	Package Leaflet: Inf		ation for the user
	Caspofungin 70 mg Powder for co	nce	ntrate for solution for infusion
	Read all of this leaflet carefully before		our doctor may need to run extra
	you or your child are given this medicine because it contains		ood tests during your treatment ome HIV medicines such as efavirenz
	important information for you.		nevirapine
	- Keep this leaflet. You may need to read		henytoin or carbamazepine (used for
Area	it again.		ie treatment of seizures) examethasone (a steroid used e.g. foi
1	 If you have further questions, please ask your doctor, nurse or pharmacist. 		e treatment of inflammations)
	 If you get any side effects, talk to your 		fampicin (an antibiotic).
	doctor, nurse or pharmacist. This	lf a	ny of the above apply to you (or you
	includes any possible side effects not		not sure), talk to your doctor, nurse
	listed in this leaflet. See section 4.		bharmacist before you are given pofungin.
	What is in this leaflet 1. What Caspofungin is and what it is		gnancy and breast-feeding
	used for		your doctor for advice before taking
	2. What you need to know before you		medicine, if you are pregnant or
	are given Caspofungin 3. How to use Caspofungin		ast-feeding or think you are pregnan aspofungin has not been studied in
	4. Possible side effects		regnant women. It should be used in
	5. How to store Caspofungin		regnancy only if the potential benefit
	 Contents of the pack and other information 		stifies the potential risk to the nborn baby.
			omen given Caspofungin should not
	 What Caspofungin is and what it is used for 	bi	reast-feed.
	What Caspofungin is		ving and using machines
	Caspofungin contains the active		ere is no information to suggest that pofungin affects your ability to drive
	substance caspofungin. This belongs to		operate machinery.
	a group of medicines called antifungals. What Caspofungin is used for		pofungin contains sodium
	Caspofungin is used to treat the		s medicinal product contains less n 1 mmol sodium (23 mg) per vial,
	following infections in children,		essentially "sodium-free".
	adolescents and adults:		·
	 serious fungal infections in your tissues or organs (called "invasive candidiasis"). 		How to use Caspofungin pofungin will always be prepared and
	This infection is caused by fungal		en to you by a healthcare professional
	(yeast) cells called <i>Candida</i> .	-	ı will be given Caspofungin:
	People who might get this type of infection include those who have just	• 01	nce each day
	had an operation or those whose		y slow injection into a vein
	immune systems are weak. Fever and		ntravenous infusion) ver about 1 hour.
	chills that do not respond to an antibiotic are the most common signs		r doctor will determine the duration
	of this type of infection.	of y	our treatment and how much
	 fungal infections in your nose, nasal 		pofungin you will be given each day
	sinuses or lungs (called "invasive aspergillosis") if other antifungal		Ir doctor will monitor how well the dicine works for you. If you weigh
	treatments have not worked or have		re than 80 kg, you may need a
	caused side effects. This infection is		erent dose.
	caused by a mould called <i>Aspergillus</i> . People who might get this type of		Idren and adolescents
	infection include those having		e dose for children and adolescents y differ from the adult dose.
	chemotherapy, those who have had a		ou have been given more
	transplant and those whose immune		pofungin than you should
	systems are weak.suspected fungal infections if you have	Υοι	ir doctor will decide how much
	a fever and a low white cell count that		pofungin you need and for how long
	have not improved on treatment with		h day. If you are worried that you ma e been given too much Caspofungin
	an antibiotic.		vour doctor or nurse straight away.

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 works

Caspofungin 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

- Do not use Caspofungin
- if you are allergic to caspofungin or any of the other ingredients of this medicine (listed in section 6).

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- used e.g. for tions)

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much or how long hat you may aspofungin, 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 If you are not sure, talk to your doctor, having an allergic reaction to the nurse or pharmacist before you are given medicin your medicine. cough, serious breathing difficulties - if Warnings and precautions you are an adult and have invasive Talk to your doctor, nurse or pharmacist aspergillosis you may be experiencing before you are given Caspofungin if: a serious respiratory problem that you are allergic to any other medicines could result in respiratory failure. you have ever had liver problems - you rash, skin peeling, mucous membrane might need a different dose of this sores, hives, large areas of peeling skin. medicine

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• you are already taking cyclosporin (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.

Caspofungin may also cause serious cutaneous adverse reactions such as Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN).

Other medicines and Caspofungin 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:

 cyclosporin or tacrolimus (used to help prevent organ transplant rejection or to suppress your immune system) as

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)
- loss of appetite, increase in amount of body fluid, imbalance of salt in the body, high sugar level in the blood, low 24LF02179PD

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The following information is intended for healthcare professionals only: Instructions of how to reconstitute and dilute Caspofungin:

Reconstitution of Caspofungin DO NOT USE ANY DILUENTS

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

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 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. The concentrations of the reconstituted vials will be 7.2 mg/ml.

Step 2 Addition of reconstituted Caspofungin to patient infusion

solution Diluents for the final solution for infusion are: sodium chloride solution for injection 9 mg/ml (0.9 %), or lactated Ringer's solution.

The solution for infusion is prepared by aseptically adding the appropriate amount of reconstituted concentrate for solution for infusion (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.

Visually inspect the infusion solution for particulate matter or discolouration. Do not use if the solution is cloudy or

has precipitated.

