Pharmacode position may change as per the supplier's m/c requirement

APPROVED
Samantha , 2022/12/19 ,07:38:06

AURO FLUCONAZOLE P1532673

AURO FLUCONAZOLE P1532673

AUROGEN

**SCHEDULING STATUS**

**SOUTH AFRICA:** S4

**NAMIBIA:** NS2

**PROPRIETARY NAME (and dosage form):**
**AURO FLUCONAZOLE 50 mg** (capsule)
**AURO FLUCONAZOLE 100 mg** (capsule)
**AURO FLUCONAZOLE 150 mg** (capsule)
**AURO FLUCONAZOLE 200 mg** (capsule)

**COMPOSITION:**
**AURO FLUCONAZOLE 50 mg:** Each capsule contains 50 mg fluconazole. Contains sugar: 50.56 mg laktose.
**AURO FLUCONAZOLE 100 mg:** Each capsule contains 100 mg fluconazole. Contains sugar: 101.12 mg laktose.
**AURO FLUCONAZOLE 150 mg:** Each capsule contains 150 mg fluconazole. Contains sugar: 151.68 mg laktose.
**AURO FLUCONAZOLE 200 mg**: Each capsule contains 200 mg fluconazole. Contains sugar: 202.24 mg laktose.

The other ingredients of **AURO FLUCONAZOLE** are maize starch, sodium lauryl sulphate, colloidal anhydrous silica 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).

**PHARMACOLOGICAL CLASSIFICATION:**
A 20.2.2 Fungicides

**PHARMACOLOGICAL ACTION:**
**Pharmacodynamics:**
**Antifungal Activity:**
Fluconazole is a fluorinated bistriazole, a member of the triazole antifungal agents, and inhibitor of fungal steroid activity.
Fluconazole has activity against *Candida albicans, Candida glabrata, Candida tropicalis, Candida neoformans, Blastomyces dermatitidis, Histoplasma capsulatum, Coccidioides immitis, Paracoccidioides brasiliensis*, and ringworm fungi (dermatophytes).

**Pharmacokinetics:**
**Absorption, Distribution and Excretion:**
Fluconazole is almost completely absorbed from the gastrointestinal tract. Concentrations in plasma are essentially the same whether fluconazole is given orally or intravenously, and bioavailability is not altered by food or gastric acidity. Peak plasma concentrations are 4 to 8 µg/ml after repetitive doses of 100 mg. Renal excretion accounts for over 90 % of elimination, and the elimination half-life is 25 to 30 hours. Fluconazole diffuses readily into body fluids, including sputum and saliva; concentrations in CSF are 50 % to 90 % of the simultaneous values in plasma. The dosage interval should be increased from 24 to 48 hours with a creatinine clearance of 21 to 40 ml/min and to 72 hours at 10 to 20 ml/min. A dose of 100 to 200 mg should be given after each haemodialysis. About 11 % to 12 % of plasma component is protein bound.

**INDICATIONS:**
**AURO FLUCONAZOLE** is indicated for the treatment of the following conditions in adults:Cryptococcal meningitis and maintenance therapy to prevent relapse of cryptococcal disease in patients with:
1. Systemic candidasis.
2. Oropharyngeal and oesophageal candidiasis.
3. Prevention of fungal infections in patients with malignancy who are predisposed to such infections as a result of cytotoxic chemotherapy and radiotherapy.

**CONTRA-INDICATIONS:**
- **AURO FLUCONAZOLE** should not be used in patients with known hypersensitivity to fluconazole or to any of the ingredients or to related azole compounds.
- Pregnancy and lactation (see "**PREGNANCY AND LACTATION**").
- Multiple dose therapy is contra-indicated in patients with renal impairment.
- Co-administration of **AURO FLUCONAZOLE** with medicines metabolised by CYP3A4 and which are known to prolong QT interval, such as cisapride, astemizole, pimozide and quinidine (see "**INTERACTIONS**").

**WARNINGS AND SPECIAL PRECAUTIONS:**
Hepatic Function:
Fluconazole such as in **AURO FLUCONAZOLE** has been associated with cases of serious hepatic toxicity including fatalities, primarily in patients with serious underlying medical conditions. In cases of fluconazole-associated hepatotoxicity, no obvious relationship to total daily dose, duration of therapy, sex or age of patient has been observed. Hepatotoxicity may be reversible on discontinuation of **AURO FLUCONAZOLE** therapy. Patients who develop abnormal liver function tests during **AURO FLUCONAZOLE** therapy should be monitored for the development of more serious hepatic injury. **AURO FLUCONAZOLE** should be discontinued if clinical signs or symptoms consistent with liver disease develop that may be attributable to fluconazole.

AIDS:
AIDS patients are more prone to the development of severe cutaneous reactions to many medicines. If patients with invasive/systemic fungal infections develop rashes, they should be monitored closely and **AURO FLUCONAZOLE** discontinued if bullous lesions or erythema multiforme develop.

Lactose:
**AURO FLUCONAZOLE** contains lactose and should not be given to patients with rare hereditary problems or a history of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption.

**Effects on ability to drive and use of machinery:**
**AURO FLUCONAZOLE** may cause abnormal vision which may affect ability to drive and use machinery.

**INTERACTIONS:**
Fluconazole has been shown to prolong prothrombin times/INR in subjects receiving warfarin. Bleeding events (bruising, epistaxis, gastrointestinal bleeding, haematuria, and melena) have been reported, in association with increases in prothrombin time/INR in patients receiving fluconazole such as in **AURO FLUCONAZOLE** concurrently with warfarin. In concomitant treatment of **AURO FLUCONAZOLE** and warfarin the dose of anticoagulant should be carefully titrated and the prothrombin time/INR should be carefully monitored. Particular attention should be paid to such patients requiring minor oral surgery and dental procedures.

Benzodiazepines (short acting): Concurrent oral administration of midazolam and fluconazole resulted in substantial increases in midazolam concentrations and its psychomotor effects. This effect on midazolam appears to be more pronounced following oral administration of fluconazole than with fluconazole administered intravenously. If concomitant benzodiazepine therapy (e.g. midazolam, triazolam) is necessary in patients on treatment with **AURO FLUCONAZOLE**, a reduction of the benzodiazepine dosage should be considered and patients should be appropriately monitored.

Fluconazole such as in **AURO FLUCONAZOLE** has been shown to prolong the serum half-life of concomitantly administered oral sulphonylureas.

No clinically significant interactions have been seen with co-administration of oral contraceptives, or cimetidine. No adverse effect has been seen on endogenous steroid levels or on ACTH stimulated cortisol response.

A kinetic study in renal transplant patients found fluconazole 200 mg daily to slowly increase ciclosporin concentrations. However, in another multiple dose study with 100 mg daily, fluconazole did not affect ciclosporin levels in patients with bone marrow transplants. Ciclosporin plasma concentration monitoring in patients receiving **AURO FLUCONAZOLE** is recommended.

Co-administration of multiple doses of hydrochlorothiazide may increase the plasma concentrations of fluconazole such as in **AURO FLUCONAZOLE**.

Concomitant administration of **AURO FLUCONAZOLE** and phenytoin may increase the levels of phenytoin to a clinically significant degree.

Concomitant administration of **AURO FLUCONAZOLE** and theophylline may increase the risk of theophylline toxicity due to a fluconazole induced decrease in plasma theophylline clearance.

Concomitant administration of **AURO FLUCONAZOLE** and rifampicin may result in a 25 % decrease in the AUC and 20 % shorter half-life of fluconazole.

