



PACKAGE LEAFLET: INFORMATION FOR THE USER

CASPOFUNGIN TEVA 70 mg POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION

Caspofungin

Read all of this leaflet carefully before you start taking 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet

- What Caspofungin Teva is and what it is used for
- What you need to know before you take Caspofungin Teva
- How to take Caspofungin Teva
- Possible side effects
- How to store Caspofungin Teva
- Contents of the pack and other information

1 What Caspofungin Teva is and what it is used for

What Caspofungin Teva is

Caspofungin Teva contains a medicine called caspofungin. This belongs to a group of medicines called antifungals.

What Caspofungin Teva is used for

Caspofungin Teva is used to treat the following infections in children,adolescents and adults:

- serious fungal infections in your tissues or organs (called ‘invasive candidiasis’). This infection is caused by fungal (yeast) cells called Candida. People who might get this type of infection include those who have just had an operation or those whose immune systems are weak. Fever and chills that do not respond to an antibiotic are the most common signs of this type of infection.
- fungal infections in your nose, nasal sinuses or lungs (called ‘invasive aspergillosis’) if other anti-fungal treatments have not worked or have caused side effects. This infection is caused by a mould called Aspergillus. People who might get this type of infection include those having chemotherapy, those who have had a transplant and those whose immune systems are weak.
- suspected fungal infections if you have a fever and a low white cell count that have not improved on treatment with an antibiotic. People who are at risk of getting a fungal infection include those who have just had an operation or those whose immune systems are weak.

How Caspofungin Teva works

Caspofungin Teva makes fungal cells fragile and stops the fungus from growing properly. This stops the infection from spreading and gives the body’s natural defences a chance to completely get rid of the infection.

2 What you need to know before you are given Caspofungin Teva

Do not use Caspofungin Teva

- if you are allergic to caspofungin or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, talk to your doctor, nurse or pharmacist before you are given your medicine.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before you are given Caspofungin Teva if:

- you are allergic to any other medicines
- you have ever had liver problems - you might need a different dose of this medicine
- you are already taking ciclosporin (used to help prevent organ transplant rejection or to suppress your immune system) - as your doctor may need to run extra blood tests during your treatment.
- if you have ever had any other medical problem.

If any of the above applies to you (or you are not sure), talk to your doctor, nurse or pharmacist before you are given Caspofungin Teva.

Other medicines and Caspofungin Teva

Please tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

This is because Caspofungin can affect the way some other medicines work. Also some other medicines can affect the way Caspofungin works.

Tell your doctor, nurse or pharmacist if you are taking any of the following medicines:

- ciclosporin or tacrolimus (used to help prevent organ transplant rejection or to suppress your immune system) as your doctor may need to run extra blood tests during your treatment
- some HIV medicines such as efavirenz or nevirapine
- phenytoin or carbamazepine (used for the treatment of seizures)
- dexamethasone (a steroid)
- rifampicin (an antibiotic).

If any of the above apply to you (or you are not sure), talk to your doctor, nurse or pharmacist before you are given Caspofungin Teva.

Pregnancy and breast-feeding

If you are pregnant or 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.

- Caspofungin Teva has not been studied in pregnant women. It should be used in pregnancy only if the potential benefit justifies the potential risk to the unborn baby.
- Women given Caspofungin Teva should not breast-feed.

Driving and using machines

No studies have been performed with Caspofungin Teva. However, undesirable effects may occur (e.g. allergic reactions, dizziness, convulsions), which may influence the ability to drive and use machines.

Caspofungin Teva contains sodium:

This medicinal product contains less than 1 mmol sodium (23 mg) per vial, i.e. essentially ‘sodium- free’.

3 How to use Caspofungin Teva

Caspofungin Teva will always be prepared and given to you by a healthcare professional.

You will be given Caspofungin Teva:

- once each day
- by slow injection into a vein (intravenous infusion)
- over about 1 hour.

