PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ERAXIS® 100 mg Powder for solution for infusion

Anidulafungin

Contains sugar (120 mg fructose and 500 mg mannitol)

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

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

What is in this leaflet

1. What ERAXIS is and what it is used for

ERAXIS belongs to a group of medicines called echinocandins. These medicines are used to treat serious fungal infections. ERAXIS is used in adults and in children and adolescents from 1 month of age.

2. What you need to know before you or your child are given ERAXIS

ERAXIS should not be administered to you or your child

if you are hypersensitive (allergic) to anidulafungin, other echinocandins (e.g. caspofungin) or any of the other ingredients of ERAXIS (listed in section 6).

Warnings and precautions

Take special care with ERAXIS

if you develop a serious allergic reaction during treatment. If these reactions occur, ERAXIS should be stopped.

if there are infusion-related side effects (side effects caused due to an injection) like rash, severe rash on the skin, difficulty breathing and low blood pressure.

if you develop liver problems during your treatment. If this happens, your doctor may decide to monitor your liver function more closely.

Children and adolescents

ERAXIS should not be given to patients under 1 month of age.

Other medicines and ERAXIS

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

There are no known interactions with other medicines likely to be given at the same time as ERAXIS (i.e. rifampicin, cyclosporin, tacrolimus, voriconazole, amphotericin B or other medicines used to treat TB or HIV).

Do not start or stop any other medicines without your doctor or pharmacist's approval.

Pregnancy and breastfeeding

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 you are given this medicine.

Safety in pregnancy and breastfeeding has not been established. You should not be given ERAXIS if you are pregnant or planning to become pregnant unless there is no safer treatment option available.

Effective contraception should be used in women of childbearing age who are receiving ERAXIS and for two weeks after discontinuation of ERAXIS treatment. Contact your doctor immediately if you become pregnant while taking ERAXIS.

ERAXIS must not be administered during breastfeeding.

Driving and using machines

You may experience side effects that can affect your eyesight, brain and spinal cord, and which can affect your ability to drive and use machinery.

It is not always possible to predict to what extent ERAXIS 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 ERAXIS affects you.

ERAXIS contains fructose and sodium

Fructose

If you (or your child) have hereditary fructose intolerance (HFI), a rare genetic disorder, you (or your child) must not receive this medicine. Patients with HFI cannot break down fructose in this medicine, which may cause serious side effects.

You must tell your doctor before receiving this medicine if you (or your child) have HFI or if your child can no longer take sweet foods or drinks because they feel sick, vomit or get unpleasant effects such as bloating, stomach cramps or diarrhoea.

Sodium

ERAXIS contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially ‘sodium-free’.

3. How ERAXIS will be administered to you or your child

Your doctor will tell you how long your treatment with ERAXIS will last.

You will not be expected to give yourself ERAXIS. ERAXIS will always be prepared and given to you by a person who is qualified to do so.

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

In adults, the treatment starts with 200 mg on the first day (loading dose). This will be followed by a daily dose of 100 mg (maintenance dose).

In children and adolescents (from 1 month to less than 18 years), the treatment starts with 3,0 mg/kg (not to exceed 200 mg) on the first day (loading dose). This will be followed by a daily dose of 1,5 mg/kg (not to exceed 100 mg) (maintenance dose). The dose that is given depends on your child's weight.

ERAXIS should be given to you once a day, by slow infusion (a drip) into your vein. This will take at least 1,5 hours for the maintenance dose and 3 hours for the loading dose. For your child/adolescent, the infusion may take less time depending on his/her weight.

Your doctor will determine the duration of treatment and how much ERAXIS you will receive each day and will monitor your response and condition.

In general, your treatment should continue for at least 14 days after the last day *Candida* was found in your blood.

If you or your child receive more ERAXIS than you should

Since a health care provider will administer ERAXIS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you are concerned that you or your child may have been given too much ERAXIS, tell your doctor or health care provider immediately.

If you or your child forget to receive a dose of ERAXIS

Since a health care provider will administer ERAXIS, it is unlikely that a dose will be missed. However, tell your doctor or health care provider if you think that a dose has been forgotten.

If you or your child stop receiving ERAXIS

You should not experience any effects from ERAXIS if your doctor stops ERAXIS treatment.

Your doctor may prescribe another medicine following your treatment with ERAXIS to continue treating your fungal infection or prevent it from returning.

If your original symptoms come back, tell your doctor or health care provider immediately.

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

4. Possible side effects

ERAXIS can have side effects.

Not all side effects for ERAXIS are included in this leaflet. Should you or your child's general health worsen or if you experience any untoward effects while receiving ERAXIS, please consult your health care provider for advice.