Zidovudine: Two kinetic studies resulted in increased levels of zidovudine most likely caused by the decreased conversion of zidovudine to its major metabolite. One study determined zidovudine levels in AIDS or ARV patients before and following fluconazole 200 mg daily for 15 days. There was a significant increase in zidovudine AUC (20 %). A second randomised, two-period, two-treatment, cross-over study examined zidovudine levels in HIV patients. On two occasions, 21 days apart, patients received zidovudine 200 mg every eight hours either with or without fluconazole 400 mg daily for seven days. The AUC of zidovudine significantly increased (74 %) during co-administration with fluconazole. Patients receiving **AURO FLUCONAZOLE** in combination with zidovudine should be monitored for the development of zidovudine-related adverse reactions.

Nevirapine: Co-administration of fluconazole and nevirapine may result in approximately 100 % increase in nevirapine exposure as compared with historical data where nevirapine is administered alone. Because of the risk of increased exposure to nevirapine, caution should be exercised if nevirapine and **AURO FLUCONAZOLE** are given concomitantly and patients should be monitored closely.

Cisapride: There have been reports of cardiac events including torsade de pointes in patients to whom fluconazole and cisapride were co-administered. Co-administration of cisapride is contraindicated in patients receiving **AURO FLUCONAZOLE**.

Rifabutin: There have been reports that an interaction exists when fluconazole is administered concomitantly with rifabutin, leading to increased serum levels of rifabutin. There have been reports of uveitis in patients to whom fluconazole and rifabutin were co-administered. Patients receiving rifabutin and **AURO FLUCONAZOLE** concomitantly should be carefully monitored.

Tacrolimus: There have been reports that an interaction exists when fluconazole is administered concomitantly with tacrolimus, leading to increased serum levels of tacrolimus. There have been reports of nephrotoxicity in patients to whom **AURO FLUCONAZOLE** and tacrolimus were co-administered. Patients receiving tacrolimus and fluconazole concomitantly should be carefully monitored for changes in plasma concentrations of tacrolimus and/or nephro- and neurotoxicity.

The use of **AURO FLUCONAZOLE** in patients concurrently taking astemizole or other medicines metabolised by the cytochrome P-450 system may be associated with elevations in serum levels of these medicines. In the absence of definitive information, caution should be used when co-administering **AURO FLUCONAZOLE**. Patients should be carefully monitored (see "**WARNINGS AND SPECIAL PRECAUTIONS**").

**PREGNANCY AND LACTATION:**
**Use during pregnancy and lactation:**
There are no adequate and well controlled studies which assessed the safety of fluconazole treatment in pregnant women. There have been reports of congenital abnormalities in infants whose mothers were treated with fluconazole. The relationship between fluconazole use and these events is unclear.
Lactation, as fluconazole is found in breast milk at concentrations similar to plasma.

**DOSAGE AND DIRECTIONS FOR USE:**
Therapy for those types of infections requiring multiple dose treatment should be continued until clinical parameters or laboratory tests indicate that active fungal infection has subsided.
An inadequate period of treatment may lead to recurrence of active infection. Patients with AIDS and cryptococcal meningitis or recurrent oropharyngeal candidiasis usually require maintenance therapy to prevent relapse.

**Use in Adults:**
1. For cryptococcal meningitis the usual dose is 400 mg on the first day followed by 200 mg once daily. Depending on the clinical response of the patient this dose may be increased to 400 mg daily. Usually, duration of treatment for cryptococcal meningitis is 6-8 weeks.
   For the prevention of relapse of cryptococcal meningitis in patients with AIDS, after the patient received a full course of primary therapy, **AURO FLUCONAZOLE** may be administered at a daily dose of 100 to 200 mg.
2. For systemic candidiasis the usual dose is 400 mg on the first day followed by 200 mg daily. Depending on the clinical response, the dose may be increased to 400 mg daily. Duration of treatment is based upon the clinical response.
3. For oropharyngeal candidiasis, the usual dose is 50 to 100 mg once daily for 7- 14 days. If necessary, treatment can be continued for longer periods in patients with severely compromised immune function.
   For the prevention of relapse of oropharyngeal candidiasis in patients with AIDS, after the patient receives a full course of primary therapy, **AURO FLUCONAZOLE** may be administered at a 150 mg once weekly dose.
   For oesophageal candidiasis, the recommended dose is 200 mg on the first day, followed by 100 mg to 200 mg once daily. Doses up to 400 mg/day may be used, based on medical judgment of the patient's response to therapy. Patients with oesophageal candidiasis should be treated for a minimum of three weeks and for at least two weeks following resolution of symptoms.
4. The recommended **AURO FLUCONAZOLE** dosage for the prevention of candidiasis is 50 mg to 400 mg once daily, based on the patient's risk for developing fungal infections. For patients at high risk of systemic infection e.g. patients who are anticipated to have profound or prolonged neutropenia, a dose of 400 mg once daily has been used. **AURO FLUCONAZOLE** administration should start several days before the anticipated onset of neutropenia and continue for 7 days after the neutrophil count rises above 1000 cells per $mm^3$.

**Use in the Elderly:**
Where there is no evidence of renal impairment, normal dosage recommendations should be adopted.

**Use in Children:**
This formulation is not suitable for dosages < 50 mg/kg.

Dosage in Patients with Impaired Renal Function:
Fluconazole is cleared primarily by renal excretion as unchanged compound. No adjustments in single dose therapy are necessary. Multiple-dose therapy should be carefully monitored in patients with renal impairment.
In patients with impaired renal function, an initial dose of 50 to 400 mg should be given. After the loading dose, the daily dose (according to indication) should be based on the following table:

| Creatinine Clearance (ml/min) | Percent of Recommended Dose |
|---|---|
| >50 | 100 % |
| <50 | 50 % |
| Regular haemodialysis | 100 % after each dialysis |

These are suggested dose adjustments based on pharmacokinetics following administration of multiple doses. Further adjustment may be needed depending upon clinical condition. When serum creatinine is the only measure of renal function available, the following formula (based on sex, weight and age of the patient) should be used to estimate the creatinine clearance:

$$\text{eGFR}^{*}\ (\text{ml/min}) = \frac{(140 - \text{age}) \times \text{Wt (kg)}}{S_{cr}\ (\text{mmol/litre})}$$

* For females multiply the GFR by 0,85.

**SIDE EFFECTS:**
**Blood and the lymphatic system disorders:**
*Less frequent:* Thrombocytopenia.
*The following side effects have been reported but the frequencies are unknown:* Neutropenia, leucopenia.

**Immune system disorders:**
*The following side effects have been reported but the frequencies are unknown:* Anaphylaxis, angioedema.

**Metabolism and nutritional disorders:**
*The following side effect has been reported but the frequency is unknown:* Hypertriglyceridemia.

**Nervous system disorders:**
*The following side effect has been reported but the frequency is unknown:* Seizures.

**Gastrointestinal disorders:**
*Less frequent:* Abdominal pain, vomiting, nausea, diarrhoea, flatulence.
*The following side effects have been reported but the frequencies are unknown:* Taste perversion, constipation, dyspepsia.

**Hepato-biliary disorders:**
*The following side effects have been reported but the frequencies are unknown:* Hepatitis, liver failure.

**Skin and subcutaneous tissue disorders:**
*Less frequent:* Stevens-Johnson syndrome
*The following side effects have been reported but the frequencies are unknown:* Alopecia, toxic epidermal necrolysis, pruritus, urticaria.

**Reproductive system and breast disorders:**
*The following side effect has been reported but the frequency is unknown:* Menstrual disorders.

**Eye disorders:**
*The following side effect has been reported but the frequency is unknown:* Abnormal vision.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:** The following events may occur with an overdosage of **AURO FLUCONAZOLE**: insomnia, irritability, vomiting, diarrhoea, abdominal pain/cramps, anorexia, bulging fontanel, elevation of alkaline phosphatase and gamma glutamyl transpeptidase, increase in serum calcium, renal failure, fatigue, facial rash, skin erythema, generalised urticaria, arthralgia, itching, numbness of the tongue and distressed mood.

In the event of overdosage, symptomatic treatment (with supportive measures and gastric lavage if necessary) may be adequate.

