AMENDED PROPOSED PATIENT INFORMATION LEAFLET (CLEAN COPY)

SCHEDULING STATUS

S4

ANIDULAFUNGIN ACCORD 100 mg

(Powder for Concentrate for Solution for Infusion)

Anidulafungin

Contains fructose 102,5 mg per vial and

Mannitol 512,5 mg per vial

Read all of this leaflet carefully before you are given ANIDULAFUNGIN ACCORD

- 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 ANIDULAFUNGIN ACCORD is and what it is used for
2. What you need to know before you are given ANIDULAFUNGIN ACCORD
3. How ANIDULAFUNGIN ACCORD will be administered to you
4. Possible side effects
5. How ANIDULAFUNGIN ACCORD should be stored
6. Contents of the pack and other information

1. What ANIDULAFUNGIN ACCORD is and what it is used for

- ANIDULAFUNGIN ACCORD contains the active substance anidulafungin.
- Anidulafungin is used to treat a type of fungal infection of the blood or other internal organs called invasive candidiasis. The infection is caused by fungal cells (yeasts) called Candida.
- Anidulafungin belongs to a group of medicines called echinocandins. These medicines are used to treat

serious fungal infections.

- Anidulafungin prevents normal development of fungal cell walls. In the presence of anidulafungin, fungal cells have incomplete or defective cell walls, making them fragile or unable to grow.
- ANIDULAFUNGIN ACCORD is used in adults and children and adolescents from 1 month of age.

2. What you need to know before you use ANIDULAFUNGIN ACCORD

ANIDULAFUNGIN ACCORD should not be administered to you:

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

Warnings and precautions

Take special care with ANIDULAFUNGIN ACCORD

- if you develop liver problems during your treatment, your doctor will conduct tests to monitor your liver function
- this medicine can cause an allergic reaction. If you experience a skin rash, nausea, vomiting or difficulty breathing, tell your doctor immediately.
- You may experience infusion-related side effects (side effects as a result of the injection). These may include an itchy skin rash, redness, difficulty breathing or low blood pressure.

Children and adolescents

ANIDULAFUNGIN ACCORD should not be used in patients under 1 month old.

Other medicines and Anidulafungin Accord

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

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

Pregnancy and breast-feeding

- 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.
- You should avoid treatment with ANIDULAFUNGIN ACCORD if you are pregnant, as safety in pregnancy has not been established.
- If you are a woman of childbearing age, you and your partner should use a good contraceptive while you are on treatment with ANIDULAFUNGIN ACCORD and for 2 weeks after your treatment stops.
- You should avoid treatment with ANIDULAFUNGIN ACCORD if you are breastfeeding as it is not known if anidulafungin passes into the breast milk.

Driving and using machines

You may experience side effects that can affect your eyesight or cause dizziness, and which can affect your ability to drive and use machinery.

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

ANIDULAFUNGIN ACCORD contains 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.

3. How ANIDULAFUNGIN ACCORD will be administered to you

You will not be expected to give ANIDULAFUNGIN ACCORD to yourself. It will be given to you by a person who is qualified to do so (there is more information about the method of preparation at the end of the leaflet in the section for medical and healthcare professionals only).

The usual dose is 200 mg on the first day (loading dose). This will be followed by a daily dose of 100mg (maintenance dose).

ANIDULAFUNGIN ACCORD 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.

Your doctor will determine the duration of your treatment and how much ANIDULAFUNGIN ACCORD 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 receive more ANIDULAFUNGIN ACCORD than you should:
Since a healthcare professional will administer ANIDULAFUNGIN ACCORD, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take ANIDULAFUNGIN ACCORD
Since a healthcare professional will administer ANIDULAFUNGIN ACCORD, it is unlikely that the dose will be missed.

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If you stop using ANIDULAFUNGIN ACCORD

You should not experience any effects from ANIDULAFUNGIN ACCORD if your doctor stops treatment. If your original symptoms come back tell your doctor or healthcare provider.

4 Possible side effects

ANIDULAFUNGIN ACCORD can have side effects.

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

If any of the following happens, ANIDULAFUNGIN ACCORD should be stopped immediately or you should go to your casualty department at your nearest hospital:

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

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

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

- Unexplained bleeding or bruising
- skin rash, nausea, vomiting or difficulty breathing – you may be experiencing a reaction to the medicine
- Seizures (fits)
- Chest pain, or changes in your heart beat

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- Yellowing of skin or eyes, stomach pain, dark urine, itchy skin or swelling of legs and ankles – these may indicate a problem with your liver

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:

- Weakness, muscle cramps, confusion and nausea – may indicate an imbalance of potassium or magnesium levels; your doctor will need to perform some tests
- Headache
- Flushing – a feeling of warmth accompanied by redness especially on the face and neck
- Tightness in chest, difficulty breathing
- Diarrhoea

Less frequent side effects:

- White patches on the inner cheeks, tongue, roof of the mouth, red patches on skin, burning sensation, swelling– might indicate a fungal infection
- Fever, chills, swollen glands – this might indicate inflammation of your glands
- Increased thirst, more frequent urination, muscle weakness, restlessness, nausea or vomiting – this may indicate an imbalance of some of the elements and proteins in your blood and your doctor will need to perform tests.
- Feeling anxious, confused, hearing sounds which are not real
- Dizziness, pins and needles, tremors, changes in taste
- Eye pain, changes in vision, blurred vision
- Deafness in one ear
- Low or high blood pressure
- nausea, vomiting

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- Swelling or pain and redness in the leg
- Stomach pain, constipation, dry mouth, inability to control your bowel movements
- Skin rash, increased sweating
- Back pain, muscle pain, joint pain or swelling and stiffness
- Fever, chills

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><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 "**Adverse drug reaction and quality problem reporting form**", found online under SAHPRA's publications: https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/.. By reporting side effects, you can help provide more information on the safety of ANIDULAFUNGIN ACCORD.

5. How to store ANIDULAFUNGIN ACCORD

- Store all medicines out of reach of children.
- Store in a refrigerator (2 °C – 8 °C). Do not freeze.
- **After reconstitution:**
- The reconstituted solution may be stored up to 25 °C for up to 24 hours. From a microbiological point of view the product should be used immediately. If not used immediately, the in-use storage times and conditions prior to use are the responsibility of the user.
- The infusion solution may be stored at 25 °C (room temperature) for 48 hours and should be administered at 25 °C (room temperature) within 48 hours.
- The vial is for single use only.

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6. Contents of the pack and other information

What ANIDULAFUNGIN ACCORD contains

- The active substance is anidulafungin.
- Each vial contains 100 mg anidulafungin.
- The other ingredients are fructose, mannitol, polysorbate 80, lactic acid, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment).

What ANIDULAFUNGIN ACCORD looks like and contents of the pack

- The cake or powder is white to off-white**.**
- The powder is contained in a 30 mL type I colorless glass vial with bromobutyl rubber stopper and aluminum flip-off cap with plastic button.
- Pack size: 1 vial

HOLDER OF CERTIFICATE OF REGISTRATION

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South Africa

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