PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

CASCAGIN 50 (50 mg) lyophilised powder for solution for IV infusion.

CASCAGIN 70 (70 mg) lyophilised powder for solution for IV infusion.

Caspofungin.

Contains sucrose.

CASCAGIN 50: Each vial contains 35,7 mg of sucrose.

CASCAGIN 70: Each vial contains 50,0 mg of sucrose.

Read all of this leaflet carefully before you are given **CASCAGIN.**

- 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 CASCAGIN is and what it is used for

2. What you need to know before you take CASCAGIN

3. How to take CASCAGIN

4. Possible side effects

5. How to store CASCAGIN

6. Contents of the pack and other information

1. What CASCAGIN is and what it is used for

CASCAGIN contains a medicine called caspofungin. It belongs to a group of medicines called antifungals.

CASCAGIN interferes with the production of the fungal cell wall, making the fungal cells fragile and unable to grow properly. This stops the infection from spreading and gives the body's natural defenses a chance to completely get rid of the infection.

CASCAGIN is used to treat certain types of fungal infections in adults and children 3 months to 17 years of age.

2. What you need to know before you take CASCAGIN

CASCAGIN should not be given to you:

- If you are allergic to caspofungin or any of the other ingredients of this medicine (listed in section 6).
- If you have severe liver dysfunction, or if you child has any degree of liver dysfunction.

Warnings and precautions

Tell your doctor or healthcare professional before being given CASCAGIN:

- If you are allergic to any other medicines or have a history of allergic skin reactions. CASCAGIN may also cause serious skin adverse reactions including skin peeling, mucous membrane sores, hives, or large areas of peeling skin (known as Stevens-Johnson Syndrome and toxic epidermal necrolysis).
- If you have or ever have had liver problems. You might need a lower dose of CASCAGIN, and your doctor might want to monitor your liver function closely.
- If you are already taking ciclosporin (used to help prevent organ transplant rejection or to suppress your immune system). Your doctor may need to run extra blood tests during treatment with CASCAGIN.

Paediatric Patients

Do not use in children under the age of 3 months since there are not enough studies regarding the effectiveness or safety of CASCAGIN in this age group.

Other medicines and CASCAGIN:

Always tell your healthcare professional 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:

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking CASCAGIN.

- Safety in pregnancy and breastfeeding has not been established.
- Do not use CASCAGIN if you are pregnant. It has not been studied in pregnant women.
- Do not breastfeed if you are receiving CASCAGIN treatment.

Driving and using machines

It is not always possible to predict to what extent CASCAGIN may interfere with your daily activities. Do not engage in any activities requiring mental alertness, judgment and / or sound coordination and vision until you are aware of the measure to which CASCAGIN affects you.

CASCAGIN may cause side effects such as dizziness, disorientation, blurred vision and drowsiness. This may impair your ability to drive or operate machinery.

CASCAGIN contains sucrose

This medicine contains sucrose (a type of sugar). If you have been told by your doctor that you cannot tolerate, or digest certain sugars talk to your doctor, nurse or pharmacist before you are given CASCAGIN.

3. How to take CASCAGIN

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

You will be given CASCAGIN:

- 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 CASCAGIN you will be given each day. Your doctor will also monitor how well CASCAGIN works for you.

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

Your doctor will tell you how long your treatment with CASCAGIN will last. Do not stop treatment because you feel better. If you have the impression that the effect of CASCAGIN is too strong or too weak, tell your doctor or pharmacist.

If you take more CASCAGIN than you should

Since a healthcare professional will administer CASCAGIN, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage. If you are worried that you may have been given too much CASCAGIN tell your doctor or nurse straight away.

If you forget to take a dose of CASCAGIN:

Since a healthcare professional will administer CASCAGIN, it is unlikely that the dose will be missed. If you are concerned that you may have missed a dose, contact your doctor or another healthcare professional immediately.

4. Possible side effects

CASCAGIN can have side effects.