Fluconazole is largely excreted in the urine; forced diuresis would probably increase the elimination rate. A three hour haemodialysis session decreases plasma levels by approximately 50 %.

**IDENTIFICATION:**
**AURO FLUCONAZOLE 50 mg:**
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.

**AURO FLUCONAZOLE 100 mg:**
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 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 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.

**PRESENTATION:**

**AURO FLUCONAZOLE 50 mg:**
**1. Blister Pack**
Capsules are packed in clear 250 µm PVC coated with 60 g/m2 PVdc and printed aluminium foil with 7 g/m2 heat seal lacquer.

**Pack size: 14s**- Each carton contains 1 blister of 14 capsules each.

**2. 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.

**Pack size: 30s**- Each container contains 30 capsules each.

**AURO FLUCONAZOLE 100 mg:**
**1. Blister Pack**
Capsules are packed in clear 250 µm PVC coated with 60 g/m2 PVdc and printed aluminium foil with 7 g/m2 heat seal lacquer.

**Pack size: 30s**- Each carton contains 3 blisters of 10 capsules each.

**2. 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.

**Pack size: 30s**- Each container contains 30 capsules.

**AURO FLUCONAZOLE 150 mg:**
**1. Blister Pack**
Capsules are packed in clear 250 µm PVC coated with 60 g/m2 PVdc and printed aluminium foil with 7 g/m2 heat seal lacquer.

**Pack size: 1s**- Each carton contains 1 blister of 1 capsule each.

**2. Blister Pack**
Capsules are packed in clear 250 µm PVC coated with 60 g/m2 PVdc and printed aluminium foil with 7 g/m2 heat seal lacquer.

**Pack size: 4s**- Each carton contains 1 blister of 4 capsules each.

**AURO FLUCONAZOLE 200 mg:**
**1. Blister Pack**
Capsules are packed in clear 250 µm PVC coated with 60 g/m2 PVdc and printed aluminium foil with 7 g/m2 heat seal lacquer.

**Pack size: 30s**- Each container contains 3 blisters of 10 capsules each.

**2. 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.

**Pack size: 30s**- Each container contains 30 capsules.

**STORAGE INSTRUCTIONS:**
**1) Blister:**
Store at or below 25 °C. Keep blisters in the original carton until required for use.

**2) HDPE Container:**
Store at or below 25 °C. Keep well closed.

**KEEP OUT OF REACH OF CHILDREN**

**REGISTRATION NUMBER:**

**SOUTH AFRICA:**
**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

**NAMIBIA:**
**AURO FLUCONAZOLE 50 mg:** 20/20.2.2/0039
**AURO FLUCONAZOLE 150 mg:** 20/20.2.2/0040
**AURO FLUCONAZOLE 200 mg:** 20/20.2.2/0041

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**
AUROGEN SOUTH AFRICA (PTY) LTD
Woodhill Office Park, Building 1,
First Floor 53 Phillip Engelbrecht AvenueMeyersdal Ext 12,
1448 Johannesburg, South Africa

**DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:**
Date of registration:
10 October 2013

Date of revision:
5 December 2022

DETACH BEFORE DISPENSING

required for use.
**2) HDPE Container:**
Store at or below 25 °C. Keep well closed.

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) Blister Pack**
Capsules are packed in clear 250 µm PVC coated with 60 g/m2 PVdc and printed aluminium foil with 7 g/m2 heat seal lacquer.
**Pack size: 14s**- Each carton contains 1 blister of 14 capsules each

**2) 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.
**Pack size: 30s**- Each container contains 30 capsules

**AURO FLUCONAZOLE 100 mg:**
**1) Blister Pack**
Capsules are packed in clear 250 µm PVC coated with 60 g/m2 PVdc and printed aluminium foil with 7 g/m2 heat seal lacquer.
**Pack size: 30s**- Each carton contains 3 blisters of 10 capsules each

**2) 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.
**Pack size: 30s**- Each container contains 30 capsules each

**AURO FLUCONAZOLE 150 mg:**
**1) Blister Pack**
Capsules are packed in clear 250 µm PVC coated with 60 g/m2 PVdc and printed aluminium foil with 7 g/m2 heat seal lacquer.
**Pack size: 1s**- Each carton contains 1 blister of 1 capsule each

**2) Blister Pack**
Capsules are packed in clear 250 µm PVC coated with 60 g/m2 PVdc and printed aluminium foil with 7 g/m2 heat seal lacquer.
**Pack size: 4s**- Each carton contains 1 blister of 4 capsules each

**AURO FLUCONAZOLE 200 mg:**
**1) Blister Pack**
Capsules are packed in clear 250 µm PVC coated with 60 g/m2 PVdc and printed aluminium foil with 7 g/m2 heat seal lacquer.
**Pack size: 30s**- Each carton contains 3 blisters of 10 capsules each

**2) 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.
**Pack size: 30s**- Each container contains 30 capsules each.

**8. IDENTIFICATION OF AURO FLUCONAZOLE**
**AURO FLUCONAZOLE 50mg:**
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.

**AURO FLUCONAZOLE 100 mg:**
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 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 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**

**SOUTH AFRICA:**
**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

**NAMIBIA:**
**AURO FLUCONAZOLE 50 mg:** 20/20.2.2/0039
**AURO FLUCONAZOLE 150 mg:** 20/20.2.2/0040
**AURO FLUCONAZOLE 200 mg:** 20/20.2.2/0041

**10. NAME AND ADDRESS OF REGISTRATION HOLDER**
AUROGEN SOUTH AFRICA (PTY) LTD
Woodhill Office Park, Building 1,
First Floor 53 Phillip Engelbrecht AvenueMeyersdal Ext 12,
1448 Johannesburg, South Africa

**11. DATE OF PUBLICATION**
Date of registration:
10 October 2013

Date of revision:
5 December 2022

**SOUTH AFRICA:** S4
**NAMIBIA:** NS2
**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. Contains sugar: 50.56 mg laktose.
**AURO FLUCONAZOLE 100 mg**: Each capsule contains 100 mg fluconazole. Contains sugar: 101.12 mg laktose.
**AURO FLUCONAZOLE 150 mg**: Each capsule contains 150 mg fluconazole. Contains sugar: 151.68 mg laktose.
**AURO FLUCONAZOLE 200 mg**: Each capsule contains 200 mg fluconazole. Contains sugar: 202.24 mg laktose.
The other ingredients of **AURO FLUCONAZOLE** are 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 Breastfeeding:**
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking **AURO FLUCONAZOLE**.

You should not take **AURO FLUCONAZOLE** if you are pregnant, planning to become pregnant or breastfeeding your baby.
**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).
Always tell your healthcare professional if you are taking any other medicine (This includes complementary or traditional medicines.)

**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.
**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.

**6. STORING AND DISPOSING OF AURO FLUCONAZOLE**
Store all medicines out of the reach of children.
**1) Blister:**
Store at or below 25 °C. Keep blisters in the original carton until

A/s: 360 x 460 mm ■ Black

| AUROBINDO Packaging Development | | Product Name | Component | Item Code | Date & Time |
|---|---|---|---|---|---|
| | | AURO FLUCONAZOLE | Leaflet | P1532673 | 16.12.2022 & 09.45 am |
| | | Country | Version No. | Reason Of Issue | Reviewed / Approved by |
| | | South Africa-U3 | 00 | Commercial | |
| Team Leader | Kiran Kumar | Dimensions (mm) | Colours | | |
| Initiator | Bhogi | 360 x 460 mm | No Of Colours: 01 | | |
| Artist | Sree Designers | Pharma Code: 32673 | 32673 | | |
| Additional Information: Supersedes: P1525007 | | | | | |

**SKEDULERINGSTATUS**

**SUID-AFRIKA: S4**

**NAMIBIË: NS2**

**EIENDOMSNAAM (en doseervorm):**
**AURO FLUCONAZOLE 50 mg** (kapsule)
**AURO FLUCONAZOLE 100 mg** (kapsule)
**AURO FLUCONAZOLE 150 mg** (kapsule)
**AURO FLUCONAZOLE 200 mg** (kapsule)

**SAMESTELLING:**
**AURO FLUCONAZOLE 50 mg:** Elke kapsule bevat 50 mg flukonasool. Bevat suiker: 50.56 mg laktose.
**AURO FLUCONAZOLE 100 mg:** Elke kapsule bevat 100 mg flukonasool. Bevat suiker: 101.12 mg laktose.
**AURO FLUCONAZOLE 150 mg:** Elke kapsule bevat 150 mg flukonasool. Bevat suiker: 151.68 mg laktose.
**AURO FLUCONAZOLE 200 mg:** Elke kapsule bevat 200 mg flukonasool. Bevat suiker: 202.24 mg laktose.

