

FINAL PROPOSED PATIENT INFORMATION LEAFLET (CLEAN COPY)

SCHEDULING STATUS

S4

CASPOLYN 50 (powder for concentrate for solution for infusion)

CASPOLYN 70 (powder for concentrate for solution for infusion)

Caspofungin acetate

Contains sugar:

Each **CASPOLYN 50** vial contains 35,7 mg sucrose and 23,8 mg mannitol.

Each **CASPOLYN 70** vial contains 50 mg sucrose and 33,3 mg mannitol.

Read all of this leaflet carefully before you are given CASPOLYN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

What is in this leaflet

1. What **CASPOLYN** is and what it is used for
2. What you need to know before you use **CASPOLYN**
3. How to use **CASPOLYN**
4. Possible side effects
5. How to store **CASPOLYN**
6. Contents of the pack and other information

1. What CASPOLYN is and what it is used for

CASPOLYN contains the active substance Caspofungin. This belongs to a group of medicines called anti-fungals.

FINAL PROPOSED PATIENT INFORMATION LEAFLET (CLEAN COPY)

CASPOLYN is used to treat a variety of fungal infections in children, adolescents and adults.

CASPOLYN 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 use CASPOLYN

CASPOLYN should not be administered to you:

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

If you have any liver problems, talk to your doctor before you are given **CASPOLYN**.

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

Warnings and precautions

Tell your doctor immediately if you experience a rash or inflamed skin, swelling around the eyes, lips, hands or feet or difficulty breathing. You may be experiencing an allergic reaction to **CASPOLYN**.

Tell your doctor or health care provider before being given **CASPOLYN** 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 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.

CASPOLYN may also cause Serious Cutaneous Adverse Reactions such as Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN).

CASPOLYN can have an effect on your liver. Your doctor will conduct tests to monitor your liver function.

FINAL PROPOSED PATIENT INFORMATION LEAFLET (CLEAN COPY)

Other medicines and CASPOLYN

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

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 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 **CASPOLYN**.

Pregnancy, breastfeeding and fertility

Pregnancy

- If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.
- **CASPOLYN** has not been studied in pregnant women. Animal studies have shown developmental toxicity. It should therefore not be used in pregnancy.
- Women given **CASPOLYN** should not breast-feed.

Driving and using machines

- There is no information to suggest that **CASPOLYN** affects your ability to drive or operate machinery.
- It is not always possible to predict to what extent **CASPOLYN** may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which

FINAL PROPOSED PATIENT INFORMATION LEAFLET (CLEAN COPY)

CASPOLYN affects you.

CASPOLYN contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

3. How to use CASPOLYN

Do not share medicines prescribed for you with any other person.

You will not be expected to give **CASPOLYN** to yourself. It will be given to you by a person who is qualified to do so.

You will be given **CASPOLYN**:

- 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 **CASPOLYN** you will be given each day. Your doctor will monitor how well the medicine works for you.

Children and adolescents

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

If you have the impression that the effect of **CASPOLYN** is too strong or too weak, tell your doctor or pharmacist.

If you receive more CASPOLYN than you should:

FINAL PROPOSED PATIENT INFORMATION LEAFLET (CLEAN COPY)

Since a healthcare professional will administer **CASPOLYN**, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take CASPOLYN

Since a healthcare professional will administer **CASPOLYN**, it is unlikely that the dose will be missed.

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

4. Possible side effects

CASPOLYN can have side effects.

Not all side effects for **CASPOLYN** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **CASPOLYN**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **CASPOLYN**. You may need urgent medical attention

Other side effects include:

Frequent side effects

- 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

FINAL PROPOSED PATIENT INFORMATION LEAFLET (CLEAN COPY)

- 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.

Less Frequent side effects

- 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 calcium level in the blood, increase 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 heartbeats, rapid heartbeat, irregular heartbeat, 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

FINAL PROPOSED PATIENT INFORMATION LEAFLET (CLEAN COPY)

- 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, generalized 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

Frequent

- Fever
- 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

FINAL PROPOSED PATIENT INFORMATION LEAFLET (CLEAN COPY)

Reporting of side effects

If you get side effects, talk to your <doctor><or><,><pharmacist><or nurse>. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug**

Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of

CASPOLYN.

5. How to store CASPOLYN

- Store all medicines out of reach of children
- Store in a refrigerator (2 °C to 8 °C).
- 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.
- Once **CASPOLYN** 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 “Instructions of how to reconstitute and dilute **CASPOLYN**”).
- Store in original package until use.
- Do not use after the expiry date stated on the label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CASPOLYN contains

- The active substance is caspofungin acetate.
- **CASPOLYN 50** powder for concentrate for solution for infusion:

FINAL PROPOSED PATIENT INFORMATION LEAFLET (CLEAN COPY)

Each vial of **CASPOLYN 50** contains 50 mg of caspofungin.

- **CASPOLYN 70** powder for concentrate for solution for infusion:

Each vial of **CASPOLYN 70** contains 70 mg of caspofungin.

- The other ingredients are sucrose, mannitol, glacial acetic acid, sodium hydroxide and nitrogen.

What CASPOLYN looks like and contents of the pack

- **CASPOLYN** is a white to off white cake or powder packed in a container consist of 10 ml Type I glass vial with a grey bromobutyl rubber stopper and a flip-off seal with a plastic cap.
- Pack size: 1 vial

HOLDER OF CERTIFICATE OF REGISTRATION

Accord Healthcare (Pty) Ltd

Tuscany Office Park,

6 Coombe Place

Rivonia

Johannesburg

South Africa

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CASPOLYN 50 : 55/20.2.2/0831

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