PREPARATION OF THE SOLUTION FOR INFUSION IN ADULTS

PREPARATION OF THE SOLUTION FOR INFOSION IN ADULTS					
DOSE*	Volume of reconstituted Caspofungin for transfer to intravenous bag or bottle		Reduced volume infusion final concentration (reconstituted Caspofungin added to 100 ml diluent)		
70 mg	10 ml	0.28 mg/ml	not recommended		
70 mg (from two 50 mg vials)**	14 ml	0.28 mg/ml	not recommended		

30

60

120

35 mg for moderate hepatic impairment (from one	5 ml	0.14 mg/ml	0.34 mg/ml		
70 mg vial)					
* 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 v					

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calcium level in the blood, increase in 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 conditions. sensitivity (especially in the skin), Do not freeze the reconstituted shaking, feeling sleepy, change in the way things taste, tingling or numbness Diluted solution for infusion 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 conditions. around the airways resulting in Do not freeze the reconstituted wheezing or coughing, fast breathing diluted solution for infusion. 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, environment. constipation, difficulty swallowing, dry mouth, indigestion, passing gas, information stomach discomfort, swelling due to build-up of fluid around the belly What Caspofungin contains 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 caspofungin. appearance, abnormal skin, red often itchy spots on your arms and legs and sometimes on the face and the rest of the body pH). back pain, pain in an arm or leg, bone pain, muscle pain, muscle weakness contents of the pack loss of kidney function, sudden loss of kidnev function off-white compact powder for 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 Ireland injection site Pinewood Laboratories Ltd., increased blood pressure and alterations in some laboratory blood Ireland tests (including kidney electrolyte and Manufacturer clotting tests), increased levels of the BAG Health Care GmbH medicines you are taking that weaken Amtsgerichtsstraße 1-5 the immune system 35423 Lich chest discomfort, chest pain, feeling of Germany body temperature change, generally Laboratorios Alcalá Farma S.L. feeling unwell, general pain, swelling Av. de Madrid, 82 of the face, swelling of the ankles, 28802 Alcalá de Henares, hands or feet, swelling, tenderness, Madrid, feeling tired. Spain Side effects in children and adolescents Very common (may affect more than under the following names: 1 in 10 people): Ireland 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

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 E reconstitution has taken place in controlled and validated aseptic 60 fold concentrate for solution for infusion. Chemical and physical in-use stability has been demonstrated for 24 hours at \leq 25 °C and for 48 hours at 2 to 8 °C. 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 dilution has taken place 120 mm in controlled and validated aseptic Do not throw away any medicines via 0 wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the 6. Contents of the pack and other The active substance is caspofungin. Each vial of Caspofungin contains 70 mg caspofungin (as acetate). After reconstitution each ml concentrate for solution for infusion contains 7.2 mg The other ingredients are sucrose, mannitol, glacial acetic acid and sodium hydroxide 3.9 % (to adjust the What Caspofungin looks like and Caspofungin is a sterile, white to concentrate for solution for infusion. Each pack contains one vial of powder. Marketing Authorisation Holder in 240 mm Ballymacarbry, Clonmel, Co. Tipperary, fold This medicinal product is authorised in the Member States of the EEA Caspofungin 70 mg Powder for concentrate for solution for infusion This leaflet was last revised in 05/2025.

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chills

test

Reporting of side effects If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.

changes in some laboratory blood

You can also report side effects directly via the national reporting system listed below:

Ireland: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971: Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: <u>medsafety@hpra.ie</u>

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

5. How to Store Caspofungin

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 (the first two numbers are the month; the next four numbers are the year). The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C to 8 °C).

The following in-use storage times of the reconstituted concentrate for solution for infusion and the diluted solution for infusion are not additive.

Reconstituted concentrate for solution for infusion

Chemical and physical in-use stability has been demonstrated for 24 hours at ≤ 25 °C. From a microbiological point of view, the product should be used immediately. If not used immediately,

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 (Mosteller¹ Formula):

Height (cm) x Weight (kg) BSA (m^{2}) = 1 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 (m^2) X 70 mg/ m^2 = 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 to room temperature.
- 3. Aseptically add 10.5 ml of water for injection^a. 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)^b of reconstituted Caspofungin to an IV bag (or bottle) containing 250 ml of sodium chloride solution for injection 9 mg/ml (0.9 %), or lactated Ringer's solution. Alternatively, the volume (ml)^b of reconstituted Caspofungin can be added to a reduced volume of sodium chloride solution for injection 9 mg/ml (0.9 %) or lactated Ringer's solution, not to exceed a final concentration of 0.5 mg/ml.

Preparation of the 50 mg/m² infusion for paediatric patients >3 months of

24LF02179PD BSA (m^2) X 50 mg/m² = Daily

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HEALTHCARE

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 to room temperature.
- 3. Aseptically add 10.5 ml of water for injection^a. This will give a final caspofungin concentration in the vial of 7.2 ma/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)^b of reconstituted caspofungin to an IV bag (or bottle) containing 250 ml of sodium chloride solution for injection 9 mg/ml (0.9 %), or lactated Ringer's solution. Alternatively, the volume (ml)^b of reconstituted Caspofungin can be added to a reduced volume of sodium chloride solution for injection 9 mg/ml (0.9 %) or lactated Ringer's solution, not to exceed a final concentration of 0.5 ma/ml.

Preparation notes:

- a. The white to off-white cake will dissolve completely. Mix gently until a clear solution is obtained.
- **b.** Caspofungin is formulated to provide the full labelled vial dose (70 mg) when 10 ml is withdrawn from the vial.

¹Mosteller RD: Simplified Calculation of Body Surface Area. N Engl J Med. 1987 Oct 22; N317(17): p.1098 (letter)



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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:



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