

Name of Medicine

CANCIDAS®

casprofungin acetate

50 mg & 70 mg single dose vial for injection

Presentation

CANCIDAS is for intravenous use and comes in a 10mL vial with a grey butyl stopper and aluminium seal with a plastic flip off lid.

Each 10mL vial contains either 50mg or 70mg of casprofungin free base as a solid white to off white cake.

The reconstitution liquid is clear.

Therapeutic Class

CANCIDAS is a sterile, lyophilized product for intravenous infusion that contains a semi-synthetic lipopeptide (echinocandin) compound synthesised from a fermentation product of *Glarea lozoyensis*. CANCIDAS is the first of a new class of antifungal medicines (echinocandins) that inhibit the synthesis of β (1,3)-D-glucan, an integral component of the fungal cell wall.

Indication

CANCIDAS is indicated for :

- Empirical therapy for presumed fungal infections in febrile, neutropenic patients
- Treatment of Invasive Candidiasis, including candidaemia, in neutropaenic and non-neutropaenic patients
- Treatment of Oesophageal Candidiasis
- Treatment of Oropharyngeal Candidiasis
- Treatment of Invasive Aspergillosis in patients who are refractory to or intolerant of other therapies.

Dosage and Administration

General Recommendations

CANCIDAS should be administered by slow intravenous infusion over approximately 1 hour.

Empirical Therapy

A single 70 mg loading dose should be administered on Day 1, followed by 50 mg daily thereafter. Duration of treatment should be based on the patient's clinical response. Empirical therapy should be continued until resolution of neutropenia. Patients found to have a fungal infection should be treated for a minimum of 14 days; treatment should continue for at least 7 days after both neutropenia and clinical symptoms are resolved. If the 50 mg dose is well tolerated but does not provide an adequate clinical response, the daily dose can be increased

to 70 mg. Although an increase in efficacy with 70 mg daily has not been demonstrated, limited safety data suggest that an increase in dose to 70 mg daily is well tolerated.

Invasive Candidiasis

A single 70-mg loading dose should be administered on Day 1, followed by 50 mg daily thereafter. Duration of treatment of invasive candidiasis should be dictated by the patient's clinical and microbiological response. In general, antifungal therapy should continue for at least 14 days after the last positive culture. Patients who remain persistently neutropaenic may warrant a longer course of therapy pending resolution of the neutropenia.

Oesophageal and Oropharyngeal Candidiasis

Fifty (50) mg should be administered daily.

Invasive Aspergillosis

A single 70 mg loading dose should be administered on Day 1, followed by 50 mg daily thereafter. Duration of treatment should be based upon the severity of the patient's underlying disease, recovery from immunosuppression, and clinical response. Although there is no information to demonstrate an increase in efficacy with higher doses, available safety data suggest that an increase in dose to 70 mg daily may be considered in patients without evidence of clinical response in whom CANCIDAS has been well tolerated.

No dosage adjustment is necessary for elderly patients (65 years of age or more).

No dosage adjustment is necessary based on gender, race, or renal impairment.

When co-administering CANCIDAS with the metabolic inducers efavirenz, nevirapine, rifampin, dexamethasone, phenytoin, or carbamazepine, use of a daily dose of 70 mg of CANCIDAS should be considered.

Patients with Hepatic Insufficiency

Patients with mild hepatic insufficiency (Child-Pugh score 5 to 6) do not need a dosage adjustment. For patients with moderate hepatic insufficiency (Child-Pugh score 7 to 9), CANCIDAS 35 mg daily is recommended. However, where recommended, a 70 mg loading dose should still be administered on Day 1. There is no clinical experience in patients with severe hepatic insufficiency (Child-Pugh score greater than 9).

Reconstitution of CANCIDAS

DO NOT USE ANY DILUENTS CONTAINING DEXTROSE, as CANCIDAS is not stable in diluents containing dextrose. DO NOT MIX OR CO-INFUSE CANCIDAS WITH ANY OTHER MEDICATIONS, as there is no data available on the compatibility of CANCIDAS with other intravenous substances, additives, or medications. Visually inspect the infusion solution for particulate matter or discoloration.

Step 1 Reconstitution of conventional vials

To reconstitute the powdered medicine, bring the refrigerated conventional vial of CANCIDAS to room temperature and aseptically add 10.5 mL of either Sterile Water for Injection, Bacteriostatic Water for Injection with methylparaben and propylparaben, or Bacteriostatic

Water for Injection with 0.9% benzyl alcohol. The concentrations of the reconstituted vials will be: 7 mg/mL (70 mg vial) or 5 mg/mL (50 mg vial).

