PATIENT INFORMATION LEAFLET

IVECAS IV RANGE

SCHEDULING STATUS:

S4

IVECAS 50 IV powder for solution for infusion

IVECAS 70 IV powder for solution for infusion

Caspofungin

Contains sugar (sucrose and the sugar alcohol, mannitol)

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

Each 70 mg vial contains sucrose 50,0 mg and mannitol 33,3 mg

Read all of this leaflet carefully before you or your child are given IVECAS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- IVECAS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What IVECAS is and what it is used for

IVECAS is an antifungal medicine containing caspofungin that interferes with the production of a component (glucan polysaccharide) of the fungal cell wall that is necessary if the fungus is to continue living and growing. Fungal cells exposed to IVECAS have incomplete or defective cell walls, making them

fragile and unable to grow.

IVECAS 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 are administered IVECAS

IVECAS should not be administered to you

Tell your doctor or healthcare professional before being given the injection if:

- if you are hypersensitive (allergic) to caspofungin or any of the other ingredients of IVECAS (see section 6)
- if you have very poor liver function.

You should not be administered IVECAS if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before IVECAS is administered to you.

Warnings and precautions

Tell your doctor or healthcare professional before being given the injection:

- if you are allergic to any other medicines
- if 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 liver problems, as your doctor may want to change your dose of IVECAS
- if you have any other medical problem.

IVECAS may also cause serious skin reactions such as Stevens-Johnson syndrome (SJS) (painful skin condition that causes painful blister and sores of the skin and mucous membranes, especially in the mouth) and toxic epidermal necrolysis (TEN) (serious illness with blistering of the skin).

Children and adolescents

No information is available on the use of IVECAS in infants under 3 months of age and it should therefore

not be administered to them.

Other medicines and IVECAS

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional 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 due to possible higher levels of certain liver enzymes and lower levels of tacrolimus in your blood
- rifampicin (an antibiotic used for tuberculosis (TB) or other infections) as the effect of IVECAS can be increased
- the following medicines as it may lower the caspofungin levels in your blood:
    - some human immunodeficiency virus (HIV) medicines such as efavirenz or nevirapine
    - phenytoin or carbamazepine (used for the treatment of seizures)
    - dexamethasone (a steroid - used for inflammation).

If you are not sure, talk to your doctor or healthcare provider before you are given IVECAS.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before IVECAS is administered to you.

IVECAS has not been studied in pregnant women. You should not use IVECAS when you are pregnant.

It is not known if IVECAS is excreted in human breastmilk. You should not breastfeed your baby whilst on treatment with IVECAS.

Driving and using machines

IVECAS may make you feel dizzy or sleepy and may cause blurry vision. You should not drive or use machines until you know how treatment with IVECAS affects you.

It is not always possible to predict to what extent IVECAS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which IVECAS affects them.

IVECAS contains sugar

IVECAS contains sucrose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor, nurse or pharmacist before you are given IVECAS.

IVECAS contains sodium

Ivecas contains less than 1 mmol (0,023 mg) sodium per 10 mL, that is to say essentially 'sodium free.'

3. How to use IVECAS

Do not share medicines prescribed for you or your child with any other person.
You will not be expected to give IVECAS to yourself. It will be given to you by a person who is qualified to do so.
IVECAS will be given once daily and will be slowly dripped into a vein (intravenous infusion), over about an hour.
Your doctor will decide on your dose. It will depend on the type of infection, your weight and your liver function.

Your doctor will work out the dose for your child, based on his/her height and weight.
The dose for children and adolescents may differ from the adult dose.

Your doctor will tell you how long your treatment with IVECAS will last.
If you have the impression that the effect of IVECAS is too strong or too weak, tell your doctor or pharmacist.

If you use more IVECAS than you should

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

If you forget to use IVECAS

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

If you stop using IVECAS

Do not stop receiving treatment before your doctor agrees; the fungus (mould) causing the disease may become resistant to IVECAS.

4. Possible side effects

IVECAS can have side effects.

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

If any of the following happens, stop using IVECAS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash that gets worse or itching
- fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- cough, serious breathing difficulties - if you are an adult and have invasive aspergillosis (infection, usually of the lungs) you may be experiencing a serious respiratory problem that could result in respiratory failure
- rash, skin peeling, mucous membrane sores, hives, large areas of peeling skin
- decreased flow of bile, enlarged liver, yellowing of the skin and/or whites of the eyes (jaundice), liver injury, liver disorder
- if your child or adolescent is having a faster heartbeat than normal.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- decreased haemoglobin (decreased oxygen carrying substance in the blood) and red blood cell count – you may feel weak, dizzy and have a headache
- feeling tired and getting infections easily (low white blood cell count)
- decreased blood albumin (a type of protein) in your blood, decreased potassium or low potassium levels in the blood
- headache
- inflammation of the vein (red and tender skin)
- shortness of breath
- nausea (feeling sick), vomiting (being sick), diarrhoea (loose bowels)
- changes in some laboratory tests (including increased values of some liver tests)
- skin rashes, itching, redness, sweating more than usual
- joint pains
- fever, chills

- itching at the site of the injection
- catheter site pain, flushing, low blood pressure.

Less frequent side effects:

- changes in some laboratory blood tests (including diseases of blood clotting, platelets and white blood cells)
- bruising or bleeding more easily and feeling tired. This could be because of various blood problems. Your blood will be tested in hospital
- loss of appetite
- swelling (increase in amount of body fluid), imbalance of salts/electrolytes 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
- confusion, feeling tired, having tremors (metabolic acidosis; this occurs when your body produces too much acid)
- low blood pressure (you may feel dizzy when getting up)
- 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, palpitations (feeling your 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, stuffy nose, 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
- 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
- injection/infusion 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, feeling hot, feeling cold
- alterations in some laboratory blood and urine 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, tenderness, feeling tired.

The following side effects have been reported but the frequency for them to occur is not known:

- Stevens-Johnson syndrome (SJS) (painful skin condition that causes painful blister and sores of the skin and mucous membranes, especially in the mouth) and toxic epidermal necrolysis (TEN) (serious illness with blistering of the skin)

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. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of IVECAS. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of

the product.

5. How to store IVECAS

Store all medicines out of reach of children.

Store in the original outer packaging in a refrigerator at or between 2 to 8 °C.

Do not freeze.

Reconstituted concentrate should be used immediately. Chemically and physically stable for 24 hours at or below 25 °C or in the refrigerator at 2 to 8 °C prior to the preparation of the infusion solution.

Your healthcare provider will check that IVECAS is not past its expiry date stated on the label and carton before giving you the injection.

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 IVECAS contains

The active substance is caspofungin.

- each 10 mL vial of IVECAS 50 IV contains caspofungin acetate equivalent to caspofungin50 mg
- each 10 mL vial of IVECAS 70 IV contains caspofungin acetate equivalent to caspofungin 70 mg

The other ingredients are glacial acetic acid, mannitol, sodium hydroxide (for pH adjustment) and sucrose.

What IVECAS looks like and contents of the pack

Unopened vials

Each vial of IVECAS contains white to off-white lyophilised powder.

Reconstituted product in vials

Clear solution essentially free from visible particles.

Diluted product for infusion

Clear solution essentially free from visible particles.

IVECAS 50 IV and 70 IV lyophilised powder for solution for infusion are supplied in clear glass type I, 10 mL vials, sealed with a rubber stopper and an aluminium band with a plastic flip-off cap.

Holder of Certificate of Registration

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