

Applicant/PHCR: AUROGEN SOUTH AFRICA (PTY) LTD
Product proprietary name: AURO FLUCONAZOLE 50/100/150/200 mg
Dosage form and strength: CAPSULE 50/100/150/200 mg

Amended: 19/03/2021

APPROVED PATIENT INFORMATION LEAFLET

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AURO FLUCONAZOLE 50 mg (Capsule)

AURO FLUCONAZOLE 100 mg (Capsule)

AURO FLUCONAZOLE 150 mg (Capsule)

AURO FLUCONAZOLE 200 mg (Capsule)

Fluconazole

Read all of this leaflet carefully before you start taking AURO FLUCONAZOLE.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **AURO FLUCONAZOLE** 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.

1. WHAT AURO FLUCONAZOLE CONTAINS

The active substance is Fluconazole

AURO FLUCONAZOLE 50 mg

Each capsule contains 50 mg fluconazole

AURO FLUCONAZOLE 100 mg

Each capsule contains 100 mg fluconazole

AURO FLUCONAZOLE 150 mg

Each capsule contains 150 mg fluconazole

AURO FLUCONAZOLE 200 mg

Each capsule contains 200 mg fluconazole

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The other ingredients of **AURO FLUCONAZOLE** are lactose monohydrate, maize starch, sodium lauryl sulphate, silica, colloidal anhydrous and magnesium stearate. The empty hard gelatin capsule shell consists of gelatin, sodium lauryl sulfate and titanium dioxide (C.I. No: 77891). The capsules are printed with edible ink, shellac and yellow iron oxide (C.I. No: 77492).

2. WHAT AURO FLUCONAZOLE IS USED FOR

AURO FLUCONAZOLE is used to treat serious fungal infections that may occur in different parts of the body.

3. BEFORE YOU TAKE AURO FLUCONAZOLE

Do not take AURO FLUCONAZOLE:

- If you have a known hypersensitivity (allergy) to fluconazole or to any of the ingredients of **AURO FLUCONAZOLE** or to related azole compounds.
- If you are taking medicines such as cisapride, astemizole, pimozide and quinidine as these medicines may prolong the QT interval and may cause irregular heartbeats.
- If you are pregnant.
- If you are breastfeeding your baby.

Take special care with AURO FLUCONAZOLE:

- You will be closely monitored by your doctor if you have an underlying liver disease.
- The dose of **AURO FLUCONAZOLE** must be adjusted if you have kidney problems.
- If you develop rashes including blisters or pink to red symmetrically arranged blotches that are itchy, stop taking **AURO FLUCONAZOLE** and contact your doctor immediately.

Pregnancy and Breast-feeding:

If you are pregnant or breast-feeding your baby, please consult your doctor, pharmacist or other health care professional for advice.

You should not take **AURO FLUCONAZOLE** if you are pregnant, planning to become pregnant or breast-feeding your baby.

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Driving and using machinery:

AURO FLUCONAZOLE may cause problems with your vision. If affected do not drive or operate machinery.

Important information about some of the ingredients of AURO FLUCONAZOLE

AURO FLUCONAZOLE contains lactose, which is a type of sugar. So before taking **AURO FLUCONAZOLE**, please consult your doctor for advice if you have an intolerance to some sugars.

Taking other medicines with AURO FLUCONAZOLE:

AURO FLUCONAZOLE interacts with warfarin (medicines that thin the blood to prevent blood clots), short acting benzodiazepines (midazolam, triazolam or similar medicines used to help you sleep), ciclosporin, tacrolimus (to prevent transplant rejection) phenytoin, theophylline (used to control asthma), zidovudine (used to treat HIV-infection), cisapride (used for stomach upsets) and rifabutin (antibiotics for infections).

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **AURO FLUCONAZOLE** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

4. HOW TO TAKE AURO FLUCONAZOLE

Always take **AURO FLUCONAZOLE** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **AURO FLUCONAZOLE** is too strong or too weak, talk to your doctor or pharmacist.

The duration of treatment and dosage depends on the severity of the infection, clinical response and bacteriological cultures.

In adults, the dosage range is 50 mg – 400 mg daily.

AURO FLUCONAZOLE is not suitable for children.

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If you take more AURO FLUCONAZOLE than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

If you forget to take AURO FLUCONAZOLE:

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose.

Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

AURO FLUCONAZOLE can have side effects.

Contact your doctor **IMMEDIATELY** if you experience any of the following side-effects:

A sudden life-threatening allergic reaction, rapid swelling of the skin of your face, yellow discolouration of your skin and eyes, dark urine, red blotchy rash and blisters in your mouth or nose.

