

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

Arandi™ 100 mg powder for concentrate for solution for infusion

Anidulafungin.

ARANDI 100 mg contains sugar (fructose 100 mg per vial)

Read all of this leaflet carefully before you are given ARANDI 100 mg

- 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 ARANDI 100 mg is and what it is used for.
2. What you need to know before you are given ARANDI 100 mg.
3. How to use ARANDI 100 mg.
4. Possible side effects.
5. How to store ARANDI 100 mg.
6. Contents of the pack and other information.

1. What ARANDI 100 mg is and what it is used for

ARANDI 100 mg contains the active substance anidulafungin and is used to treat:

- A type of fungal infection of the blood or other internal organs called invasive candidiasis in adult patients. The infection is caused by fungal cells (yeasts) called *Candida*.

How it works:

- ARANDI 100 mg belongs to a group of medicines called echinocandins. These medicines are used to treat serious fungal infections.
- ARANDI 100 mg prevents normal development of fungal cell walls. In the presence of ARANDI 100 mg, fungal cells have incomplete or defective cell walls, making them fragile or unable to grow.

2. What you need to know before you are given ARANDI 100 mg

ARANDI 100 mg 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 ARANDI 100 mg (listed in section 6).
- You are pregnant or breastfeeding.
- You are under 18 years of age.

You should not be given anidulafungin if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before you are given anidulafungin. This is because anidulafungin can make these problems worse.

Warnings and precautions:

Tell your doctor or pharmacist if any of the following apply to you before starting treatment. This is because ARANDI 100 mg can make these problems worse. Special care should be taken with ARANDI 100 mg:

- If you have liver problems.
- If you have previously been prescribed anidulafungin or other echinocandins and experienced any hypersensitive (allergic) or infusion-related reactions.

Your doctor may decide to monitor you:

- More closely for liver function if you develop liver problems during your treatment.
- If you are given anaesthetics during your treatment with ARANDI 100 mg.

- For signs of an allergic reaction such as itching, wheezing, blotchy skin.
- For shortness of breath/breathing difficulties, dizziness or light-headedness.

Children and adolescents:

ARANDI 100 mg should not be given to patients under the age of 18 years.

Other medicines and ARANDI 100 mg:

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

Important information about some of the ingredients of ARANDI 100 mg:

If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you receive ARANDI 100 mg.

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 using this medicine.

It is not known if anidulafungin will affect an unborn baby.

Therefore, ARANDI 100 mg is not recommended during pregnancy.

The effect of ARANDI 100 mg in breastfeeding women is not known. Ask your doctor, pharmacist or other healthcare provider for advice before using ARANDI 100 mg while breastfeeding.

3. How to use ARANDI 100 mg

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

You will not be expected to give yourself ARANDI 100 mg. It will be given to you by a person who is qualified to do so.

The treatment starts with 200 mg on the first day. This will be followed by a daily dose of 100 mg. ARANDI 100 mg should be given to you once a day by slow infusion (a drip) into your vein.

Your doctor will tell you how long your treatment with ARANDI 100 mg will last. If you have the impression that the effect of ARANDI 100 mg is too strong or too weak, tell your doctor or pharmacist.

If you receive more ARANDI 100 mg than you should:

Since a health care provider will administer ARANDI 100 mg, they will control the dosage.

However, in the event of an overdose your doctor will manage the overdose. In case of overdose, side-effects may occur as mentioned in section 4.

If you are concerned that you may have been given too much ARANDI 100 mg, tell your doctor or other health care provider immediately.

If you forget to use ARANDI 100 mg:

Since a health care provider will administer ARANDI 100 mg, it is unlikely that the dose will be missed.

Tell your doctor, pharmacist or other health care provider if you think that a dose has been forgotten.

If you stop using ARANDI 100 mg:

Your doctor will decide when to stop treatment based on your clinical response to treatment.

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

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

4. Possible side effects

ARANDI 100 mg can have side effects.

Not all side effects reported for ARANDI 100 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ARANDI 100 mg, please consult your healthcare provider for advice.

If any of the following happens, stop using ARANDI 100 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Sudden contraction of the muscles around the airways resulting in difficulty in breathing, wheezing or coughing.
- Convulsion (seizure).
- Flushing.
- Rash, pruritus (itching).
- Hot flush.
- Hives.

These are all very serious side effects. If you have any of these side effects, you may have had a serious reaction to ARANDI 100 mg. 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:

- Presence of fungi or yeasts in the blood (fungaemia).
- Fungal infections caused by a yeast (a type of fungus) called Candida.

- Swelling or inflammation of the large intestine (colon) due to an overgrowth of *Clostridium difficile* bacteria (pseudomembranous colitis).
- Low blood potassium (hypokalaemia).
- High blood potassium (hyperkalaemia).
- Low blood magnesium (hypomagnesaemia).
- High blood calcium (hypercalcaemia).
- High blood sodium (hypernatraemia).
- Eye disorders: eye pain, visual disturbances and blurred vision.
- Heart disorders: irregular heartbeat that is either too fast or too slow, extra heartbeats.
- Changes in blood tests of liver function.
- Changes in blood tests of kidney function.
- Abnormal flow of bile from the gallbladder into the intestine (cholestasis).
- High blood sugar.
- High blood pressure.
- Low blood pressure.
- Disorder of the blood clotting system.

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:

- Diarrhoea.
- Nausea.
- Headache.
- Vomiting.

Less frequent side effects:

- Stomach pain.
- Bowel incontinence.

- Constipation.
- Back pain.
- Pain at injection site.

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.

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 ARANDI 100 mg.

Suspected adverse reactions can also be reported directly to the holder of the certificate of registration (HCR) via Patientsafety.sacg@novartis.com.

5. How to store ARANDI 100 mg

- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- **Before reconstitution:** Store at or between 2 °C to 8 °C (in a refrigerator). Do not freeze.
- The powder can be returned to refrigerated storage if it has been left out of the refrigerator for no longer than 96 hours at a temperature of no more than 25 °C.
- **Reconstituted solution:** The reconstituted solution may be stored at up to 25 °C for up to 24 hours.
- **Infusion solution:** The infusion solution may be stored at 25 °C for 48 hours. Do not freeze.
- Do not use ARANDI 100 mg if you notice that the solution is not clear, or you see particles in the solution.
- Do not use after the expiry date printed on the label / carton.

6. Contents of the pack and other information

What ARANDI 100 mg contains:

- The active substance is anidulafungin. 1 vial contains 100 mg anidulafungin.
- The other ingredients are fructose, mannitol, polysorbate 80, (S)-lactic acid, sodium hydroxide (for pH-adjustment), hydrochloric acid, concentrated (for pH-adjustment).

What ARANDI 100 mg looks like and contents of the pack:

ARANDI 100 mg powder for concentrate for solution for infusion is a white to off-white cake or powder.

ARANDI 100 mg powder for concentrate for solution for infusion is packed in a 30 ml colourless glass vial with a rubber stopper and aluminium flip-off cap with grey coloured disk. ARANDI 100 mg powder for concentrate for solution for infusion is packed in a carton with an enclosed leaflet.

Each carton contains 1 vial.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd¹

Magwa Crescent West

Waterfall City

Jukskei View

Midrand

2090

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Access to the corresponding Professional Information

Not applicable

¹Company Reg. No.: 1990/001979/07