Die ander bestanddele van **AURO FLUCONAZOLE** is mieliestysel, natriumlourielsulfaat, kolloïdale anhidriese silika en magnesiumstearaat. Die leë, harde gelatienkapsule bestaan uit gelatien, natriumlourielsulfaat en titaandioksied (C.I. Nr.: 77891). Die kapsule word gedruk met voedselgraad ink, skellak en geel ysteroksied (C.I. Nr.: 77492).

**FARMAKOLOGIESE KLASSIFIKASIE:**
A 20.2.2 Swamdoders

**FARMAKOLOGIESE WERKING:**
**Farmakodinamika:**
**Swamwerende aktiwiteit:**
Flukonasool is 'n gefluoreerde bistriasool, 'n lid van die triasool swamwerende middels, en 'n inhibeerder van steroïedaktiwiteit van swamme.
Flukonasool is aktief teen *Candida albicans, Candida glabrata, Candida tropicalis, Candida neoformans, Blastomyces dermatitidis, Histoplasma capsulatum, Coccidioides immitis, Paracoccidioides brasiliensis* en omloopswamme (dermatofiete).

**Farmakokinetika:**
**Absorpsie, Verspreiding en Uitskeiding:**
Flukonasool word byna volledig vanuit die maagdermkanaal geabsorbeer. Die konsentrasie in die plasma is essensieel dieselfde, ongeag of flukonasool oraal of intraveneus toegedien word en die biobeskikbaarheid word nie deur voedsel of maagsuurheid beïnvloed nie. Piek plasmakonsentrasies is 4 tot 8 µg/ml na herhaalde dosisse van 100 mg. Nieruitskeiding is verantwoordelik vir meer as 90 % van die eliminasie, en die eliminasiehalfleeftyd is 25 tot 30 ure. Flukonasool versprei geredelik in die liggaamsvloeistowwe, insluitende sputum en speeksel; konsentrasies in die SSV is 50 % tot 90 % van die gelyktydige plasmawaardes. Die doseringsinterval behoort verhoog te word van 24 na 48 ure met 'n kreatinienopruiming van 21 tot 40 ml/min en na 72 ure teen 10 tot 20 ml/min. 'n Dosis van 100 tot 200 mg behoort na elke hemodialise toegedien te word. Ongeveer 11 % tot 12 % van die plasmakomponent word aan proteïen gebind.

**INDIKASIES:**
**AURO FLUCONAZOLE** word aangedui vir die behandeling van die volgende kondisies in volwassenes:Kriptokokmeningitis en onderhoudsterapie om die terugval van kriptokoksiekte in pasiënte met die volgende kondisies te voorkom:
1. Sistemiese kandidiase.
2. Orofaringeale en esofageale kandidiase.
3. Voorkoming van swaminfeksies in pasiënte met 'n kwaadaardigheid wat as gevolg van sitotoksiese chemo-en radioterapie tot sulke infeksies predisponeer.

**KONTRA-INDIKASIES:**
- **AURO FLUCONAZOLE** behoort nie in pasiënte met 'n bekende hipersensitiwiteit teen flukonasool of enige van die bestanddele of verwante asoolmiddels gebruik te word nie.
- Swangerskap en laktasie (sien "**SWANGERSKAP EN LAKTASIE**").
- Veelvuldige dosisterapie word teenaangedui in pasiënte met ingekorte nierfunksie.
- Die medetoediening van **AURO FLUCONAZOLE** saam met medisyne wat deur die CYP3A4 gemetaboliseer word en wat daarvoor bekend staan dat hulle die QT-interval verleng, soos kisapried, astemisool, pimosied en kinidien (sien "**INTERAKSIES**").

**WAARSKUWINGS EN SPESIALE VOORSORGSMAATREËLS:**

Lewerfunksie:
Flukonasool, soos in **AURO FLUCONAZOLE**, is geassosieer met gevalle van ernstige lewertoksisiteit, insluitende fatale gevalle, hoofsaaklik in pasiënte met ernstige onderliggende mediese kondisies. In gevalle van flukonasoolverwante lewertoksisiteit, is geen duidelike verwantskap met die totale daaglikse dosis, duurte van terapie, geslag of ouderdom van die pasiënt waargeneem nie. Lewertoksisiteit kan met die staking van **AURO FLUCONAZOLE** omkeerbaar wees. Pasiënte wat abnormale lewerfunksie-toetse gedurende **AURO FLUCONAZOLE** terapie ontwikkel, behoort vir die ontwikkeling van meer ernstige lewerbeskadiging gemonitor te word. Die gebruik van **AURO FLUCONAZOLE** behoort gestaak te word as kliniese tekens of simptome konsistent met lewersiekte ontwikkel, wat aan flukonasool toegeskryf kan word.

VIGS:
VIGS-pasiënte is meer geneig tot die ontwikkeling van erge velreaksies teen menige medisyne. As pasiënte met ingrypende/sistemiese swaminfeksies uitslag ontwikkel, behoort hulle noukeurig gemonitor te word en **AURO FLUCONAZOLE** behoort onttrek te word as bulleuse letsels of erythema multiforme ontwikkel.

Laktose:
**AURO FLUCONAZOLE** bevat laktose en behoort nie aan pasiënte met selde voorkomende oorerflike probleme of 'n geskiedenis van galaktoseïntoleransie, Lapp-laktasetekort of glukose-galaktose wanabsorpsie toegedien te word nie.

**Effekte op die vermoë om te bestuur en met masjinerie te werk:**
**AURO FLUCONAZOLE** kan abnormale visie veroorsaak wat die vermoë om te bestuur en met masjinerie te werk kan affekteer.

**INTERAKSIES:**
Daar is aangetoon dat **AURO FLUCONAZOLE** die protrombientyd/INR in pasiënte wat warfarien ontvang, verhoog. Bloedingsepisodes (kneusing, epistakse, gastroïntestinale bloeding, hematurie en melena) is in assosiasie met toenames in protrombientyd/INR in pasiënte wat flukonasool soos in **AURO FLUCONAZOLE** gelyktydig met warfarien ontvang, aangemeld. In die meegaande behandeling met **AURO FLUCONAZOLE** en warfarien behoort die dosis van die teenstolmiddel versigtig getitreer en die protrombientyd/INR noukeurig gemonitor te word. Aandag behoort veral aan dié pasiënte gegee te word wat minder ernstige mondchirurgie of tandheelkundige prosedures vereis.

Bensodiasepiene (kortwerkend): Die gelyktydige orale toediening van midasolam en flukonasool het tot aansienlike toenames in midasolam-konsentrasies en die psigomotoriese effekte daarvan gelei. Hierdie effek op midasolam blyk meer uitgesproke te wees na orale toediening van flukonasool as met flukonasool wat intraveneus toegedien word. As gelyktydige bensodiasepienterapie (bv. midasolam, triasolam) nodig is in pasiënte op behandeling met **AURO FLUCONAZOLE**, behoort 'n verlaging van die bensodiasepiendosis oorweeg te word en hierdie pasiënte behoort dienooreenkomstig gemonitor te word.