If you experience any of these side-effects, you should immediately stop taking **AURO FLUCONAZOLE**.

Contact your doctor **AS SOON AS POSSIBLE** if you notice any of the following side-effects:

Abdominal pain, diarrhoea, flatulence, nausea, vomiting, changes in the way food tastes (taste perversion), fever, frequent infections, bruising, nose bleeds, itchy skin, hair loss, seizures (fits), constipation, menstrual disorders and abnormal vision.

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

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6. STORING AND DISPOSING OF AURO FLUCONAZOLE

Store all medicines out of the reach and sight of children.

1) Blister:

Store at or below 25 °C. Keep blisters in the original carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

2) HDPE Container:

Store at or below 25 °C. Keep well closed.

KEEP OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF AURO FLUCONAZOLE

AURO FLUCONAZOLE 50 mg:

1) **Pack size: 14's Blister Pack**

Capsules are packed in clear 250 micron PVC coated with 60 gsm PVdc and printed aluminium foil with 7 gsm heat seal lacquer.

Each carton contains 1 blister of 14 capsules each.

2) **Pack size: 30's HDPE Container Pack**

Capsules are packed in a 40 ml white opaque HDPE container with a white opaque polypropylene stock ribbed closure with induction seal wad.

Each container contains 30 capsules.

AURO FLUCONAZOLE 100 mg:

1) **Pack size: 30's Blister Pack**

Capsules are packed in clear 250 micron PVC coated with 60 gsm PVdc and printed aluminium foil with 7 gsm heat seal lacquer.

Each carton contains 3 blisters of 10 capsules each.

2) **Pack size: 30's HDPE Container Pack**

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Capsules are packed in a 40 ml white opaque HDPE container with a white opaque polypropylene stock ribbed closure with induction seal wad.

Each container contains 30 capsules.

AURO FLUCONAZOLE 150 mg:

1) Pack size: 1's Blister Pack

Capsules are packed in clear 250 micron PVC coated with 60 gsm PVdc and printed aluminium foil with 7 gsm heat seal lacquer.

Each carton contains 1 blister of 1 capsule each.

2) Pack size: 4's Blister Pack

Capsules are packed in clear 250 micron PVC coated with 60 gsm PVdc and printed aluminium foil with 7 gsm heat seal lacquer.

Each carton contains 1 blister of 4 capsules each.

AURO FLUCONAZOLE 200 mg:

1) Pack size: 30's Blister Pack

Capsules are packed in clear 250 micron PVC coated with 60 gsm PVdc and printed aluminium foil with 7 gsm heat seal lacquer.

Each carton contains 3 blisters of 10 capsules each.

2) Pack size: 30's HDPE Container Pack

Capsules are packed in a 60 ml white opaque HDPE container with a white opaque polypropylene stock ribbed closure with induction seal wad.

Each container contains 30 capsules.

8. IDENTIFICATION OF AURO FLUCONAZOLE

AURO FLUCONAZOLE 50 mg:

White to off-white opaque/white to off-white opaque size '4' hard gelatin capsule filled with white to off-white powder and imprinted with 'E' on white to off-white opaque cap and '95' on white to off-white opaque body with yellow ink.

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AURO FLUCONAZOLE 100 mg:

White to off-white opaque/white to off-white opaque size '2' hard gelatin capsule filled with white to off-white powder and imprinted with 'E' on white to off-white opaque cap and '96' on white to off-white opaque body with yellow ink.

AURO FLUCONAZOLE 150 mg:

White to off-white opaque/white to off-white opaque size '1' hard gelatin capsule filled with white to off-white powder and imprinted with 'E' on white to off-white opaque cap and '97' on white to off-white opaque body with yellow ink.

AURO FLUCONAZOLE 200 mg:

White to off-white opaque/white to off-white opaque size '0' hard gelatin capsule filled with white to off-white powder and imprinted with 'E' on white to off-white opaque cap and '98' on white to off-white opaque body with yellow ink.

9. REGISTRATION NUMBER/REFERENCE NUMBER

AURO FLUCONAZOLE 50 mg: 43/20.2.2/0560

AURO FLUCONAZOLE 100 mg: 43/20.2.2/0561

AURO FLUCONAZOLE 150 mg: 43/20.2.2/0562

AURO FLUCONAZOLE 200 mg: 43/20.2.2/0563

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Aurogen South Africa (Pty) Ltd

Woodhill Office Park, Building 1, 53 Phillip Engelbrecht Avenue

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Johannesburg

South Africa

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11. DATE OF PUBLICATION

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10 October 2013

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5 December 2022