

# Mycamine®

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## 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.

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### 1. Why am I using MYCAMINE?

Mycamine contains the active ingredient micafungin (as sodium). Mycamine is used to treat a number of different conditions and illnesses (see Section [1. Why am I using MYCAMINE?](#) in the CMI for full detail). The most common uses are to treat a serious fungal infection called invasive candidiasis; fungal infection in the food pipe (oesophagus); 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.

### 2. What should I know before I use MYCAMINE?

Do not use if you have ever had an allergic reaction to Mycamine or any of the ingredients listed at the end of the CMI.

There are a number of circumstances in which a person should not use this medicine or may need to use caution. It is important to understand if these apply to you before taking Mycamine (see Section [2. What should I know before I use MYCAMINE?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with MYCAMINE 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 do I use MYCAMINE?

Mycamine must be prepared and given to you by a nurse or another health care professional. Your doctor will decide how much Mycamine you will receive each day.

More instructions can be found in Section [4. How do I use MYCAMINE?](#) in the full CMI.

### 5. What should I know while using MYCAMINE?

| <b>Things you should do</b> |   |
|-----------------------------|---|
|                             | <ul style="list-style-type: none"><li>• If you are about to be started on any new medicine, remind your doctor and pharmacist</li></ul> |

|                                    |   |
|------------------------------------|---|
|                                    | <p>that you are receiving Mycamine.</p> <ul style="list-style-type: none"> <li>• Tell any other doctors, dentists, and pharmacists who treat you that you are having this medicine.</li> <li>• 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.</li> <li>• If you become pregnant while receiving this medicine, tell your doctor immediately.</li> </ul> |
| <b>Driving or using machines</b>   | <ul style="list-style-type: none"> <li>• Mycamine is unlikely to have an effect on driving or using machines. Be careful when driving or operating machinery until you know how Mycamine affects you.</li> </ul>  |
| <b>Drinking alcohol</b>            | <ul style="list-style-type: none"> <li>• Tell your doctor if you drink alcohol.</li> </ul>  |
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"> <li>• Unopened vials should be kept in a cool dry place where the</li> </ul>   |

|  |                               |
|--|-------------------------------|
|  | temperature stays below 25°C. |
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For more information, see Section [5. What should I know while using MYCAMINE?](#) in the full CMI.

## **6. Are there any side effects?**

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). Some serious side effects may include swelling of the hands, ankles or feet; shortness of breath or difficulty in breathing; rash, itchiness or hives; fast heartbeat or irregular heartbeat; passing smaller amount of urine; yellowing of the skin or eyes.

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.

# Mycamine®

**Active ingredient(s):** *Micafungin (as sodium)*

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## **Consumer Medicine Information (CMI)**

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.

### **Where to find information in this leaflet:**

- [1. Why am I using MYCAMINE?](#)
- [2. What should I know before I use MYCAMINE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use MYCAMINE?](#)
- [5. What should I know while using MYCAMINE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

# 1. Why am I using MYCAMINE?

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.

## **2. What should I know before I use MYCAMINE?**

### **Warnings**

**Do not use 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.**

**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:**

**Check with 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.

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**

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

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.**

### **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 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.

### **4. How do I use MYCAMINE?**

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.

## **When Mycamine 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 Mycamine**

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 of Mycamine**

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 Mycamine (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.

## **5. What should I know while using MYCAMINE?**

### **Things you should 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.**

### **Driving or using machines**

Mycamine is unlikely to have an effect on driving or using machines. Be careful when driving or operating machinery until you know how Mycamine affects you.

## **Drinking alcohol**

Tell your doctor if you drink alcohol.

## **Looking after your medicine**

- 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.

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **6. Are there any 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.**

### **Less serious side effects**

| <b>Less serious side effects</b>  | <b>What to do</b>   |
|---|---|
| <ul style="list-style-type: none"><li>● Diarrhoea</li><li>● Nausea or vomiting</li><li>● Constipation</li><li>● Fever or high temperature</li><li>● Headache</li><li>● Stomach pain or discomfort</li><li>● Indigestion</li><li>● Tiredness</li><li>● Loss of appetite</li><li>● Joint or back pain</li><li>● Difficulty sleeping</li><li>● Cough</li></ul> | <p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> |

## Serious side effects

| Serious side effects   | What to do  |
|--|---|
| <ul style="list-style-type: none"><li>• Swelling of the hands, ankles or feet</li><li>• Shortness of breath or difficulty breathing</li><li>• Rash, itchiness or hives</li><li>• Fast heartbeat or changes in the way the heart beats</li><li>• Difficulty passing urine</li><li>• Yellowing of the skin or eyes</li></ul> | <b>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.</b> |

**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 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.

## 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](http://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 MYCAMINE contains

|   |   |
|---|---|
| <b>Active ingredient<br/>(main ingredient)</b>      | Mycamine contains 50 mg or 100 mg of micafungin (as sodium) as the active ingredient.   |
| <b>Other ingredients<br/>(inactive ingredients)</b> | Each vial also contains: <ul style="list-style-type: none"><li>• lactose monohydrate</li><li>• citric acid</li><li>• sodium hydroxide.</li></ul> This medicine does not contain, sucrose, gluten, tartrazine or any other azo dyes. |

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

## **What MYCAMINE looks like**

Mycamine 50 mg (AUST R 196108) 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 (AUST R 196109) 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.

## **Who distributes MYCAMINE**

Mycamine is supplied in Australia by:

Astellas Pharma Australia Pty Ltd

Suite 2.01, 2 Banfield Road

Macquarie Park NSW 2113

Medical Information:

1800 751 755

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