The white to off-white compact powder will dissolve completely. Mix gently until a clear solution is obtained. Reconstituted solutions should be visually inspected for particulate matter or discoloration. This reconstituted solution may be stored for up to 24 hours at or below 25°C (77°F).

Step 2 Addition of Reconstituted CANCIDAS to patient infusion solution

Diluents for the final patient infusion solutions are: Sterile Saline for Injection, or Lactated Ringer's Solution. The standard patient infusion is prepared by aseptically adding the appropriate amount of reconstituted medicine (as shown in the table below) to a 250 mL intravenous bag or bottle. Reduced volume infusions in 100 mL may be used, when medically necessary, for 50 mg or 35 mg daily doses. Do not use if the solution is cloudy or precipitated. This infusion solution must be used within 24 hours if stored at or below 25°C (77°F) or within 48 hours if stored refrigerated at 2° to 8°C (36°F to 46°F). CANCIDAS should be administered by slow intravenous infusion over approximately 1 hour.

PREPARATION OF THE PATIENT INFUSION SOLUTIONS

DOSE*	Volume of reconstituted CANCIDAS for transfer to intravenous bag or bottle	Typical preparation (reconstituted CANCIDAS added to 250 mL) final concentration	Reduced volume infusion (reconstituted CANCIDAS added to 100 mL) final concentration
70 mg	10 mL	0.27 mg/mL	not recommended
70 mg (from two 50 mg vials)**	14 mL	0.27 mg/mL	not recommended
50 mg	10 mL	0.19 mg/mL	0.45 mg/mL
35 mg for moderate hepatic insufficiency (from one 70 mg vial)	5 mL	0.14 mg/mL	0.33 mg/mL
35 mg for moderate hepatic insufficiency (from one 50 mg vial)	7 mL	0.14 mg/mL	0.33 mg/mL

* 10.5 mL should be used for reconstitution of all vials

**If 70 mg vial is not available, the 70 mg dose can be prepared from two 50 mg vials

Contraindications

CANCIDAS is contraindicated in patients with hypersensitivity to any component of this product.

Warnings and Precautions

Concomitant use of CANCIDAS with cyclosporine has been evaluated in healthy volunteers and in patients. Some healthy subjects who received two 3 mg/kg doses of cyclosporine with caspofungin showed transient increases in alanine transaminase (ALT) and aspartate transaminase (AST) of less than or equal to 3 fold the upper limit of normal (ULN) that resolved with discontinuation of the medicines. There was also an increase of approximately 35% in the area under the curve (AUC) of caspofungin when CANCIDAS and cyclosporine were co-administered; blood levels of cyclosporine remained unchanged. In a retrospective study of 40 patients treated during marketed use with CANCIDAS and cyclosporine for 1 to 290 days (median 17.5 days), no serious hepatic adverse events were noted. As expected in patients with allogenic hematopoietic stem cell transplants or solid organ transplants, hepatic

enzyme abnormalities occurred commonly ; however, no patient had elevations in ALT that were considered medicine related. Elevations in AST considered at least possibly related to therapy with CANCIDAS and/or cyclosporine occurred in 5 patients, but all were less than 3.6 times the ULN. Discontinuations due to laboratory abnormalities in hepatic enzymes from any cause occurred in 4 patients. Of these, 2 were considered possibly related to therapy with CANCIDAS and/or cyclosporine as well as other possible causes. In the prospective invasive aspergillosis and compassionate use studies, there were 6 patients treated with CANCIDAS and cyclosporine for 2 to 56 days; none of these patients experienced increases in hepatic enzymes. These data suggest that CANCIDAS can be used in patients receiving cyclosporine when the potential benefit outweighs the potential risk.

Pregnancy

There is no clinical experience involving pregnant women. In rats, caspofungin caused decreases in foetal body weights and an increase in the incidence of incomplete ossification of the skull and torso, at a maternally toxic dose of 5 mg/kg/day. In addition, at this same maternally toxic dose, there was an increase in the incidence of cervical rib in rats. Caspofungin has been shown to cross the placental barrier in animal studies.

CANCIDAS should not be used during pregnancy unless clearly necessary.

Nursing Mothers

It is not known whether this medicine is excreted in human milk; therefore, women receiving CANCIDAS should not breast feed.

Paediatric Use

Caspofungin acetate has not been studied in paediatric patients. Use in patients under 18 years of age is not recommended.

