

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

FLUCORIC 50 mg CAPSULES

FLUCORIC 100 mg CAPSULES

FLUCORIC 150 mg CAPSULES

FLUCORIC 200 mg CAPSULES

Fluconazole

FLUCORIC 50 CAPSULES: Contains sugar: 38,5 mg lactose monohydrate per capsule

FLUCORIC 100 CAPSULES: Contains sugar: 77,5 mg lactose monohydrate per capsule

FLUCORIC 150 CAPSULES: Contains sugar: 115,5 mg lactose monohydrate per capsule

FLUCORIC 200 CAPSULES: Contains sugar: 154 mg lactose monohydrate per capsule

Read all of this leaflet carefully before you start taking FLUCORIC

- 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.
- FLUCORIC 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.

What is in this leaflet

1. What FLUCORIC is and what it is used for
2. What you need to know before you take FLUCORIC
3. How to take FLUCORIC
4. Possible side effects
5. How to store FLUCORIC
6. Contents of the pack and other information

1. What FLUCORIC is and what it is used for

FLUCORIC is one of a group of medicines called “antifungals”. The active ingredient is fluconazole.

FLUCORIC is used to treat infections caused by fungi including yeasts and may also be used to stop you from getting a fungal infection.

2. What you need to know before you take FLUCORIC

Do not take FLUCORIC:

- if you are hypersensitive (allergic) to fluconazole, other medicines you have taken to treat a fungal infection, or to any of the other ingredients of FLUCORIC (listed in section 6). The symptoms of an allergic reaction may include itching, reddening of the skin or difficulty in breathing
- if you are taking astemizole or terfenadine (an antihistamine for allergies)
- if you are taking cisapride (used for stomach upsets)
- if you are taking erythromycin (for treating infections (antibiotic))
- if you are taking pimozide (for treating schizophrenia)
- if you are taking quinidine (used for irregular heartbeats)
- if you are pregnant or breastfeeding.

Warnings and precautions

Take special care with FLUCORIC :

- if you have liver or kidney problems
- if you suffer from heart disease, including heart rhythm problems
- if laboratory investigations have shown abnormal levels of potassium, calcium or magnesium in your blood
- if you develop severe skin reactions (itching, reddening of the skin or difficulty in breathing)

- if you develop signs of 'adrenal insufficiency' where the adrenal glands do not produce adequate amounts of certain steroid hormones such as cortisol (chronic, or long-lasting fatigue, muscle weakness, loss of appetite, weight loss, abdominal pain)
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking FLUCORIC.

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with FLUCORIC treatment. Stop taking FLUCORIC and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Talk to your health care provider if the fungal infection does not improve, as alternative antifungal therapy may be needed.

Other medicines and FLUCORIC

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

Tell your doctor immediately if you are taking astemizole or terfenadine (an antihistamine for treating allergies) or cisapride (used for stomach upsets) as these should not be taken with FLUCORIC.

There are some medicines that may interact with FLUCORIC. Make sure your doctor knows if you are taking any of the following medicines:

- halofantrine (to treat malaria)
- amiodarone (used for treating uneven heartbeats 'arrhythmias')
- water tablets, such as hydrochlorothiazide, used to treat fluid retention and high blood pressure
- medicines for treating infections (antibiotics) such as azithromycin, rifampicin or rifabutin
- alfentanil, fentanyl or methadone (for treating pain)

- amitriptyline, nortriptyline (used to treat depression)
- amphotericin B, voriconazole (used to treat serious fungal infections)
- warfarin (or similar medicines) that thin the blood to prevent blood clots
- benzodiazepines such as midazolam, triazolam used to help you sleep or for anxiety
- carbamazepine or phenytoin (used to control epilepsy)
- calcium channel blockers or losartan for lowering blood pressure
- celecoxib (used to treat some types of arthritis)
- ciclosporin, sirolimus or tacrolimus (to prevent transplant rejection)
- cyclophosphamide, prednisone, vinca alkaloids or ibrutinib (for treating some forms of blood cancer e.g. leukaemia)
- atorvastatin, simvastatin or fluvastatin (for lowering cholesterol)
- non-steroidal anti-inflammatory drugs (such as aspirin and ibuprofen) that are used to treat pain and fever
- olaparib (used for treating ovarian cancer)
- oral contraceptives (the pill) (to prevent pregnancy)
- saquinavir or zidovudine, also known as AZT (used in HIV-infected patients)
- medicines for diabetes such as chlorpropamide, glibenclamide, glipizide or tolbutamide
- theophylline (used to control asthma)
- tofacitinib (used for treating rheumatoid arthritis)
- tolvaptan (used to treat low levels of sodium in blood or to slow kidney function decline)
- vitamin A (as a trans-retinoid acid used to treat acne)