Daar is aangetoon dat flukonasool, soos in **AURO FLUCONAZOLE** die serumhalfleeftyd van gelyktydig toegediende orale sulfonilureas verleng.

Geen klinies beduidende interaksies is in die medetoediening van orale voorbehoedmiddels of simetidien waargeneem nie. Geen nadelige effekte is op endogene steroïedvlakke of AKTH-gestimuleerde kortisolrespons waargeneem nie.

'n Kinetiese studie in nieroorplantingspasiënte het gevind dat flukonasool 200 mg per dag die siklosporienkonsentrasies langsaam verhoog. In 'n ander veelvuldige dosisstudie met 100 mg daagliks, het flukonasool nie die siklosporienkonsentrasies in pasiënte met beenmurgoorplantings geaffekteer nie. Die monitering van plasmakonsentrasies van siklosporien in pasiënte wat **AURO FLUCONAZOLE** ontvang, word aanbeveel.

Die medetoediening van veelvuldige dosisse van hidrochlorotiasied kan die plasmakonsentrasies van flukonasool soos in **AURO FLUCONAZOLE** verhoog.

Die gelyktydige toediening van **AURO FLUCONAZOLE** en fenitoïen kan die vlakke van fenitoïen tot 'n kliniese beduidende vlak laat toeneem.

Die gelyktydige toediening van **AURO FLUCONAZOLE** en teofillien kan die risiko van teofillientoksisiteit weens 'n flukonasoolgeïnduseerde afname in plasma teofillienopruiming laat toeneem

Die gelyktydige toediening van **AURO FLUCONAZOLE** en rifampisien kan tot 'n 25 % afname in die AOK en 20 % korter halfleeftyd van flukonasool lei.

Sidovudien: Twee kinetiese studies het tot 'n toename in sidovudienvlakke gelei, mees waarskynlik veroorsaak deur die afname in omskakeling van sidovudien na sy belangrikste metaboliet. Een studie het sidovudienvlakke in VIGS of ARV-pasiënte vóór en na flukonasool 200 mg per dag vir 15 dae bepaal. Daar was 'n beduidende toename in die AOK van sidovudien (20 %). 'n Tweede, twee-periode, twee-behandeling oorkruisstudie het die sidovudienvlakke in MIV-pasiënte bestudeer. Met twee geleenthede, 21 dae uitmekaar, het pasiënte 200 mg sidovudien elke agt ure met of sonder 400 mg flukonasool vir sewe dae ontvang. Die AOK van sidovudien het beduidend (74 %) gedurende die medetoediening van flukonasool toegeneem. Pasiënte wat **AURO FLUCONAZOLE** in kombinasie met sidovudien ontvang behoort vir die ontwikkeling van sidovudienverwante newe effekte gemonitor te word.

Nevirapien: Die medetoediening van flukonasool en nevirapien kan tot 'n byna 100 % toename in nevirapienblootstelling lei, in vergelyking met historiese data waar nevirapien alleen toegedien word. Weens 'n risiko in die toename in blootstelling aan nevirapien, behoort sorg aan die dag gelê te word as nevirapien en **AURO FLUCONAZOLE** saam toegedien word en pasiënte behoort noukeurig gemonitor te word.

Kisapried: Daar bestaan vermeldings van hartepisodes, insluitende torsade de pointes in pasiënte aan wie flukonasool en kisapried saam toegedien is. Die medetoediening van kisapried word teenaangedui in pasiënte wat **AURO FLUCONAZOLE** ontvang.

Rifabutien: Daar bestaan vermeldings van 'n interaksie wanneer flukonasool saam met rifabutien toegedien word, wat tot 'n toename in die serumvlakke van rifabutien lei. Daar bestaan vermeldings van uveitis in pasiënte in wie flukonasool en rifabutien saam toegedien is. Pasiënte wat beide rifabutien en **AURO FLUCONAZOLE** ontvang, behoort noukeurig gemonitor te word.

Takrolimus: Daar bestaan vermeldings van 'n interaksie wanneer flukonasool saam met takrolimus toegedien word, wat lei tot 'n toename in serumvlakke van takrolimus. Daar bestaan vermeldings van nefrotoksisiteit in pasiënte aan wie **AURO FLUCONAZOLE** en takrolimus saam toegedien is. Pasiënte wat gelyktydiglik takrolimus en flukonasool ontvang, behoort noukeurig vir veranderinge in die plasmakonsentrasies en/of nefro- en neurotoksisiteit gemonitor te word.

Die gebruik van **AURO FLUCONAZOLE** in pasiënte wat tegelykertyd astemisool of ander medisyne wat deur die sitochroom P-450 sisteem gemetaboliseer word, kan geassosieer word met toenames in die serumvlakke van hierdie medisyne. In die afwesigheid van definitiewe inligting, behoort sorg aan die dag gelê te word wanneer **AURO FLUCONAZOLE** saam toegedien word. Pasiënte behoort noukeurig gemonitor te word (sien "**WAARSKUWINGS EN SPESIALE VOORSORGSMAATREËLS**").

**SWANGERSKAP EN LAKTASIE:**

**Gebruik gedurende swangerskap en laktasie:**
Daar bestaan onvoldoende en geen goed gekontroleerde studies wat die veiligheid van flukonasoolbehandeling in swanger vroue bestudeer het nie. Daar bestaan vermeldings van kongenitale abnormaliteite in babas wie se moeders met flukonasool behandel is. Die verwantskap tussen die gebruik van flukonasool en hierdie episodes is onduidelik.

Laktasie, aangesien flukonasool in borsmelk gevind word, soortgelyk aan die konsentrasie in plasma.

**DOSIS EN GEBRUIKSAANWYSINGS:**
Terapie vir die tipes infeksies wat veelvuldige dosisbehandeling vereis, behoort voortgesit te word totdat kliniese parameters of laboratoriumtoetse aandui dat die aktiewe swaminfeksies verdwyn het.

'n Onvoldoende periode van behandeling kan tot herhaling van die aktiewe infeksie lei. Pasiënte met VIGS en kriptokokmeningitis of herhalende orofaringeale kandidiase vereis gewoonlik onderhoudsterapie om 'n terugval te voorkom.

**Gebruik in volwassenes:**
1. Vir kriptokokmeningitis is die normale dosis 400 mg op die eerste dag, gevolg deur 200 mg een keer per dag. Afhangende van die kliniese respons kan hierdie dosis na 400 mg per dag verhoog word. Die duurte van behandeling van kriptokokmeningitis is gewoonlik 6 - 8 weke.

   Vir die voorkoming van 'n terugval van kriptokokmeningitis in pasiënte met VIGS, nadat die pasiënt 'n volle kursus van die primêre terapie ontvang het, kan **AURO FLUCONAZOLE** toegedien word teen 'n daaglikse dosis van 100 tot 200 mg.

2. Vir sistemiese kandidiase is die normale dosis 400 mg op die eerste dag, gevolg deur 200 mg per dag daarna. Afhangende van die kliniese respons, kan hierdie dosis na 400 mg per dag verhoog word. Die duurte van behandeling word op die kliniese respons gebaseer.

3. Vir orofaringeale kandidiase is die normale dosis 50 tot 100 mg een keer per dag vir 7 - 14 dae. Indien nodig kan die behandeling vir langer voortgesit word in pasiënte met 'n erg beklemde immuunfunksie.

   Vir die voorkoming van 'n terugval van orofaringeale kandidiase in pasiënte met VIGS, nadat die pasiënt 'n volle kursus van die primêre terapie ontvang het, kan **AURO FLUCONAZOLE** toegedien word teen 'n dosis van 150 mg een keer per week.