Use in the Elderly

The plasma concentration of caspofungin in healthy older men and women (65 years of age or more) was increased slightly (approximately 28% in AUC) compared to young healthy males. In patients who were treated empirically or who had invasive candidiasis, a similar modest effect of age was seen in older patients relative to younger patients. No dosage adjustment is necessary for elderly patients (65 years of age or more).

Animal toxicology

Acute Toxicity

The approximate intravenous lethal dose₅₀ (LD₅₀) for female mice and rats was calculated as 19 and 38mg/kg, respectively.

Chronic Toxicity

Several treatment-related changes were noted in intravenous toxicity studies in rats and Rhesus monkeys. In these studies, signs of histamine release were observed in rats, serum transaminase levels were increased in monkeys, and injection-site irritation was seen in both

species.

In 5 and 14 week intravenous toxicity studies in rats, 5mg/kg/day produced signs of histamine release consisting of hyperaemia and swelling of the extremities, sluggish movement or ataxia, and recumbency. These signs occurred only during the first 7 to 9 days of dosing presumably due to endogenous histamine depletion. Overall, in the rat studies, 2mg/kg/day was established as the no-effect level for histamine release. No signs of histamine release were reported in 5, 14, and 27 week intravenous dosing studies in monkeys. In ancillary pharmacology studies, a 20 minute infusion at 8mg/kg produced no adverse effects in monkeys; however, bolus injections of 5 or 8mg/kg did produce signs of histamine release. Similar signs of histamine release that were produced with a structural analog of caspofungin acetate in monkeys were reversed upon injection of cyproheptadine.

In 5, 14, and 27 week intravenous toxicity studies in monkeys, ALT and/or AST levels increased slightly, but these levels returned to baseline or remained slightly elevated over the course of the studies. In one 5 week study, scattered small foci of subcapsular necrosis were observed microscopically in the livers of some animals; however, this histopathological finding was not seen in other studies of up to 27 weeks duration at the same or higher doses. The no-effect level for serum transaminase elevations after intravenous treatment was 1.5 mg/kg/day in monkeys, and greater than 7.2 mg/kg/day in rats (the highest dose tested).

During the 5, 14, and 27 week intravenous toxicity studies in rats and monkeys, clinical and histopathological signs of injection-site irritation were observed. Overall, the no-effect dosage level for irritation at the injection site in rats was 1.8 mg/kg/day (0.18 mg/mL), and in monkeys it was 3 mg/kg/day (0.25 mg/mL). Effective pre- and post-dose flushing of catheter lines minimised injection-site irritation in animal studies.

Carcinogenicity

No long-term studies in animals have been performed to evaluate the carcinogenic potential of caspofungin.

Mutagenesis

Caspofungin acetate was evaluated in the following series of in vitro assays and found to be neither mutagenic nor genotoxic: bacterial (Ames) and mammalian cell (V79 Chinese hamster lung fibroblasts) mutagenesis assays, the alkaline elution/rat hepatocyte DNA strand break test, and the chromosomal aberration assay in Chinese hamster ovary cells. Additionally, in the in vivo mouse bone marrow chromosomal test, caspofungin acetate was not genotoxic at doses up to 12.5 mg/kg, administered intravenously.

Reproduction

Female rats administered 0.5, 2, and 5 mg/kg/day of caspofungin acetate intravenously for 16 days prior to cohabitation, during cohabitation, and through gestation Day 7 showed no drug-related effects on mating performance, fecundity, fertility, or embryonic survival. Male rats treated intravenously with 0.5, 2, and 5 mg/kg/day (maximum dosage tested) for 28 days prior to mating showed no effect on fertility.

Development

In rats, there were no developmental effects at a dose of 2 mg/kg/day. At a maternally toxic dose of 5 mg/kg/day, which resulted in a plasma exposure approximately 1.5 times the plasma exposure seen in humans administered 70 mg, caspofungin caused decreases in foetal body weights and an increase in the incidence of incomplete ossification of the skull and torso. In addition, at this same maternally toxic dose, there was an increase in the incidence of cervical rib in rats.

In rabbits, there were no treatment-related external, visceral, or skeletal foetal morphological findings in an intravenous toxicity study where caspofungin acetate was administered to pregnant rabbits at dosages of 1, 3, and 6 mg/kg/day on gestation days 7 through 20. Therefore, the no-effect level for developmental toxicity was greater than 6 mg/kg/day. The no-effect level for maternal toxicity (based on minimal decreases in average maternal body weight gain and food consumption) was 3 mg/kg/day. Pregnant rabbits administered 5 mg/kg/day had plasma exposures approximately 1.5 times the plasma exposure seen in humans administered 70 mg.