Your doctor will determine the duration of your treatment and how much Caspofungin Teva you will be given each day. Your doctor will monitor how well the medicine works for you. If you weigh more than 80 kg, you may need a different dose.

Use in children and adolescents

The dose for children and adolescents may differ from the adult dose.

If you have been given more Caspofungin Teva than you should

Your doctor will decide how much Caspofungin Teva you need and for how long each day. If you are worried that you may have been given too much Caspofungin Teva, tell your doctor or nurse straight away.

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

4 Possible side effects

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

Tell your doctor or nurse straight away if you notice any of the following side effects – you may need urgent medical treatment:

- rash, itching, feeling warm, swelling of your face, lips or throat or difficulty breathing - you may be having a histamine reaction to the medicine.
- difficulty breathing with wheezing or a rash that gets worse - you may be having an allergic reaction to the medicine.
- cough, serious breathing difficulties - if you are an adult and have invasive aspergillosis you may be experiencing a serious respiratory problem that could result in respiratory failure.

As with any prescription medicine, some side effects may be serious. Ask your doctor for more information.

Other side effects in adults include

Common: may affect up to 1 in 10 people:

- Decreased haemoglobin (decreased oxygen carrying substance in the blood), decreased white blood cells
- Decreased blood albumin (a type of protein) in your blood, decreased potassium or low potassium levels in the blood
- Headache
- Inflammation of the vein
- Shortness of breath
- Diarrhoea, nausea or vomiting
- Changes in some laboratory blood tests (including increased values of some liver tests)
- Itching, rash, skin redness or sweating more than usual
- Joint pain
- Chills, fever
- Itching at the injection site.

Uncommon: may affect up to 1 in 100 people:

- Changes in some laboratory blood tests (including disease of blood clotting, platelets, red blood cells and white blood cells)



The following information is intended for healthcare professionals only:

Instructions of how to reconstitute and dilute Caspofungin Teva:

Reconstitution of Caspofungin Teva

DO NOT USE ANY DILUENTS CONTAINING GLUCOSE, as Caspofungin Teva is not stable in diluents containing glucose. DO NOT MIX OR CO-INFUSE CASPOFUNGIN TEVA WITH ANY OTHER MEDICINES, as there are no data available on the compatibility of Caspofungin Teva with other intravenous substances, additives, or medicinal products. Visually inspect the infusion solution for particulate matter or discolouration.

Chemical and physical in-use stability of the reconstituted concentrate has been demonstrated for 24 hours at 25°C or less when reconstituted with water for injection.

Chemical and physical in-use stability of the diluted patient infusion solution has been demonstrated for 24 hours at 25°C and for 48 hours at (2 to 8°C) when diluted with sodium chloride solution 9 mg/ml (0.9 %), 4.5 mg/ml (0.45 %), or 2.25 mg/ml (0.225 %) for infusion, or lactated Ringer's solution.

From a microbiological point of view, the product should be used immediately. If not used immediately, in use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution and dilution have taken place in controlled validated aseptic conditions.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

INSTRUCTIONS FOR USE IN ADULT PATIENTS

Step 1 Reconstitution of conventional vials

To reconstitute the powder bring the vial to room temperature and aseptically add 10.5 ml of water for injection. The concentrations of the reconstituted vials will be: 7.2 mg/ml.

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

Step 2 Addition of reconstituted Caspofungin Teva to patient infusion solution

Diluents for the final solution for infusion are: sodium chloride solution for injection, or lactated Ringer's solution. The solution for infusion is prepared by aseptically adding the appropriate amount of reconstituted concentrate (as shown in the table below) to a 250 ml infusion 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 has precipitated.