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

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 with wheezing. You may be having a histamine reaction or an allergic reaction to CASCAGIN.
- 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.
- rash, peeling skin, mucous membrane sores, hives and large areas of peeling skin (known as Stevens-Johnson Syndrome and toxic epidermal necrolysis).

These are all very serious side effects. If you have them, you may have had a serious reaction to of side effect from CASCAGIN. You may need urgent medical attention or hospitalisation.

Other frequent side effects in adults include:

- Anaemia, decreased haemoglobin (decreased oxygen carrying substance in the blood), or decreased haematocrit (decrease in volume percentage of red blood cells in 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 a vein which can be related to a blood clot.
- 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 and itching at the injection site.

Other less frequent side effects in adults include:

- Changes in some laboratory blood tests (including that 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 blood sugar level, low calcium level in the blood, increase calcium level in the blood, increase magnesium level in the blood and increase in acid level in the blood.
- Disorientation, feeling nervous and being unable to sleep.
- Feeling dizzy, decreased feeling or sensitivity (especially in the skin), shaking, feeling sleepy, change in the way things taste and tingling or numbness.

- Blurred vision, increase in tears, swollen eyelid and yellowing of the whites of the eyes.
- Sensation of fast or irregular heartbeats, rapid heartbeat, irregular heartbeat, abnormal heart rhythm and heart failure.
- Flushing, hot flush, high blood pressure and low blood pressure.
- 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 and throat pain.
- Belly pain, upper belly pain, bloating, constipation, difficulty swallowing, dry mouth, indigestion, passing gas, stomach discomfort and 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 medicine or chemical, liver disorder / abnormal liver function and increase in the liver enzyme, gamma-glutamyltransferase.
- Abnormal skin tissue, generalised itching, hives, rash of varying appearance, and 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 and muscle weakness.
- Loss of kidney function or sudden onset of kidney function loss.
- Catheter site pain, injection / infusion site complaints (redness, hard lump, pain, swelling, irritation, rash, hives, leaking of fluid from the catheter into the tissue) and inflammation of the vein at injection site.
- Changes (increased / decreased) in some laboratory blood tests (including kidney electrolyte and clotting tests) and increased levels of the medicines you are taking that weaken the immune system.

- Chest discomfort, chest pain, feeling of body temperature change (feeling hot or feeling cold), generally feeling unwell, general pain, swelling of the face, swelling of the ankles, hands or feet, swelling, tenderness, feeling tired.

Frequent side effects in children and adolescents:

- Headache, itching, rash, catheter site pain, fever and chills.
- Fast heartbeat, flushing and low blood pressure.
- Changes in some laboratory blood tests and increased values of some liver tests.

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

Reporting of side effects

If you get 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 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 this medicine.

5. How to store CASCAGIN

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Unopened vials must be stored in a refrigerator (2 - 8 °C).
- Once CASCAGIN 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 directions should prepare the medicine.
- CASCAGIN should not be used if the solution is cloudy or has a precipitate.
- Do not use after the expiry date printed on the label or carton.

- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CASCAGIN contains

The active substance is caspofungin.

CASCAGIN 50: Each 10 ml vial contains 50 mg caspofungin (as acetate).

CASCAGIN 70: Each 10 ml vial contains 70 mg caspofungin (as acetate).

The other ingredients are: carbon dioxide (to adjust the pH), hydrochloric acid (to adjust the pH), mannitol, sodium hydroxide (to adjust the pH) and sucrose.

What CASCAGIN looks like and contents of the pack

Unopened vials: Each vial of CASCAGIN contains a white to off-white cake or powder.

Once reconstituted and diluted, it is a clear solution free of visible particles.

Each pack/carton of CASCAGIN contains one (1) glass vial. CASCAGIN 50 has a white plastic flip-off cap. CASCAGIN 70 has a blue plastic flip-off cap.

Holder of Certificate of Registration

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