Caspofungin acetate has been shown to cross the placental barrier in animal studies.

Effects of Ability to Drive and Use Machinery

No data are available on whether CANCIDAS impairs the ability to drive or operate machinery.

Medicine Interactions

Studies in vitro show that caspofungin acetate is not an inhibitor of any enzyme in the cytochrome P450 (CYP) system. In clinical studies, caspofungin did not induce the CYP3A4 metabolism of other medicines. Caspofungin is not a substrate for P-glycoprotein and is a poor substrate for cytochrome P450 enzymes.

In two clinical studies, cyclosporine (one 4 mg/kg dose or two 3 mg/kg doses) increased the AUC of caspofungin by approximately 35%. These AUC increases are probably due to reduced uptake of caspofungin by the liver. CANCIDAS did not increase the plasma levels of cyclosporine. There were transient increases in liver ALT and AST when CANCIDAS and cyclosporine were co-administered. In a retrospective study of 40 patients treated during marketed use with CANCIDAS and/or cyclosporine for 1 to 290 days (median 17.5 days), no serious hepatic adverse events were noted (see Warnings and Precautions).

Clinical studies in healthy volunteers show that the pharmacokinetics of CANCIDAS are not altered by itraconazole, amphotericin B, mycophenolate, nelfinavir or tacrolimus. CANCIDAS has no effect on the pharmacokinetics of itraconazole, amphotericin B, rifampin or the active metabolite of mycophenolate.

CANCIDAS reduced the 12-hour blood concentration (C_{12hr}) of tacrolimus (FK-506) by 26%. For patients receiving both therapies, standard monitoring of tacrolimus blood concentrations and appropriate tacrolimus dosage adjustments are recommended.

Results from two clinical medicine interaction studies indicate that rifampin both induces and inhibits caspofungin disposition with net induction at steady state. In one study, rifampin and caspofungin were co-administered for 14 days with both therapies initiated on the same day.

In the second study, rifampin was administered alone for 14 days to allow the induction effect to reach steady state, and then rifampin and caspofungin were co-administered for an additional 14 days. When the induction effect of rifampin was at steady state, there was little change in caspofungin AUC or end-of-infusion concentration, but caspofungin trough concentrations were reduced by approximately 30%. The inhibitory effect of rifampin was demonstrated when rifampin and caspofungin treatments were initiated on the same day, and a transient elevation in caspofungin plasma concentrations occurred on Day 1 (approximately 60% increase in AUC). This inhibitory effect was not seen when caspofungin was added to preexisting rifampin therapy, and no elevation in caspofungin concentrations occurred. In addition, results from population pharmacokinetic screening suggest that co-administration of other inducers of medicine clearance (efavirenz, nevirapine, phenytoin, dexamethasone, or carbamazepine) with CANCIDAS may also result in clinically meaningful reductions in caspofungin concentrations. Available data suggest that the inducible medicine clearance mechanism involved in caspofungin disposition is likely an uptake transport process, rather than metabolism. Therefore, when CANCIDAS is co-administered with inducers of medicine clearance, such as efavirenz, nevirapine, rifampin, dexamethasone, phenytoin, or carbamazepine, use of a daily dose of 70 mg of CANCIDAS should be considered (see Dosage and Administration).

Adverse Effects

In clinical studies, 1440 individuals received single or multiple doses of CANCIDAS: 564 febrile neutropenic patients (empirical therapy study), 125 patients with invasive candidiasis, 285 patients with oesophageal and/or oropharyngeal candidiasis, 72 patients with invasive aspergillosis and 394 individuals in phase I studies. In the empirical therapy study patients had received chemotherapy for malignancy or had undergone hematopoietic stem-cell transplantation. In the studies involving patients with documented *Candida* infections, the majority of the patients had serious underlying medical conditions (e.g. haematologic or other malignancy, recent major surgery, HIV) requiring multiple concomitant medications. Patients in the noncomparative *Aspergillus* study often had serious predisposing medical conditions (e.g. bone marrow or peripheral stem cell transplants, haematologic malignancy, solid tumours or organ transplants) requiring multiple concomitant medications.

Reported medicine related clinical and laboratory abnormalities among all patients treated with CANCIDAS (total 989) were typically mild and rarely led to discontinuation.