PREPARATION OF THE SOLUTION FOR INFUSION IN ADULTS

DOSE*	Volume of reconstituted Caspofungin Teva for transfer to intravenous bag or bottle	Standard preparation (reconstituted Caspofungin Teva added to 250 ml) final concentration	Reduced volume infusion (reconstituted Caspofungin Teva added to 100 ml) final concentration
70 mg	10 ml	0.28 mg/ml	Not Recommended
70 mg (from two 50 mg vial)**	14 ml	0.28 mg/ml	Not Recommended
35 mg for moderate hepatic impairment (from one 70 mg vial)	5 ml	0.14 mg/ml	0.34 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



Design Department Harlow

PRODUCT: Caspofungin 70mg Powder for Conc. for Sol. for Inf. 1 vial (Godollo) TEI Hosp	Colours: Cutter Guide PMS Process Black	Fonts: (Artwork) Body: Syntax roman/bold/Italic 9pts Med info: 8pts Subhead: Univers 65 Bld 11pts Header: Univers 65 Bld 13pts	Amends: Draft: 1 Rev date: 11-5-16 Reviser: WA Artworker's Signature:	Approval: Artwork Planner Signed Date <input type="checkbox"/> • Subject to Reg. Agency approval <input type="checkbox"/> • Approved by Reg. Dept. for print Signed Date
Job No: 44410 SAP No: -				
Designer: WA Date: 10-5-16				
Component: Leaflet				
Dimensions: 268 x 414mm				
Spell Check: <input checked="" type="checkbox"/> Template Check: <input checked="" type="checkbox"/>				
Supplier Instructions Artwork, text and content must NOT be altered. The only exceptions to this are: bleeds, chokes, spreads or other adjustments required for print reproduction purposes only. If you have any difficulties please contact the Teva Artwork Team. We must receive a copy of the 3rd Party Vendors Proof before final approval can be made.		Software used: Indesign CS6		
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- Loss of appetite, increase in amount of body fluid, imbalance of salt in the body, high sugar level in the blood, low calcium level in the blood, low magnesium level in the blood, increase in acid level in the blood
- Disorientation, feeling nervous, being unable to sleep Feeling dizzy, decreased feeling or sensitivity (especially in the skin), shaking, feeling sleepy, change in the way things taste, tingling or numbness
- Blurred vision, increase in tears, swollen eyelid, yellowing of the whites of the eyes
- Sensation of fast or irregular heart beats, rapid heart beat, irregular heart beat, abnormal heart rhythm, heart failure
- Flushing, hot flush, high blood pressure, low blood pressure, redness along a vein which is extremely tender when touched
- Tightening of the bands of muscle around the airways resulting in wheezing or coughing, fast breathing rate, shortness of breath that wakes you up, shortage of oxygen in the blood, abnormal breath sounds, crackling sounds in the lungs, wheezing, nasal congestion, cough, throat pain
- Belly pain, upper belly pain, bloating, constipation, difficulty swallowing, dry mouth, indigestion, passing gas, stomach discomfort, swelling due to build-up of fluid around the belly
- Decreased flow of bile, enlarged liver, yellowing of the skin and/or whites of the eyes, liver injury caused by a drug or chemical, liver disorder
- Abnormal skin tissue, generalised itching, hives, rash of varying appearance, abnormal skin, red often itchy spots on your arms and legs and sometimes on the face and the rest of the body
- Back pain, pain in an arm or leg, bone pain, muscle pain, muscle weakness
- Loss of kidney function, sudden loss of kidney function
- Catheter site pain, injection site complaints (redness, hard lump, pain, swelling, irritation, rash, hives, leaking of fluid from the catheter into the tissue), inflammation of vein at injection site
- Increased blood pressure and alterations in some laboratory blood tests (including kidney electrolyte and clotting tests), increased levels of the medicines you are taking that weaken the immune system
- Chest discomfort, chest pain, feeling of body temperature change, generally feeling unwell, general pain, swelling of the face, swelling of the ankles, hands or feet, swelling, tenderness, feeling tired.