   Vir esofageale kandidiase is die aanbevole dosis 200 mg op die eerste dag, gevolg deur 100 tot 200 mg een keer per dag. Dosisse van tot soveel as 400 mg/dag kan gebruik word, gebaseer op die mediese beoordeling van die pasiënte se respons op terapie. Pasiënte met esofageale kandidiase behoort vir 'n minimum van drie weke behandel te word en vir ten minste twee weke na verdwyning van die simptome daarna.

4. Die aanbevole **AURO FLUCONAZOLE** dosis vir die voorkoming van kandidiase is 50 mg tot 400 mg een keer per dag, gebaseer op die pasiënt se risiko vir die ontwikkeling van swaminfeksies. Vir pasiënte met 'n hoë risiko van sistemiese infeksie bv. pasiënte met 'n verwagte uitgesproke of verlengde neutropenie is 'n dosis van 400 mg een keer per dag gebruik. Die toediening van **AURO FLUCONAZOLE** behoort verskeie dae vóór die verwagte aanvangs van neutropenie te begin en vir 7 dae nadat die neutrofieltelling na meer as 1000 selle per mm3 styg.

**Gebruik in bejaardes:**
Waar daar geen bewys van ingekorte nierfunksie is nie, behoort die normale dosisaanbevelings gevolg te word.

**Gebruik in kinders:**
Die formulasie is nie geskik vir dosisse < 50 mg/kg nie.

Dosis in Pasiënte met Ingekorte Nierfunksie:
Flukonasool word hoofsaaklik deur nieruitskeiding as onveranderde middel opgeruim. Geen dosisaanpassings is in enkeldosisterapie nodig nie. Veelvuldige dosisterapie behoort noukeurig in pasiënte met ingekorte nierfunksie gemonitor te word.

In pasiënte met ingekorte nierfunksie behoort 'n enkel dosis van 50 tot 400 mg toegedien te word. Na die aanvanklike dosis behoort die daaglikse dosis (volgens die indikasie) op die volgende tabel gebaseer te word:

| Kreatinienopruiming (ml/min) | Persent van Aanbevole Dosis |
|---|---|
| >50 | 100 % |
| <50 | 50 % |
| Gereelde hemodialise | 100 % na elke dialise |

Hierdie is voorgestelde dosisaanpassings gebaseer op die farmakokinetika na toediening van veelvuldige dosisse. Afhangende van die kliniese kondisie mag verdere aanpassing nodig wees. As serumkreatinien die enigste beskikbare maatstaf van nierfunksie is, behoort die volgende formule (gebaseer op geslag, massa en ouderdom van die pasiënt) gebruik te word om die kreatinienopruiming te skat

$$\text{eGFT* (ml/min)} = \frac{\text{(140 -ouderdom) X Massa (kg)}}{S_{kr}\ \text{(mmol/litre)}}$$

*Vir vroue word die GFT met 0,85 vermenigvuldig.

**NEWE EFFEKTE:**

**Afwykings van die bloed- en limfsisteem:**
*Dikwels:* Trombositopenie.
*Die volgende newe effekte is aangemeld maar die frekwensies is onbekend:* Neutropenie, leukopenie.

**Afwykings van die immuunstelsel:**
*Die volgende newe effekte is aangemeld maar die frekwensies is onbekend:* Anafilakse, angioëdeem.

**Metaboliese en voedingsafwykings:**
*Die volgende newe effek is aangemeld maar die frekwensie is onbekend:* Hipertrigliseridemie.

**Afwykings van die senuweestelsel:**
*Die volgende newe effek is aangemeld maar die frekwensie is onbekend:* Stuipaanvalle.

**Gastroïntestinale afwykings:**
*Dikwels:* Buikpyn, braking, naarheid, diarree, winderigheid.
*Die volgende newe effekte is aangemeld maar die frekwensies is onbekend:* Smaakafwyking, hardlywigheid, dispepsie.

**Hepatobileêre afwykings:**
*Die volgende newe effekte is aangemeld maar die frekwensies is onbekend:* Hepatitis, lewerversaking.

**Afwykings van die vel en subkutane weefsel:**
*Dikwels:* Stevens-Johnson se sindroom.
*Die volgende newe effekte is aangemeld maar die frekwensies is onbekend:* Alopesie, toksiese epidermale nekrolise, pruritus, urtikarie.

**Geslagstelsel- en borsafwykings:**
*Die volgende newe effek is aangemeld maar die frekwensie is onbekend:* Menstruele afwykings.

**Oogafwykings:**
*Die volgende newe effek is aangemeld maar die frekwensie is onbekend:* Abnormale gesig.

**BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:**
Die volgende episodes kan met 'n oordosering van **AURO FLUCONAZOLE** voorkom: slaaploosheid, geïrriteerdheid, braking, diarree, buikpyn/-krampe, anoreksie, bultende fontenel, toename in alkaliese fosfatase en gammaglutamieltranspeptidase, toename in serumkalsium, nierversaking, moegheid, gesigsuitslag, eriteem, algemene urtikarie, artralgie, jeuk, gevoelloosheid van die tong en 'n gevoel van nood.

In die geval van oordosering kan simptomatiese behandeling (met ondersteunende maatreëls en maagspoeling, indien nodig) voldoende wees.

Flukonasool word hoofsaaklik deur die niere uitgeskei; geforseerde diurese sal waarskynlik die eliminasiekoers verhoog. 'n Drie ure hemodialisesessie verminder die plasmavlakke met ongeveer 50 %.

**IDENTIFIKASIE:**

**AURO FLUCONAZOLE 50 mg:**
Wit tot byna-wit ondeursigtige grootte '4' harde gelatienkapsule gevul met 'n wit tot byna-wit poeier en met 'E' op die wit tot byna-wit dop en '95' op die wit tot byna-wit liggaam met geel ink gedruk.

**AURO FLUCONAZOLE 100 mg:**
Wit tot byna-wit ondeursigtige grootte '2' harde gelatienkapsule gevul met 'n wit tot byna-wit poeier en met 'E' op die wit tot byna-wit dop en '96' op die wit tot byna-wit liggaam met geel ink gedruk.

**AURO FLUCONAZOLE 150 mg:**
Wit tot byna-wit ondeursigtige grootte '1' harde gelatienkapsule gevul met 'n wit tot byna-wit poeier en met 'E' op die wit tot byna-wit dop en '97' op die wit tot byna-wit liggaam met geel ink gedruk.

**AURO FLUCONAZOLE 200 mg:**
Wit tot byna-wit ondeursigtige grootte '0' harde gelatienkapsule gevul met 'n wit tot byna-wit poeier en met 'E' op die wit tot byna-wit dop en '98' op die wit tot byna-wit liggaam met geel ink gedruk.

**AANBIEDING:**
**AURO FLUCONAZOLE 50 mg:**
1. **Stolpverpakking**
   Kapsules word in helder 250 µm PVC, bedek met 60 g/m2 PVdc en gedrukte aluminiumfoelie met 7 g/m2 hitte seëllak verpak.
   **Pakgrootte: 14s**- Elke karton bevat 1 stolpstrokie met 14 kapsules elk.
2. **HDPE houer**
   Kapsules word in 'n 40 ml wit ondeursigtige HDPE houer met 'n wit ondeursigtige polipropileen skroefdop met induksie seëlprop verpak.
   **Pakgrootte: 30s**- Elke houer bevat 30 kapsules.

**AURO FLUCONAZOLE 100 mg:**
1. **Stolpverpakking**
   Kapsules word in helder 250 µm PVC, bedek met 60 g/m2 PVdc en gedrukte aluminiumfoelie met 7 g/m2 hitte seëllak verpak.
   **Pakgrootte: 30s**- Elke karton bevat 3 stolpstrokie met 10 kapsules elk.
2. **HDPE houer**
   Kapsules word in 'n 40 ml wit ondeursigtige HDPE houer met 'n wit ondeursigtige polipropileen skroefdop met induksie seëlprop verpak.
   **Pakgrootte: 30s**- Elke houer bevat 30 kapsules.

