Package leaflet: Information for the user

Mycamine 50 mg powder for solution for infusion
Mycamine 100 mg powder for solution for infusion

micafungin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Mycamine is and what it is used for

Mycamine contains the active substance micafungin. Mycamine is called an antifungal medicine because it is used to treat infections caused by fungal cells.
Mycamine is used to treat fungal infections caused by fungal or yeast cells called Candida. Mycamine is effective in treating systemic infections (those that have penetrated within the body). It interferes with the production of a part of the fungal cell wall. An intact cell wall is necessary for the fungus to continue living and growing. Mycamine causes defects in the fungal cell wall, making the fungus unable to live and grow.

Your doctor has prescribed Mycamine for you in the following circumstances when there are no other suitable antifungal treatments available (see section 2):

- To treat adults, adolescents and children including neonates who have a serious fungal infection called invasive candidiasis (infection that has penetrated the body).
- To treat adults and adolescents ≥ 16 years of age who have a fungal infection in the gullet (oesophagus) where treatment into a vein (intravenous) is appropriate.
- To prevent infection with Candida in patients who are having a bone-marrow transplant or who are expected to have a neutropenia (low levels of neutrophils, a type of white blood cell) for 10 days or more.

2. What you need to know before you use Mycamine

Do not use Mycamine
- if you are allergic to micafungin, other echinocandins (Ecalta or Cancidas) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

In rats, long-term treatment with micafungin led to liver damage and subsequent liver tumours. The potential risk of developing liver tumours in humans is not known, and your doctor will assess the benefits and risks of Mycamine treatment before starting your medicine. Please tell your doctor if you have severe liver problems (e.g. liver failure or hepatitis) or have had abnormal liver function tests. During treatment your liver functions will be monitored more closely.

Talk to your doctor or pharmacist before using Mycamine
- if you are allergic to any medicine
- if you have haemolytic anaemia (anaemia due to breakdown of red blood cells) or haemolysis (breakdown of red blood cells).
- if you have kidney problems (e.g. kidney failure and abnormal kidney function test). If this happens, your doctor may decide to monitor your kidney function more closely.

Micafungin may also cause severe inflammation/eruption of the skin and mucous membranes (Stevens-Johnson syndrome, toxic epidermal necrolysis).

Other medicines and Mycamine
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is especially important to inform your doctor if you are using amphotericin B desoxycholate or itraconazole (antifungal antibiotics), sirolimus (an immunosuppressant) or nifedipine (calcium channel blocker used to treat high blood pressure). Your doctor may decide to adjust the dose of these medicines.

Mycamine with food and drink
As Mycamine is given intravenously (into a vein), no restrictions on food or drink are required.

Pregnancy and breast-feeding
If you are pregnant of breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Mycamine should not be used during pregnancy unless clearly necessary. If you use Mycamine you should not breast-feed.

Driving and using machines
Micafungin is unlikely to have an effect on driving or using machines. However some people may feel dizzy when taking this medicine and if this happens to you, do not drive or use any tools or machines. Please inform your doctor if you experience any effects that may cause you to have problems with driving or using other machinery.

3. How to use Mycamine

Mycamine must be prepared and given to you by a doctor or another healthcare professional.
Mycamine should be administered once daily by slow intravenous (into a vein) infusion. Your doctor will determine how much Mycamine you will receive each day.

Use in adults, adolescents ≥ 16 years of age and elderly
- The usual dose to treat an invasive Candida infection is 100 mg per day for patients weighing 40 kg or more 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 to prevent invasive Candida infections 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.

Use in children > 4 months of age and adolescents < 16 years of age
- The usual dose to treat an invasive Candida infection is 100 mg per day for patients weighing 40 kg or more and 2 mg/kg per day for patients weighing 40 kg or less.
- The usual dose to prevent invasive Candida infections 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.

Use in children and newborns < 4 months of age

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

If you receive more Mycamine than you should
Your doctor monitors your response and condition to determine what dose of Mycamine is needed. However, if you are concerned that you may have been given too much Mycamine, speak to your doctor or another healthcare professional immediately.

If you miss a dose of Mycamine
Your doctor monitors your response and condition to determine what Mycamine treatment is needed. However, if you are concerned that you may have missed a dose, speak to your doctor or another healthcare professional immediately.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience an allergic attack, or a severe skin reaction (e.g. blistering and peeling of the skin), you must inform your doctor or nurse immediately

Mycamine may cause the following other side effects:

Common (may affect up to 1 in 10 people)
- abnormal blood tests (decreased white blood cells [leucopenia; neutropenia]); decreased red blood cells (anaemia)
- decreased potassium in the blood (hypokalaemia); decreased magnesium in the blood (hypomagnesaemia); decreased calcium in the blood (hypocalcaemia)
- headache
- inflammation of the vein wall (at injection-site)
- nausea (feeling sick); vomiting (being sick); diarrhoea; abdominal pain
- abnormal liver function tests (increased alkaline phosphatase; increased aspartate aminotransferase, increased alanine aminotransferase)
- increased bile pigment in the blood (hyperbilirubinaemia)
- rash
- fever
- rigors (shivering)