Side effects in children and adolescents

Very common: may affect more than 1 in 10 people:

- Fever

Common: may affect up to 1 in 10 people:

- Headache
- Fast heart beat
- Flushing, low blood pressure
- Changes in some laboratory blood tests (increased values of some liver tests)
- Itching, rash
- Catheter site pain
- Chills
- Changes in some laboratory blood tests.

Other side effects reported since this medicine has been on the market

Not known: frequency cannot be estimated:

- Liver problems
- Swelling of the ankles, hands or feet
- Increased calcium levels in the blood have been reported.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

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

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Caspofungin Teva

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

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

Store in a refrigerator (2°C to 8°C).

Once Caspofungin Teva has been prepared, it should be used straight away. This is because it does not contain any ingredients to stop the growth of bacteria. Only a trained healthcare professional who has read the complete directions should prepare the medicine (please see below “Instructions of how to reconstitute and dilute Caspofungin Teva”).

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information

What Caspofungin Teva contains

- The active substance is caspofungin. Each vial contains 70 mg of caspofungin. After reconstitution each ml of the concentrate contains 7.2 mg of caspofungin.
- The other ingredients are sucrose, mannitol (E421), glacial acetic acid (E260) and sodium hydroxide (for pH adjustment) (E524) (please see section 2).

What Caspofungin Teva looks like and contents of the pack

Caspofungin Teva is a sterile, white to off-white colour powder. 10 ml colourless clear Type I glass vial with a grey (bromobutyl) rubber stopper with aluminium band and an orange (polypropylene) plastic flip off cap.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Teva B.V.

Swensweg 5

2031GA Haarlem

Netherlands

Manufacturer

PLIVA Hrvatska d.o.o. (PLIVA Croatia Ltd)

Prilaz baruna Filipovica 25

Zagreb, 1000

Croatia

Merckle GmbH

Ludwig-Merckle-Strasse 3

Blaubeuren

Baden-Wuerttemberg, 89143

Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Caspofungin ratiopharm 70 mg Pulver für ein Konzentrat zur Herstellung einer Infusionslösung
Belgium	Caspofungin Teva 70 mg poeder voor concentraat voor oplossing voor infusie
Czech Republic	CASPOFUNGIN TEVA 70 mg, prášek pro přípravu koncentrátu pro přípravu infúzního roztoku
Germany	Caspofungin-ratiopharm 70 mg Pulver für ein Konzentrat zur Herstellung einer Infusionslösung
Denmark	Caspofungin Teva
Estonia	Caspofungin Teva
Spain	Caspofungina Teva 70 mg polvo para concentrado para solución para perfusión EFG
Finland	Caspofungin Teva 70 mg kuiva-aine välikonsentraatiksi infuusionestettä varten, liuos
France	Caspofungine Teva 70 mg poudre pour solution à diluer pour perfusion
Croatia	Kasprofungin Pliva Hrvatska 70 mg prašak za koncentrat za otopinu za infuziju
Hungary	Caspofungin Teva 70 mg por oldatos infúzióhoz való koncentrátumhoz
Ireland	Caspofungin Teva 70 mg Powder for Concentrate for Solution for Infusion
Iceland	Caspofungin Teva 70 mg Stofn fyrir innrennslisþykknir, lausn
Italy	Caspofungin Teva 70 mg Polvere per concentrato per soluzione per infusione
Lithuania	Caspofungin Teva 70 mg milteliai infuzinio tirpalo koncentratui
Malta	Caspofungin Teva 70 mg Powder for Concentrate for Solution for Infusion
Netherlands	Caspofungine Teva 70 mg, poeder voor concentraat voor oplossing voor infusie
Poland	Caspofungin Teva
Portugal	Caspofungina Teva
Romania	CASPOFUNGINĂ TEVA 70 mg pulbere pentru concentrat pentru soluție perfuzabilă
Sweden	Caspofungin Teva
Slovenia	Kasprofungin Teva 70 mg prašek za koncentrat za raztopino za infundiranje
Slovakia	Casprofungin Teva 70 mg
United Kingdom	Caspofungin Teva 70 mg Powder for concentrate for solution for infusion

This leaflet was last revised in May 2016.