**AURO FLUCONAZOLE 150 mg:**
1. **Stolpverpakking**
   Kapsules word in helder 250 µm PVC, bedek met 60 g/m2 PVdc en gedrukte aluminiumfoelie met 7 g/m2 hitte seëllak verpak.
   **Pakgrootte: 1s** - Elke karton bevat 1 stolpstrokie met 1 kapsule elk.
2. **Stolpverpakking**
   Kapsules word in helder 250 µm PVC, bedek met 60 g/m2 PVdc en gedrukte aluminiumfoelie met 7 g/m2 hitte seëllak verpak.
   **Pakgrootte: 4s** - Elke karton bevat 1 stolpstrokie met 4 kapsules elk.

**AURO FLUCONAZOLE 200 mg:**
1. **Stolpverpakking**
   Kapsules word in helder 250 µm PVC, bedek met 60 g/m2 PVdc en gedrukte aluminiumfoelie met 7 g/m2 hitte seëllak verpak.
   **Pakgrootte: 30s**- Elke karton bevat 3 stolpstrokies met 10 kapsules elk.
2. **HDPE houer**
   Kapsules word in 'n 60 ml wit ondeursigtige HDPE houer met 'n wit ondeursigtige polipropileen skroefdop met induksie seëlprop verpak.
   **Pakgrootte: 30s**- Elke houer bevat 30 kapsules.

**BERGINGSINSTRUKSIES:**
1) **Stolpverpakking:**
   Bewaar by of benede 25 °C. Hou die stopstrokies in die karton tot voor gebruik.
2) **HDPE houer:**
   Bewaar by of benede 25 °C. Hou dig toe.

**HOU BUITE BEREIK VAN KINDERS.**

**REGISTRASIENOMMMER:**

**SUID-AFRIKA:**
**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

**NAMIBIË:**
**AURO FLUCONAZOLE 50 mg:** 20/20.2.2/0039
**AURO FLUCONAZOLE 150 mg:** 20/20.2.2/0040
**AURO FLUCONAZOLE 200 mg:** 20/20.2.2/0041

**NAAM EN ADRES VAN DIE REGISTRASIEHOUER:**
AUROGEN SOUTH AFRICA (EDMS) BPK
Woodhill Kantoorpark, Gebou Nr. 1,
Eerste Vloer Phillip Engelbrechtlaan 53,
Meyersdal, Uitbr. 12, Johannesburg,1448,
Suid-Afrika

**DATUM VAN PUBLIKASIE VAN HIERDIE PROFESSIONELE INLIGTING:**
Datum van registrasie:
10 Oktober 2013

Datum van hersiening:
5 Desember 2022

P1532673

DETACH BEFORE DISPENSING

**SUID-AFRIKA: S4**

**NAMIBIË: NS2**

**AURO FLUCONAZOLE 50 mg** (kapsule)
**AURO FLUCONAZOLE 100 mg** (kapsule)
**AURO FLUCONAZOLE 150 mg** (kapsule)
**AURO FLUCONAZOLE 200 mg** (kapsule)

Flukonasool

**Lees die hele brosjure sorgvuldig voordat u begin om AURO FLUCONAZOLE te neem.**
-Hou hierdie blaadjie. U mag dit moontlik weer wil lees.
-Indien u enige verdere vrae het, moet u asseblief u dokter of apteker raadpleeg.
-**AURO FLUCONAZOLE** is vir u persoonlik voorgeskryf en u behoort nie u medisyne met ander mense te deel nie. Dit mag hulle skade aandoen, ookal het hulle dieselfde simptome as u.

**1. WAT AURO FLUCONAZOLE BEVAT**
Die aktiewe bestanddeel is flukonasool.
**AURO FLUCONAZOLE 50 mg:** Elke kapsule bevat 50 mg flukonasool. Bevat suiker: 50.56 mg laktose.
**AURO FLUCONAZOLE 100 mg:** Elke kapsule bevat 100 mg flukonasool. Bevat suiker: 101.12 mg laktose.
**AURO FLUCONAZOLE 150 mg:** Elke kapsule bevat 150 mg flukonasool. Bevat suiker: 151.68 mg laktose.
**AURO FLUCONAZOLE 200 mg:** Elke kapsule bevat 200 mg flukonasool. Bevat suiker: 202.24 mg laktose.

Die ander bestanddele van **AURO FLUCONAZOLE** is mieliestysel, natriumlourielsulfaat, kolloïdale anhidriese silika en magnesiumstearaat. Die leë, harde gelatienkapsule bestaan uit gelatien, natriumlourielsulfaat en titaandioksied (C.I. Nr.: 77891). Die kapsule word gedruk met voedselgraad ink, skellak en geel ysteroksied (C.I. Nr.: 77492).

**2. WAARVOOR AURO FLUCONAZOLE GEBRUIK WORD**
**AURO FLUCONAZOLE** word gebruik om ernstige swaminfeksies te behandel wat op verskillende plekke van die liggaam kan voorkom.

**3. VOORDAT U AURO FLUCONAZOLE NEEM**
**Moenie AURO FLUCONAZOLE neem nie:**
* As u 'n bekende hipersensitiwiteit (allergie) teen flukonasool of enige van die bestanddele van **AURO FLUCONAZOLE** of teen enige asoolmiddels het.
* As u medisyne soos kisapried, astemisool, pimosied en kinidien neem, aangesien hierdie medisyne die QT-interval kan verleng en ongereelde harttempo kan veroorsaak.
* As u swanger is.
* As u baba borsvoed.

**Neem spesiale sorg met AURO FLUCONAZOLE:**
* U sal noukeurig deur u dokter gemonitor word as u aan 'n onderliggende lewersiekte ly.
* Die dosis van **AURO FLUCONAZOLE** moet aangepas word as u aan nierprobleme ly.
* As u uitslag ontwikkel met blasies of pienk tot rooi simmetries gerangskikte kolle wat jeukerig is, moet u met die gebruik van **AURO FLUCONAZOLE** staak en onmiddellik u dokter raadpleeg.

**Swangerskap en borsvoeding:**

As u swanger is of u baba borsvoed, moet u asseblief u dokter, apteker of ander gesondheidsbeampte vir advies nader voor u **AURO FLUCONAZOLE** neem.

U behoort nie **AURO FLUCONAZOLE** te neem as u swanger is, beoog om swanger te raak of as u u baba borsvoed nie.

**Bestuur en die gebruik van masjinerie:**
**AURO FLUCONAZOLE** kan gesigsprobleme veroorsaak. As u só geaffekteer word, moet u nie bestuur of met masjinerie werk nie.

**Belangrike inligting oor sommige van die bestanddele van AURO FLUCONAZOLE:**
**AURO FLUCONAZOLE** bevat laktose wat 'n soort suiker is. Voordat u **AURO FLUCONAZOLE** neem, moet u asseblief u dokter vir advies raadpleeg as u intolerant teen sekere suikers is.

**Die neem van ander medisyne saam met AURO FLUCONAZOLE:**
Daar bestaan 'n interaksie tussen **AURO FLUCONAZOLE** en warfarien (medisyne wat die bloed verdun om bloedklonte te voorkom), kortwerkende bensodiasepiene (midasolam, triasolam of soortgelyke medisyne wat u help om te slaap), siklosporien, takrolimus (om oorplantingsverwerping te voorkom), fenitoïen, teofillien (gebruik om asma te beheer), sidovudien (gebruik om MIV-infeksie te behandel), kisapried (gebruik vir maagongesteldhede) en rifabutien (antibiotika vir infeksies).

Stel altyd u professionele gesondheidswerker in kennis as u enige ander medisyne neem (Dit sluit komplementêre en tradisionele medisyne in).

