MYCAMINE® for Infusion 50 mg

(Micafungin sodium for injection)

ACTION

Micafungin is a new, broad spectrum antifungal agent originally developed by Fujisawa Pharmaceutical Co. Japan which belongs to the echinocandin class. It has a significant activity against Candida sp, and Aspergillus sp. the main causative fungi of deep seated mycosis. Micafungin exhibits potent in vitro activity against Candida sp. that are resistant to fluconazole or itraconazole. Micafungin is fungicidal against Candida sp. and inhibits germination and hyphal extension in Aspergillus sp. Micafungin also has potent protective or therapeutic effect against disseminated candidiasis, oral and esophageal candidiasis, disseminated aspergillosis and pulmonary aspergillosis.

Mechanism of action: Micafungin non-competitively inhibits biosynthesis of 1, 3 ß-D-glucan which is an essential component of fungal cell walls.

INDICATIONS

Mycamine is indicated for the treatment of the following infections caused by Aspergillus sp. and Candida sp.: Fungemia, respiratory mycosis, gastrointestinal mycosis.

DOSAGE AND ADMINISTRATION

Aspergillosis:

For adults, the usual single daily dose is 50 – 150 mg of Mycamine infused intravenously once daily. The dosage can be increased according to the patient's condition for severe or refractory aspergillosis up to 300 mg / day.

Candidiasis:

For adults, the usual single daily dose is 50 mg of Mycamine infused intravenously once daily. The dosage can be increased according to the patient's condition for severe or refractory candidiasis up to 300 mg /day.

CONTRAINDICATIONS

Mycamine is contraindicated in patients with a history of hypersensitivity to Micafungin or any of the ingredients of this product.

WARNINGS

Uses during Pregnancy, Delivery or Lactation:

- *Pregnancy:* The safety of Micafungin sodium in pregnant women has not been established. Micafungin sodium should be administered in pregnant women or women who may possibly be pregnant only if the expected therapeutic benefits outweigh the possible risks associated with treatment.
- *Lactating mothers:* In animal studies, micafungin sodium was found to be excreted in breast milk. Therefore, it is advisable to avoid using micafungin sodium in lactating mothers. If use of micafungin sodium is judged to be essential, breast feeding must be discontinued during treatment.

Pediatric Use

The safety of micafungin sodium in children has not been established.

Uses in the Elderly

Since elderly patients often have reduced physiological function, Mycamine dosage should be carefully determined and other appropriate measures should be considered.

PRECAUTIONS

• Micafungin sodium should be administered with care in the following patients:

1) Patients with a history of hypersensitivity to drugs
2) Patients with hepatic impairment (Administration of micafungin sodium may aggravate hepatic impairment.)

• Important Precautions:

1) Hepatic function disorder or jaundice may develop in patients receiving Micafungin sodium. See "Other Clinically Significant Adverse Reactions".
   Additionally, hepatic lesions were noted in the high dose treatment group in animal studies. Patients should be carefully monitored by conducting liver function tests, etc.
2) When it becomes clear that the causative organism is not Aspergillus sp. or candida sp., or when efficacy is not obtained by administration of Mycamine, appropriate measures such as converting to other products should be taken.
3) As the safety of this product in increased doses up to 300 mg (potency) daily for severe or refractory infections has not been fully established, the product at these dose levels should be administered with caution such as close observation of the patients condition (there are no clinical experiences at doses exceeding 150 mg (potency) daily.
4) For patients who weigh 50 kg or less, the dosage should not exceed 6 mg (potency)/kg body weight daily.

PRECAUTIONS Concerning Use

Precaution in preparation: Do not shake the infusion bag strongly to dissolve Mycamine because it foams easily and the bubbles do no disappear easily.

Precaution during administration: Keep Mycamine away from direct sunlight since micafungin sodium is gradually decomposed by light. When it takes more than 6 hours from preparation to the end of infusion, protect the infusion bag from light. On the other hand, it is not necessary to protect the infusion tube from light.

