

SIZE : 78MMX184MM

MICAWEMTM
Injection 50mg

(Micafungin Sodium) For Injection
INTRAVENOUS INFUSION (not for IV bolus injection)

DESCRIPTION MICAWEM

is a sterile, lyophilized product for intravenous (IV) infusion that contains micafungin sodium. Micafungin sodium is a semisynthetic lipopeptide (echinocandin) synthesized by a chemical modification of a fermentation product of *Coleophomaempetri* F-11899. Micafungin inhibits the synthesis of 1, 3- β -D-glucan, an integral component of the fungal cell wall. Each single-use vial contains 50 mg or 100 mg micafungin sodium, 200 mg lactose, with citric acid and/or sodium hydroxide (used for pH adjustment). MYCAMINE must be diluted with 0.9% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP (see DOSAGE AND ADMINISTRATION). Following reconstitution with 0.9% Sodium Chloride Injection, USP, the resulting pH of the solution is between 5.0-7.0

CLINICAL PHARMACOLOGY

Pharmacokinetics The pharmacokinetics of micafungin were determined in healthy subjects, hematopoietic stem cell transplant recipients, and patients with esophageal candidiasis up to a maximum daily dose of 8 mg/kg body weight. The relationship of area under the concentration-time curve (AUC) to micafungin dose was linear over the daily dose range of 50 mg to 150 mg and 3 mg/kg to 8 mg/kg body weight.

CONTRAINDICATIONS MICAWEM

is contraindicated in patients with hypersensitivity to any component of this product. **WARNINGS:** Isolated cases of serious hypersensitivity (anaphylaxis and anaphylactoid) reactions (including shock) have been reported in patients receiving MICAWEM. If these reactions occur, MICAWEM infusion should be discontinued and appropriate treatment administered.

OVERDOSAGE MICAWEM

is highly protein bound and, therefore, is not dialyzable. No cases of MICAWEM overdose have been reported. Repeated daily doses up to 8 mg/kg (maximum total dose of 896 mg) in adult patients have been administered in clinical trials with no reported dose-limiting toxicity. The minimum lethal dose of MICAWEM is 125 mg/kg in rats, equivalent to 8.1 times the recommended human clinical dose for esophageal candidiasis based on body surface area comparisons. **DOSAGE AND ADMINISTRATION** Do not mix or co-infuse MICAWEM with other medications. MICAWEM has been shown to precipitate when mixed directly with a number of other commonly used medications.

Reconstitution MICAWEM 50 mg vial

Aseptically add 5 mL of 0.9% Sodium Chloride Injection, (without a bacteriostatic agent) to each 50 mg vial to yield a preparation containing approximately 10 mg micafungin/mL

STORAGE OF MICAWEM

The reconstituted product may be stored in the original vial for up to 24 hours at room temperature, 25° C (77° F). The diluted infusion should be protected from light and may be stored for up to 24 hours at room temperature, 25° C (77° F).

Mfg. Lic. No. : NL-MNB/2022/446 & NL-MB/2022/447



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Good To Talk

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