Common (> 1/100): *General*: fever, headache, abdominal pain, pain, chills; *GI*: nausea, diarrhoea, vomiting; *Liver*: elevated liver enzyme levels (AST, ALT, alkaline phosphatase, direct and total bilirubin); *Kidney*: increased serum creatinine; *Blood*: anaemia (decreased haemoglobin and haematocrit); *Cardiac*: tachycardia; *Peripheral Vascular*: phlebitis/thrombophlebitis, infused-vein complication, flushing; *Respiration*: dyspnea; *Skin*: rash, pruritus, sweating

Possible histamine-mediated symptoms have been reported including reports of rash, facial swelling, pruritus, sensation of warmth, or bronchospasm. Anaphylaxis has been reported during administration of CANCIDAS.

Post-Marketing Experience:

The following post-marketing adverse events have been reported: *Hepatobiliary*: rare cases of hepatic dysfunction; *Cardiovascular*: swelling and peripheral oedema; *Laboratory abnormalities*: hypercalcaemia.

Laboratory Test Findings

Other medicine related laboratory abnormalities reported were low albumin, low potassium, hypomagnesemia, decreased white blood cells, increased eosinophils, low platelets, decreased neutrophils, increased urinary red blood cells, increased partial thromboplastin time, decreased total serum protein, increased urinary protein, increased prothrombin time, low sodium, increased urinary white blood cells, and low calcium.

Overdosage

In clinical studies, the highest dose was 210 mg, which was administered as a single dose to 6 healthy subjects, and was generally well tolerated. In addition, 100 mg once daily for 21 days has been administered to 15 healthy subjects and was generally well tolerated. Caspofungin is not dialysable.

Actions

Activity in vitro

Caspofungin has in vitro activity against *Aspergillus* species (including *Aspergillus fumigatus*, *Aspergillus flavus*, *Aspergillus niger*, *Aspergillus nidulans*, *Aspergillus terreus* and *Aspergillus candidus*) and *Candida* species (including *Candida albicans*, *Candida dubliniensis*, *Candida glabrata*, *Candida guilliermondii*, *Candida kefyr*, *Candida krusei*, *Candida lipolytica*, *Candida lusitanae*, *Candida parapsilosis*, *Candida rugosa*, and *Candida tropicalis*). Susceptibility testing was performed according to a modification of both the National Committee for Clinical Laboratory Standards (NCCLS) method M38-A (for *Aspergillus* species) and method M27-A (for *Candida* species). Standardised susceptibility testing methods for echinocandins have not been established, and results of susceptibility studies do not necessarily correlate with clinical outcome.

Activity in vivo

Caspofungin was active when parenterally administered to immune-competent and immune-suppressed animals with disseminated infections of *Aspergillus* and *Candida* for which the endpoints were prolonged survival of infected animals (*Aspergillus* and *Candida*) and clearance of fungi from target organs (*Candida*). Caspofungin was also active in immunodeficient animals after disseminated infection with *C. glabrata*, *C. krusei*, *C. lusitanae*, *C. parapsilosis*, or *C. tropicalis* in which the endpoint was clearance of *Candida* from target organs. In a lethal, rat pulmonary-infection model with *A. fumigatus*, caspofungin was highly active in the prevention and treatment of pulmonary aspergillosis.

Cross-resistance

Caspofungin acetate is active against strains of *Candida* with intrinsic or acquired resistance to fluconazole, amphotericin B, or flucytosine consistent with their different mechanisms of action.

Medicine Resistance

Mutants of *Candida* with reduced susceptibility to caspofungin have been identified in some patients during treatment. MIC values for caspofungin should not be used to predict clinical outcome, since a correlation between MIC values and clinical outcome has not been

established. The relevance to clinical outcome is unknown. *In vitro* medicine resistance development to caspofungin in *Aspergillus* species has not been studied. In limited clinical experience, medicine resistance in patients with invasive aspergillosis has not been observed. The incidence of medicine resistance in various clinical isolates of *Candida* and *Aspergillus* species is unknown.

Medicine Interactions

In vitro and *in vivo* studies of caspofungin acetate, in combination with amphotericin B, demonstrate no antagonism of antifungal activity against either *A. fumigatus* or *C. albicans*. Results from *in vitro* studies suggest that there was some evidence of additive/indifferent or synergistic activity against *A. fumigatus* and additive/indifferent activity against *C. albicans*. The clinical significance of these results is unknown.