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

- convulsions (seizure)
- rash, pruritus (itching)
- hives
- bronchospasm* (sudden contraction of the muscles around the airways resulting in wheezing or coughing)
- anaphylactic shock and reactions* (life threatening allergic reactions on the body, skin and face)

**Side effects reported during post-marketing.*

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

Tell your doctor if you notice any of the following:

Frequent side effects

- disorder of clotting system
- convulsions (seizures)
- headache
- flushing
- diarrhoea
- rash, pruritus (itching)

Your doctor will perform various tests which will determine your heart rate, kidney and liver function as well the mineral (potassium, magnesium, sodium, calcium), uric acid, bilirubin, creatinine and blood cell levels (red and white) in your body.

Less frequent side effects

- fungal infections including oral thrush
- inflammation of the colon (diarrhoea with or without blood, abdominal pain, fever, urgency to have a bowel movement, nausea, bloating, fatigue and weight loss)

- blood disorders. Symptoms for the various blood disorders which you may notice can include:
  - thrombocythemia: blood clots, bruising easily, bleeding from your nose, gums, and gastrointestinal tract, bloody stools, bleeding after injury or surgery, weakness, headache and dizziness
  - neutropenia: fever, chills or sweating, sores in your mouth, toothache, sore throat, cough or shortness of breath, abdominal pain, pain near your anus, pain or burning when urinating, urinating often, diarrhoea or sores around your anus
  - leukopenia: mouth or skin sores, sore throat, cough, trouble breathing, feeling light-headed, fever, chills, body aches
  - anaemia: fatigue, weakness, irregular heartbeats, shortness of breath, dizziness, chest pain, cold hands and feet, pale or yellowish skin
- high blood sugar
- eye pain, blurry vision
- heart rhythm disturbances
- blood clots
- high blood pressure
- hot flush
- stomach pain
- nausea, vomiting
- inability to control bowel movements
- constipation
- abnormal flow of bile from gallbladder into the intestine (cholestasis)
- hives
- back pain
- pain at injection site
- feeling anxious and confused
- hearing noises
- feeling dizzy
- the sensation of ‘pins and needles’ on the body

- nervous system disorders (confusion, hallucinations, problems with your balance, difficulty swallowing, disturbances in taste, reduced alertness, drowsiness, slurred speech, weakness in your face, arms, or legs, usually affecting both sides of your body)
- tremors
- unable to see properly
- swelling of the veins
- low blood pressure
- swelling of the lymph glands (hard lumps or masses may be felt under your skin in the area of the swollen lymph node. You may also experience fever, night sweats, weight loss, loss of appetite and abdominal pain)
- indigestion
- dry mouth
- ulcers in the food pipe
- liver disease (your skin and eyes appear yellowish (jaundice), abdominal pain and swelling, swelling of your legs and ankles, itchy skin, the colour of your urine may be dark and your stool pale in colour, chronic fatigue, nausea or vomiting)
- swelling of the body and face
- excessive sweating
- muscle pain
- swelling of the joints
- kidney failure (you may have a decreased urine output, swelling in your legs, ankles or feet, shortness of breath, fatigue, confusion, nausea, weakness and an irregular heartbeat)
- presence of blood in urine
- fever and chills

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

Reporting of side effects

If you or your child get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions 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 ERAXIS.

5. How to store ERAXIS

- Store all medicines out of reach of children.
- Store in a refrigerator (2 °C – 8 °C).
- Excursions for up to 96 hours at temperatures up to 25 ºC are permitted, and the powder may be returned to refrigerated storage (2 °C – 8 ºC).
- The reconstituted solution may be stored at temperatures up to 25 °C for up to 24 hours. Do not freeze.
- The infusion solution may be stored at 25 °C for up to 48 hours. Do not freeze.
- Do not use ERAXIS after the expiry date which is 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. What ERAXIS contains

The active substance is anidulafungin. Each vial of powder contains 100 mg anidulafungin.

The reconstituted solution contains 3,33 mg/mL anidulafungin and the diluted solution contains 0,77 mg/mL anidulafungin.

The other ingredients are

Fructose

Mannitol

Polysorbate 80

Tartaric acid

What ERAXIS looks like and contents of the pack

A vial containing a white to off-white powder.

ERAXIS is available in a carton containing one clear vial of ERAXIS 100 mg powder for solution for infusion.

Holder of Certificate of Registration

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton 2196

South Africa

Tel: +27(0)11 320 6000 / 0860 734 937 (Toll-free South Africa)

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