**4. HOE OM AURO FLUCONAZOLE TE NEEM**

Neem **AURO FLUCONAZOLE** altyd presies soos deur u dokter voorgeskryf. Bevestig met u dokter of apteker as u onseker is. As u van mening is dat die effek van **AURO FLUCONAZOLE** te sterk of te swak is, moet u u dokter of apteker raadpleeg.

Die duurte van behandeling en die dosis sal van die graad van erns, die kliniese respons en bakteriologiese kulture afhang.

In volwassenes is die dosisreikwydte 50 mg - 400 mg daagliks.

**AURO FLUCONAZOLE** is nie geskik vir gebruik in kinders nie.

**As u te veel AURO FLUCONAZOLE geneem het:**

In die geval van oordosering, raadpleeg u dokter of apteker. As hulle nie beskikbaar is nie, kontak u naaste hospitaal of gifbeheersentrum.

**As u vergeet het om AURO FLUCONAZOLE te neem:**
As u vergeet het om 'n dosis te neem, neem dit dan sodra u daarvan onthou, tensy dit byna tyd vir die volgende dosis is. Moenie 'n dubbel dosis neem om vir 'n oorgeslaande dosis op te maak nie.

**5. MOONTLIKE NEWE EFFEKTE**
**AURO FLUCONAZOLE** kan newe effekte hê.

Raadpleeg **ONMIDDELLIK** u dokter as u enige van die volgende newe effekte ondervind:

'n Skielike, lewensbedreigende allergiese reaksie, vinnige swelling van die vel van die gesig, geel verkleuring van die vel of oë, donker urien, rooi gevlekte uitslag en blasies in u mond of neus.

As u enige van hierdie newe effekte ondervind, behoort u onmiddellik met die gebruik van **AURO FLUCONAZOLE** te staak.

Raadpleeg u dokter **SO GOU AS MOONTLIK** as u enige van die volgende newe effekte waarneem:

Buikpyn, diarree, winderigheid, naarheid, braking, smaakveranderinge, koors, gereelde infeksies, kneusing, neusbloei, jeukerige vel, haarverlies, stuipaanvalle, hardlywigheid, menstruele afwykings en abnormale gesig.

Nie al die newe effekte wat vir **AURO FLUCONAZOLE** aangemeld is, word in hierdie brosjure ingesluit nie. As u algemene gesondheid agteruitgaan of as u enige ongewone effekte ondervind terwyl u **AURO FLUCONAZOLE** neem, moet u asseblief u dokter, apteker of ander professionele gesondheidswerker om advies raadpleeg.

**6. OPBERGING EN WEGDOEN VAN AURO FLUCONAZOLE**

Bewaar al medisyne buite die bereik van kinders

1) **Stolpverpakking:**
Bewaar by of benede 25 °C. Hou die stopstrokies in die karton tot voor gebruik.

2) **HDPE houer:**
Bewaar by of benede 25 °C. Hou dig toe.

Neem alle ongebruikte medisyne na u apteker terug. Moenie enige ongebruikte medisyne in die drein of riolering (bv. toilette) weggooi nie.

**7. AANBIEDING VAN AURO FLUCONAZOLE**

**AURO FLUCONAZOLE 50 mg:**

**1. Stolpverpakking**
Kapsules word in helder 250 µm PVC, bedek met 60 g/m2 PVdc en gedrukte aluminiumfoelie met 7 g/m2 hitte seëllak verpak.

**Pakgrootte: 14s**- Elke karton bevat 1 stolpstrokie met 14 kapsules elk.

**2. HDPE houer**
Kapsules word in 'n 40 ml wit ondeursigtige HDPE houer met 'n wit ondeursigtige polipropileen skroefdop met induksie seëlprop verpak.

**Pakgrootte: 30s**- Elke houer bevat 30 kapsules.

**AURO FLUCONAZOLE 100 mg:**
**1. Stolpverpakking**
Kapsules word in helder 250 µm PVC, bedek met 60 g/m2 PVdc en gedrukte aluminiumfoelie met 7 g/m2 hitte seëllak verpak.

**Pakgrootte: 30s**- Elke karton bevat 3 stolpstrokies met 10 kapsules elk.

**2. HDPE houer**
Kapsules word in 'n 40 ml wit ondeursigtige HDPE houer met 'n wit ondeursigtige polipropileen skroefdop met induksie seëlprop verpak.

**Pakgrootte: 30s**- Elke houer bevat 30 kapsules.

**AURO FLUCONAZOLE 150 mg:**
**1. Stolpverpakking**
Kapsules word in helder 250 µm PVC, bedek met 60 g/m2 PVdc en gedrukte aluminiumfoelie met 7 g/m2 hitte seëllak verpak.

**Pakgrootte: 1s**- Elke karton bevat 1 stolpstrokie met 1 kapsule elk.

**2. Stolpverpakking**
Kapsules word in helder 250 µm PVC, bedek met 60 g/m2 PVdc en gedrukte aluminiumfoelie met 7 g/m2 hitte seëllak verpak.

**Pakgrootte: 4s**- Elke karton bevat 1 stolpstrokie met 4 kapsules elk.

**AURO FLUCONAZOLE 200 mg:**
**1. Stolpverpakking**
Kapsules word in helder 250 µm PVC, bedek met 60 g/m2 PVdc en gedrukte aluminiumfoelie met 7 g/m2 hitte seëllak verpak.

**Pakgrootte: 30s**- Elke karton bevat 3 stolpstrokies met 10 kapsules elk.

**2. HDPE houer**
Kapsules word in 'n 60 ml wit ondeursigtige HDPE houer met 'n wit ondeursigtige polipropileen skroefdop met induksie seëlprop verpak.

**Pakgrootte: 30s**- Elke houer bevat 30 kapsules.

**8. IDENTIFIKASIE VAN AURO FLUCONAZOLE**

**AURO FLUCONAZOLE 50 mg:**
Wit tot byna-wit ondeursigtige grootte '4' harde gelatienkapsule gevul met 'n wit tot byna-wit poeier en met 'E' op die wit tot byna-wit dop en '95' op die wit tot byna-wit liggaam met geel ink gedruk.

**AURO FLUCONAZOLE 100 mg:**
Wit tot byna-wit ondeursigtige grootte '2' harde gelatienkapsule gevul met 'n wit tot byna-wit poeier en met 'E' op die wit tot byna-wit dop en '96' op die wit tot byna-wit liggaam met geel ink gedruk.

**AURO FLUCONAZOLE 150 mg:**
Wit tot byna-wit ondeursigtige grootte '1' harde gelatienkapsule gevul met 'n wit tot byna-wit poeier en met 'E' op die wit tot byna-wit dop en '97' op die wit tot byna-wit liggaam met geel ink gedruk.

**AURO FLUCONAZOLE 200 mg:**
Wit tot byna-wit ondeursigtige grootte '0' harde gelatienkapsule gevul met 'n wit tot byna-wit poeier en met 'E' op die wit tot byna-wit dop en '98' op die wit tot byna-wit liggaam met geel ink gedruk.

**9. REGISTRASIENOMMER / VERWYSINGSNOMMER**

**SUID-AFRIKA:**
**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

**NAMIBIË:**
**AURO FLUCONAZOLE 50 mg:** 20/20.2.2/0039
**AURO FLUCONAZOLE 150 mg:** 20/20.2.2/0040
**AURO FLUCONAZOLE 200 mg:** 20/20.2.2/0041

**10. NAAM EN ADRES VAN DIE REGISTRASIEHOUER**
AUROGEN SOUTH AFRICA (EDMS) BPK
Woodhill Kantoorpark, Gebou Nr. 1,
Eerste Vloer Phillip Engelbrechtlaan 53,
Meyersdal, Uitbr. 12, Johannesburg,1448,
Suid-Afrika

**11. DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET**
Datum van registrasie:
10 Oktober 2013

Datum van hersiening:
5 Desember 2022