anorexia (loss of appetite) • Diarrhoea • Mouth or gum sores <p>Skin-related</p> <ul style="list-style-type: none"> • Alopecia (loss of hair) • Rash <p>Bladder-related</p> <p>When administered into the bladder, side effects may include:</p> <ul style="list-style-type: none"> • 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 • Burning, tingling, or stinging when urinating • Blood in the urine 	<p>Speak to your doctor or nurse 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"> • Shortness of breath, cough, difficulty breathing • tiredness, headaches, shortness of breath when, dizziness, looking pale, fast heart rate • passing little or no urine, drowsiness, poor appetite, weakness, fever, irritable • nausea, vomiting, diarrhoea, abdominal pain, loss of appetite with yellowing of the skin and eyes, bleeding, fatigue, weakness, or confusion • Fatigue, fluid on the ankles or abdomen, dizziness <p>Infection-related</p> <ul style="list-style-type: none"> • Infection, • fever • chills • dizziness • sore throat <p>Bleeding-related</p> <ul style="list-style-type: none"> • bruising easily • bleeding longer than usual after minor cuts or scrapes 	<p>Speak to your doctor or nurse as soon as possible if you have any of these serious side effects. You may need urgent medical attention or hospitalisation.</p>

<ul style="list-style-type: none"> • bleeding gums or nose bleeds • bleeding longer than usual after minor cuts or scrapes • blood in your stool, urine, or vomit <p>Injection site</p> <ul style="list-style-type: none"> • burning, stinging, pain, tenderness, redness or swelling at the injection site • rash of small reddish-purple spots on your skin 	
<p>Allergic reaction:</p> <ul style="list-style-type: none"> • chills, fever, fast heartbeat, wheezing or coughing, difficulty breathing, dizziness, flushing, sweating, and swelling of the face, tongue or other parts of the body. <p>Infection-related:</p> <ul style="list-style-type: none"> • fever, confusion, fast heartbeat, rapid breathing 	<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>

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

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 Mitocin contains

Active ingredient (main ingredient)	Each vial contains 20 mg of mitomycin
Other ingredients (inactive ingredients)	Each vial contains 40 mg of mannitol
Potential allergens	mitomycin

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

Before being given to you Mitocin will be dissolved in sterile water and added to an intravenous fluid.

For intravesical administration, Mitocin will be dissolved in sterile water or a sterile saline solution.

What Mitocin looks like

Mitocin is a blue-violet powder in a vial (Aust R 370360).

Who distributes Mitocin

Echo Therapeutics Pty Ltd
1-2 Kochia Lane
Lindfield NSW 2070

This leaflet was prepared in 25 July 2022.