Incompatibility: Precipitation may occur when micafungin sodium is dissolved concomitantly with other drugs. Further, micafungin sodium is unstable in basic solution, where potency of micafungin sodium may decrease.
The main drugs that cause precipitation immediately after combination with micafungin sodium are: Vancomycin hydrochloride, arbekacin sulfate, gentamicin sulfate, tobramycin, dibekacin sulfate, minocycline hydrochloride, ciprofloxacin, pazufloxacin mesilate, cimetidine, dobutamine hydrochloride, doxapram hydrochloride, pentazocine, nafamostat mesilate, gabexate mesilate, thiamine disulfide/ pyridoxine hydrochloride/hydroxocobalamin acetate, menatetrenone, freeze-dried pepsin treated human normal immunoglobulin, doxorubicin hydrochloride.
The main drugs, which reduce potency of micafungin sodium immediately after combination are: Ampicillin, sulfamethoxazole/trimethoprim, acyclovir, ganciclovir, acetazolamide.

Drug Interactions
Micafungin does not interact with major cytochrome P450 isozymes.
There are no known drug interactions for Micafungin.

SIDE EFFECTS

• Clinically significant adverse reactions
Hematologic disorder: Neutropenia (incidence 1.5%), thrombocytopenia or hemolytic anemia (incidence unknown) may occur. Patients should be carefully monitored by periodic examination, etc. and appropriate measures such as discontinuation of treatment should be taken if such abnormalities are observed.
Shock, anaphylactoid reactions: Shock or anaphylactoid reactions (incidence unknown) may occur. Patients should be carefully monitored and if abnormalities such as decreased blood pressure, oral cavity discomfort, dyspnea, generalized flushing, angioedema, or urticaria, etc. are observed, this product should be discontinued, and if necessary, appropriate measures
such as maintenance of the airway or administration of adrenaline, steroids or antihistamines, etc. should be taken.
Hepatic function disorder or jaundice: Hepatic function disorder with increased AST (GOT), ALT (GPT), gamma GT or ALP, etc., or jaundice may occur (incidence unknown). Patients should be carefully monitored by periodic examination, etc. and appropriate measures such as discontinuation of treatment should be taken if such abnormalities are observed.
Acute renal failure: Serious renal disorder such as acute renal failure may occur (incidence unknown). Patients should be carefully monitored by periodic examination, etc. and appropriate measures such as discontinuation of treatment should be taken if such abnormalities are observed.
Incidence unknown: incidence is not calculated because of spontaneous reports.

• Other adverse reactions

	≥ 5%	1% - < 5%
Hepatic	Increased AST (GOT), increased ALT (GPT), increased ALP	Bilirubinemia
Metabolic		Hypomagnesemia, hypocalcemia, hyperchloremia, hypokalemia, hypoproteinemia, hyponatrmia
Hematologic		leucopenia, thrombocytopenia, anemia, eosinophilia
Dermatologic		Rash
Cardiovascular		Vasodilation, Hypertension, palpitation
Gastrointestinal		Vomiting, nausea, diarrhea, anorexia, loose stools
Renal		Increased creatinine, Increased BUN
Others		Fever, abdominal pain, asthenia, chills, pain, phlebitis, headache, arthritis, Vascular pain, Rigors

Note: In case of occurrence of any serious adverse effects related to the use of this product, please contact Hikma Pharmaceuticals.

OVERDOSAGE

No cases of overdosage have been reported with the use of Micafungin sodium. There is no specific antidote. In cases of overdosage, symptomatic treatment measures should be initiated.

PRESENTATIONS

Vials
MYCAMINE 50: 50 mg (potency) of Micafungin sodium

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary instructions is dangerous.
- Follow the doctor's prescription strictly, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

astellas

Under License of
Astellas Toyama Co., Ltd. Japan

Manufactured by
HIKMA Pharmaceuticals, Amman - Jordan

HIKMA

Keep medicament out of the reach of children
2INMYCL-AEF-06/2007