

Mycamine®

Micafungin (as sodium)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Mycamine.

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 you having Mycamine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Mycamine is used for

This medicine is used to treat:

- adults, adolescents and children who have a serious fungal infection called invasive candidiasis (an infection caused by a yeast called Candida that has penetrated the body)
- adults and adolescents 16 years of age and above who have a fungal infection in the food pipe (oesophagus) where treatment into a vein is appropriate
- adults, adolescents and children who are at risk of developing a Candida (yeast) infection while undergoing a certain type of stem cell transplant or if you are expected to have white blood cell counts below a certain level.

This medicine belongs to a group of medicines called echinocandins

which are used to treat infections caused by fungal or yeast cells called Candida.

It works by interfering with the production of a part of the fungal cell wall making the fungus unable to live and grow.

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.

Before you are given Mycamine

When you must not have it

Do not have Mycamine if you have an allergy to:

- any medicine containing micafungin
- any of the ingredients listed at the end of this leaflet
- any other medicines belonging to the echinocandin group.

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

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

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

Before you start to take it

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:

- haemolytic anaemia (anaemia due to breakdown of red blood cells) or haemolysis (breakdown of red blood cells)
- kidney problems such as kidney failure or an abnormal kidney function test
- liver problems such as liver failure, hepatitis or abnormal liver function tests.

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

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start receiving Mycamine.

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 Mycamine may interfere with each other. These include:

- itraconazole, medicines used to treat fungal infections
- sirolimus, a medicine used to prevent kidney transplant rejection
- nifedipine, a medicine used to treat high blood pressure.

These medicines may be affected by Mycamine. You may need different amounts of these 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 receiving this medicine.

How Mycamine is given

This medicine must be prepared and given to you in the hospital by a nurse or another health care professional.

How much you will be given

Your doctor will decide how much Mycamine you will receive each day.

For adults, adolescents 16 years of age and above and elderly:

- the usual dose to treat an invasive Candida infection is 100 mg per day for patients weighing more than 40 kg, and 2 mg/kg per day for patients weighing 40 kg or less
- the dose to treat a Candida infection of the oesophagus is 150 mg for patients weighing more than 40 kg and 3 mg/kg per day for patients weighing 40 kg or less
- the usual dose for patients at risk of developing a Candida infection is 50 mg per day for patients weighing more than 40 kg and 1 mg/kg per day for patients weighing 40 kg or less.

For children and adolescents above 4 months of age and under 16 years of age:

- the usual dose to treat an invasive Candida infection is 100 mg per day for patients weighing more than 40 kg, and 2 mg/kg per day for patients weighing 40 kg or less

- the usual dose for patients at risk of developing a Candida infection is 50 mg per day for patients weighing more than 40 kg and 1 mg/kg per day for patients weighing 40 kg or less.

For children and newborns under 4 months of age:

- The usual dose to treat an invasive Candida infection is 4 to 10 mg/kg per day.
- The usual dose to prevent invasive Candida infections is 2 mg/kg per day.

When it will be given

This medicine is given once daily by a slow infusion into a vein. The infusion usually lasts one hour.

How long will you be given it

For the treatment of an invasive Candida infection, you will usually receive this medicine for at least 14 days but treatment will usually continue for at least one week after symptoms and blood results show the infection has been cleared.

For a Candida infection of the oesophagus, treatment will usually continue for at least one week after symptoms have disappeared.

For the prevention of Candida infection, treatment will usually continue for at least one week after white blood cell numbers are back to normal.

If you miss a dose

Your doctor monitors your response and condition to determine how long treatment is needed. However, if you are concerned that you may have missed a dose, speak to your doctor or another health care professional immediately.

If you are given too much (overdose)

Your doctor monitors your response and condition to determine what dose is needed. However, if you are concerned that you may have been

given too much Mycamine, speak to your doctor or another health care professional immediately.

While you are receiving Mycamine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are receiving Mycamine.

Tell any other doctors, dentists, and pharmacists who treat you that you are having this medicine.

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

It may affect other medicines used during surgery.

If you become pregnant while receiving this medicine, tell your doctor immediately.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving Mycamine.

This medicine helps most people with prevention or treatment of fungal infections but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the 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:

- Diarrhoea
- Nausea or vomiting

- Constipation
- Fever or high temperature
- Headache
- Stomach pain or discomfort
- Indigestion
- Tiredness
- Loss of appetite
- Joint or back pain
- Difficulty sleeping
- Cough

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

- Swelling of the hands, ankles or feet
- Shortness of breath or difficulty breathing
- Rash, itchiness or hives
- Fast heartbeat or changes in the way the heart beats
- Difficulty passing urine
- Yellowing of the skin or eyes

The above list includes serious side effects that may require medical attention.

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

Other side effects not listed above may also occur in some people.

Some of these side effects (for example, changes in blood test results or blood pressure) can only be found when your doctor does tests from time to time to check your progress.

After receiving Mycamine

Storage

Unopened vials should be kept in a cool dry place where the temperature stays below 25°C.

The prepared infusion solution should be used immediately and kept protected from light. If the infusion solution appears cloudy, it should not be used.

Product description

What it looks like

Mycamine 50 mg is a white coloured powder for injection contained within a glass vial with a rubber stopper, blue flip off cap and UV protective shrink wrapping film.

Mycamine 100 mg is a white coloured powder for injection contained within a glass vial with a rubber stopper, red flip off cap and UV protective shrink wrapping film.

Both strengths are available as packs of 1 vial.

Ingredients

Mycamine contains 50 mg or 100 mg of micafungin (as sodium) as the active ingredient.

Each vial also contains:

- lactose monohydrate
- citric acid
- sodium hydroxide.

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

Supplier

Mycamine is supplied in Australia by:

Astellas Pharma Australia Pty Ltd
6 Eden Park Drive
Macquarie Park NSW 2113

Medical Information: 1800 751 755

® = Registered Trademark

Australian registration numbers:

50 mg - AUST R 196108

100 mg - AUST R 196109

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