Pharmacokinetics

Absorption

Absorption is not relevant since caspofungin acetate is administered intravenously.

Distribution

Plasma concentrations of caspofungin decline in a polyphasic manner following single 1 hour intravenous infusions. A short α -phase occurs immediately post-infusion, followed by a β -phase with a half-life of 9 to 11 hours that characterises much of the profile and exhibits clear log-linear behaviour from 6 to 48 hours post-dose, during which the plasma concentration decreases by an order of magnitude. An additional γ -phase also occurs (half life 40-50 hours). Distribution, rather than excretion or biotransformation, is the dominant mechanism influencing plasma clearance. Caspofungin is extensively bound to albumin (approximately 97%), and distribution into red blood cells is minimal. Mass balance results showed that approximately 92% of the administered radioactivity was distributed to tissues by 36 to 48 hours after a single 70-mg dose of [³H] caspofungin acetate. There is little excretion or biotransformation of caspofungin during the first 30 hours after administration.

Metabolism

Caspofungin is slowly metabolised by hydrolysis and N-acetylation. Caspofungin also undergoes spontaneous chemical degradation to an open-ring peptide compound. At later time points (≥ 5 days post-dose), there is a low level (≤ 7 picomoles/mg protein, or $\leq 1.3\%$ of administered dose) of covalent binding of radiolabel in plasma following single-dose administration of [³H] caspofungin acetate, which may be due to two reactive intermediates formed during the chemical degradation of caspofungin. Additional metabolism involves hydrolysis into constitutive amino acids and their derivatives, including dihydroxyhomotyrosine and N-acetyl-dihydroxyhomotyrosine. These two tyrosine derivatives are found only in urine, suggesting rapid clearance of these derivatives by the kidneys.

Elimination

Two single-dose, radiolabeled pharmacokinetic studies were conducted. In one study, plasma, urine, and faeces were collected over 27 days, and in the second study plasma was collected over 6 months. Approximately 75% of the radioactivity was recovered: 41% in urine and 34% in faeces. Plasma concentrations of radioactivity and of caspofungin were similar during the first 24 to 48 hours postdose; thereafter drug levels fell more rapidly. In plasma, caspofungin concentrations fell below the limit of quantitation after 6 to 8 days postdose, while

radiolabel fell below the limit of quantitation at 22.3 weeks postdose. A small amount of caspofungin is excreted unchanged in urine (approximately 1.4% of dose). Renal clearance of parent drug is low (approximately 0.15 mL/min).

Characteristics in Patients

Gender

The plasma concentration of caspofungin was similar in healthy men and women on Day 1 following a single 70 mg dose. After 13 daily 50 mg doses, the caspofungin plasma concentration in some women was elevated approximately 20% relative to men.

Hepatic Insufficiency

Plasma concentrations of caspofungin after a single 70 mg dose in patients with mild hepatic insufficiency (Child-Pugh score 5 to 6) were increased by approximately 55% in AUC compared to healthy control subjects. In a 14 day multiple-dose study (70 mg on Day 1 followed by 50 mg daily thereafter), plasma concentrations in patients with mild hepatic insufficiency were increased modestly (19 to 25% in AUC) on Days 7 and 14 relative to healthy control subjects.

Pharmaceutical Precautions

Storage of unopened vials

The lyophilised compact powder in vials should be stored at 2° to 8°C (36° to 46°F).

Storage of reconstituted CANCIDAS in vials

Reconstituted CANCIDAS may be stored at or below 25°C (77 °F) for 24 hours prior to the preparation of the patient infusion solution.

Storage of diluted product for infusion

The final patient infusion solution in the intravenous bag or bottle can be stored at or below 25°C (77°F) for 24 hours, or for 48 hours when refrigerated at 2 to 8°C (36 to 46°F).

Medicine Classification

Prescription medicine.

Package Quantities

10 mL single dose vial containing 50 mg caspofungin acetate

10 mL single dose vial containing 70 mg caspofungin acetate

Further Information

Chemistry

CANCIDAS contains, as the active ingredient, caspofungin acetate, which is described chemically as 1-[(4*R*,5*S*)-5-[(2-aminoethyl)amino]-*N*²-(10,12-dimethyl-1-oxotetradecyl)-4-hydroxy-L-ornithine]-5-[(3*R*)-3-hydroxy-L-ornithine]pneumocandin B₀ diacetate (salt)

The empirical formula is C₅₂H₈₈N₁₀O₁₅•2C₂H₄O₂.

The CAS registry number is 179463-17-3.

