

Abridged Prescribing Information

CASPERCID®

Caspofungin Acetate For Injection 50 / 70mg (Lyophilized)

COMPOSITION

CASPERCID® 50 / 70 : Each vial contains Caspofungin Acetate equivalent to Caspofungin 50 mg / 70mg

THERAPEUTIC INDICATIONS

CASPERCID® is indicated in adults and paediatric patients (3 months and older) for the following: Empirical therapy for presumed fungal infections in febrile, neutropenic patients; treatment of candidaemia and the following *Candida* infections - intra-abdominal abscesses, peritonitis and pleural space infections; treatment of oesophageal candidiasis; treatment of invasive aspergillosis in patients who are refractory to or intolerant of other therapies (e.g. amphotericin B, lipid formulations of amphotericin B, itraconazole). It has not been studied in endocarditis, osteomyelitis and meningitis due to *Candida* and as initial therapy for invasive aspergillosis.

DOSAGE AND ADMINISTRATION

CASPERCID® should be administered by slow I.V. infusion over approximately 1 hour. CASPERCID® should not be administered by I.V. bolus administration. Do not mix or co infuse with other medications. Do not use diluents containing dextrose.

Dosage in Adults [18 years of age and older] : Administer a single 70-mg loading dose on Day 1, followed by 50 mg once daily for all indications except esophageal candidiasis. For esophageal candidiasis, use 50 mg once daily with no loading dose.

Dosage in Pediatric Patients [3 months to 17 years of age] : Dosing should be based on the patient's body surface area. For all indications, administer a single 70-mg/m² loading dose on Day 1, followed by 50 mg/m² once daily thereafter. Maximum loading dose and daily maintenance dose should not exceed 70 mg, regardless of the patient's calculated dose.

Dosage Adjustments in Patients with Hepatic Impairment : Reduce dosage for adult patients with moderate hepatic impairment (35 mg once daily, with a 70 mg loading dose on Day 1 where appropriate).

Dosage Adjustment in Patients Receiving Concomitant Inducers of Hepatic CYP Enzymes : Use 70-mg once daily dose for adult patients on rifampin. Consider dose increase to 70 mg once daily for adult patients on nevirapine, efavirenz, carbamazepine, dexamethasone, or phenytoin. Pediatric patients receiving these same concomitant medications may also require an increase in dose to 70 mg/m² once daily (maximum daily dose not to exceed 70 mg).

SAFETY-RELATED INFORMATION

Contraindications: The drug is contraindicated in patients with known hypersensitivity to any component of this product.

Warnings and Precautions: *Hypersensitivity:* Anaphylaxis has been reported during administration of caspofungin. If this occurs, caspofungin should be discontinued and appropriate treatment administered. Possible histamine-mediated adverse reactions, including rash, facial swelling, angioedema, pruritus, sensation of warmth or bronchospasm and cases of Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported. This require discontinuation and/or administration of appropriate treatment. *Elevated Liver Enzymes During Concomitant use with cyclosporine* : Limit use to patients for whom potential benefit outweighs potential risk. Monitor patients who develop abnormal liver function tests (LFTs) during concomitant use with caspofungin. *Hepatic Effects:* Laboratory abnormalities in liver function tests have been seen in healthy volunteers and in adult and paediatric patients treated with caspofungin acetate. In some adult and paediatric patients with serious underlying conditions who were receiving multiple concomitant medications with caspofungin acetate, isolated cases of clinically significant hepatic dysfunction, hepatitis and hepatic failure have been reported. Monitor patients who develop abnormal liver enzymes for evidence of worsening hepatic function, and evaluate risk/benefit of continuing CASPERCID®.

Pregnancy and Lactation: CASPERCID® should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. Women receiving caspofungin should not breast-feed.

Adverse Reactions: *Adults:* Most common adverse reactions (incidence 10% or greater) are diarrhea, pyrexia, ALT/AST increased, blood alkaline phosphatase increased, and blood potassium decreased.

Pediatric patients: Most common adverse reactions (incidence ≥10%) are pyrexia, diarrhea, rash, ALT/AST increased, blood potassium decreased, hypotension, and chills.

For full prescribing information, please contact SANOFI INDIA LIMITED, Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai - 72.

Source:

- Prescribing Information of Caspogin Injection (Cipla) dated October 2013, published Sep 2014.
- US SmPC of Cancidas® (Merck Sharp & Dohme) dated March 2018 (Reference ID: 4233543) accessed on 11th April 2018

Updated: June 2018