INSTRUCTIONS FOR USE IN PAEDIATRIC PATIENTS

Calculation of Body Surface Area (BSA) for paediatric dosing

Before preparation of infusion, calculate the body surface area (BSA) of the patient using the following formula: (Mosteller Formula)

$$BSA(m^2) = \sqrt{\frac{\text{Height(cm)} \times \text{Weight(kg)}}{3600}}$$

Preparation of the 70 mg/m² infusion for paediatric patients >3 months of age (using a 70-mg vial)

1. Determine the actual loading dose to be used in the paediatric patient by using the patient's BSA (as calculated above) and the following equation:
BSA (m²) X 70 mg/m² = Loading Dose
The maximum loading dose on Day 1 should not exceed 70 mg regardless of the patient's calculated dose.
2. Equilibrate the refrigerated vial of Caspofungin Teva to room temperature.
3. Aseptically add 10.5 ml of water for injection^a. This reconstituted solution may be stored for up to 24 hours at or below 25°C^b. This will give a final caspofungin concentration in the vial of 7.2 mg/ml.
4. Remove the volume of medicinal product equal to the calculated loading dose (Step 1) from the vial. Aseptically transfer this volume (ml)^c of reconstituted Caspofungin Teva to an IV bag (or bottle) containing 250 ml of 0.9 % , 0.45 % , or 0.225 % Sodium Chloride Injection, or Lactated Ringers Injection. Alternatively, the volume (ml)^c of reconstituted Caspofungin Teva can be added to a reduced volume of 0.9 % , 0.45 % , or 0.225 % Sodium Chloride Injection or Lactated Ringers Injection, not to exceed a final concentration of 0.5 mg/ml. This infusion solution must be used within 24 hours if stored at or below 25°C or within 48 hours if stored refrigerated at 2 to 8°C.

Preparation of the 50 mg/m² infusion for paediatric patients >3 months of age (using a 70-mg vial)

1. Determine the actual daily maintenance dose to be used in the paediatric patient by using the patient's BSA (as calculated above) and the following equation:
BSA (m²) X 50 mg/m² = Daily Maintenance Dose
The daily maintenance dose should not exceed 70 mg regardless of the patient's calculated dose.
2. Equilibrate the refrigerated vial of Caspofungin Teva to room temperature.
3. Aseptically add 10.5 ml of water for injection.^a This reconstituted solution may be stored for up to 24 hours at or below 25°C.^b This will give a final caspofungin concentration in the vial of 7.2 mg/ml.

4. Remove the volume of medicinal product equal to the calculated daily maintenance dose (Step 1) from the vial. Aseptically transfer this volume (ml) ^c of reconstituted Caspofungin Teva to an IV bag (or bottle) containing 250 ml of 0.9 % , 0.45 % , or 0.225 % Sodium Chloride Injection, or Lactated Ringers Injection. Alternatively, the volume (ml)^c of reconstituted Caspofungin Teva can be added to a reduced volume of 0.9 % , 0.45 % , or 0.225 % Sodium Chloride Injection or Lactated Ringers Injection, not to exceed a final concentration of 0.5 mg/ml. This infusion solution must be used within 24 hours if stored at or below 25°C or within 48 hours if stored refrigerated at 2 to 8°C

Preparation notes:

- a. The white to off-white colour powder will dissolve completely. Mix gently until a clear solution is obtained.
- b. Visually inspect the reconstituted solution for particulate matter or discolouration during reconstitution and prior to infusion. Do not use if the solution is cloudy or has precipitated.
- c. Caspofungin Teva is formulated to provide the full labeled vial dose (70 mg) when 10 ml is withdrawn from the vial.