Uncommon (may affect up to 1 in 100 people)
- abnormal blood tests (decreased blood cells [pancytopenia]); decreased blood platelets (thrombocytopenia); increases in a certain type of white blood cells called eosinophils; decreased albumin in the blood (hypoalbuminaemia)
- hypersensitivity
- increased sweating
- decreased sodium in the blood (hyponatraemia); increased potassium in the blood (hyperkalaemia); decreased phosphates in the blood (hypophosphataemia); anorexia (eating disorder)
- insomnia (difficulty in sleeping); anxiety; confusion
- feeling lethargic (somnolence); trembling; dizziness; disturbed taste
- increased heart rate; stronger heartbeat; irregular heartbeat
- high or low blood pressure; skin flushing
- shortness of breath
- indigestion; constipation

- liver failure; increased liver enzymes (gamma-glutamyltransferase); jaundice (yellowing of the skin or whites of the eyes caused by liver or blood problems); reduced bile reaching the intestine (cholestasis); enlarged liver; liver inflammation
- itchy rash (urticaria); itching; skin flushing (erythema)
- abnormal kidney function tests (increased blood creatinine; increased urea in the blood); aggravated kidney failure
- increase in an enzyme called lactate dehydrogenase
- clotting in vein at injection-site; inflammation at injection-site; pain at injection-site; collection of fluid in your body

Rare (may affect up to 1 in 1,000 people)
- anaemia due to breakdown of red blood cells (haemolytic anaemia), breakdown of red blood cells (haemolysis)

Not known (frequency cannot be estimated from the available data)
- disorder of blood clotting system
- shock
- damage to liver cells including death
- kidney problems; acute kidney failure

Additional side effects in children and adolescents
The following reactions have been reported more often in paediatric patients than in adult patients:
Common (may affect up to 1 in 10 people)
- decreased blood platelets (thrombocytopenia)
- increased heart rate (tachycardia)
- high or low blood pressure
- increased bile pigment in the blood (hyperbilirubinaemia); enlarged liver
- acute kidney failure; increased urea in the blood

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.
United Kingdom
Yellow Card Scheme
www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

5. How to store Mycamine

Keep this medicine out of the sight and reach of children.

Do not use Mycamine after the expiry date which is stated on the vial and on the carton. The expiry date refers to the last day of that month.

The unopened vial does not require any special storage conditions.

The reconstituted concentrate and the diluted infusion solution should be used immediately, because it does not contain any preservatives to prevent bacterial contamination. Only a trained healthcare professional who has read the complete directions properly can prepare this medicine for use.

Do not use the diluted infusion solution if it is cloudy or precipitated.

In order to protect the infusion bottle / bag containing the diluted infusion solution from light it should be inserted into a closable opaque bag.

The vial is for single use only. Therefore, please discard unused reconstituted concentrate immediately.

6. Contents of the pack and other information

What Mycamine contains

- The active substance is micafungin (as sodium).
  1 vial contains 50 mg or 100 mg micafungin (as sodium).
- The other ingredients are lactose monohydrate, citric acid anhydrous and sodium hydroxide.

What Mycamine looks like and contents of the pack

Mycamine 50 mg or 100 mg powder for solution for infusion is a white compact freeze-dried powder.
Mycamine is supplied in a box containing 1 vial.

Marketing Authorisation Holder
Astellas Pharma Europe B.V.
Sylviusweg 62
2333 BE Leiden
Netherlands

Manufacturer
Astellas Ireland Co., Ltd.
Killorglin, County Kerry
Ireland

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

Ireland
Astellas Pharma Co. Ltd.
Tel: +353 (0)1 4671555

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Tel: +44 (0) 203 3798700

This leaflet was last approved in February 2018.

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu/.

The following information is intended for medical or healthcare professionals only:

Mycamine must not be mixed or co-infused with other medicinal products except those mentioned below. Using aseptic techniques at room temperature, Mycamine is reconstituted and diluted as follows:

1. The plastic cap must be removed from the vial and the stopper disinfected with alcohol.
2. Five ml of sodium chloride 9 mg/ml (0.9%) solution for infusion or glucose 50 mg/ml (5%) solution for infusion (taken from a 100 ml bottle/bag) should be aseptically and slowly injected into each vial along the side of the inner wall. Although the concentrate will foam, every effort should be made to minimise the amount of foam generated. A sufficient number of vials of Mycamine must be reconstituted to obtain the required dose in mg (see table below).
3. The vial should be rotated gently. DO NOT SHAKE. The powder will dissolve completely. The concentrate should be used immediately. The vial is for single use only. Therefore, unused reconstituted concentrate must be discarded immediately.
4. All of the reconstituted concentrate should be withdrawn from each vial and returned into the infusion bottle/bag from which it was originally taken. The diluted infusion solution should be used immediately. Chemical and physical in-use stability have been demonstrated for 96 hours at 25°C when protected from light and diluted as described above.
5. The infusion bottle/bag should be gently inverted to disperse the diluted solution but NOT agitated in order to avoid foaming. The solution must not be used if it is cloudy or has precipitated.
6. The infusion bottle/bag containing the diluted infusion solution should be inserted into a closable opaque bag for protection from light.

Preparation of the solution for infusion

Dose (mg)	**Mycamine vial to be used (mg/vial)**	**Volume of sodium chloride (0.9%) or glucose (5%) to be added per vial**	**Volume (concentration) of reconstituted powder**	**Standard infusion (added up to 100 ml) Final concentration**
50	1 x 50	5 ml	approx. 5 ml (10 mg/ml)	0.5 mg/ml
100	1 x 100	5 ml	approx. 5 ml (20 mg/ml)	1.0 mg/ml
150	1 x 100 + 1 x 50	5 ml	approx. 10 ml	1.5 mg/ml
200	2 x 100	5 ml	approx. 10 ml	2.0 mg/ml