FLUCORIC with food and drink

You can take FLUCORIC capsules with or without a meal at any time of the day.

Pregnancy, breast-feeding and fertility

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 taking this medicine.

You should not take FLUCORIC while you are pregnant or if you are breastfeeding.

Effective contraceptive measures must be considered in women of childbearing potential throughout treatment with FLUCORIC and for approximately 1 week after the final dose.

Driving and using machines

Treatment with FLUCORIC may lead to dizziness or seizures to occur and could affect your ability to drive or use machinery.

It is not always possible to predict to what extent FLUCORIC may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which FLUCORIC affects them.

FLUCORIC capsules contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take FLUCORIC

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

Always take FLUCORIC exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You can take FLUCORIC capsules with or without a meal at any time of the day.

Elderly

The usual adult dose should be given unless you have kidney problems.

Patients with kidney problems

Your doctor may modify your dose, depending on your kidney function.

If you are not sure, ask your doctor or pharmacist.

It is best to take your medicine at the same time each day. You may take it with or without meals.

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

If you take more FLUCORIC than you should

Taking too much FLUCORIC may make you unwell.

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

If you forget to take FLUCORIC

Do not take a double dose to make up for forgotten individual doses. If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the dose that you missed.

4. Possible side effects

FLUCORIC can have side effects.

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

You may develop allergic reactions. If any of the following happens, tell your doctor immediately.

- Sudden wheezing, difficulty in breathing or tightness in chest
- Swelling of eyelids, face or lips
- Itching all over the body, reddening of the skin or itchy red spots
- Skin rash
- Severe skin reactions such as a rash that causes blistering (this can affect the mouth and tongue)
- Hypersensitivity reaction with skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia) and inflammation of internal organs (liver, lungs, heart, kidneys and large intestine); stop taking FLUCORIC and seek medical attention immediately if you notice any of the following symptoms: widespread rash, high body temperature and enlarged lymph nodes (swollen glands) (DRESS syndrome or drug hypersensitivity syndrome)

These are all serious side effects. You may need urgent medical attention.

If you are an AIDS patient, you are more likely to get severe skin reactions to medicines including FLUCORIC.

Tell your doctor if you notice any of the following:

Frequent side effects

- headache
- stomach discomfort
- diarrhoea
- feeling sick (nausea)
- vomiting
- increases in blood tests of liver function
- rash

Less frequent side effects

- insomnia (difficulty in sleeping)
- somnolence (feeling sleepy)
- seizures (fits)
- dizziness
- tingling or pricking (pins and needles)
- altered sense of taste
- sensation of spinning (vertigo)
- indigestion
- wind
- dry mouth
- decrease in bile flow
- yellowing of the skin and eyes (jaundice)
- higher than normal levels of bilirubin in your blood (seen in blood tests)
- itching
- increased sweating
- myalgia (muscle pain)
- fatigue
- tiredness
- general feeling of being unwell
- fever
- lower than normal white blood cells that help defend against infections and blood cells that help to stop bleeding
- high blood levels of cholesterol, fats or salt
- low blood potassium levels
- tremor
- change in heart rate or rhythm

- liver damage or failure
- hair loss

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, pharmacist or nurse. 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 FLUCORIC.

5. How to store FLUCORIC

- Store all medicines out of reach of children.
- Store at or below 25 °C, protected from moisture.
- Do not use FLUCORIC after the expiry date which is stated on the pack. The expiry date refers to the last day of the month.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What FLUCORIC contains

The active substance is fluconazole.

Flucoric 50 Capsules: Each capsule contains fluconazole 50 mg.

Flucoric 100 Capsules: Each capsule contains fluconazole 100 mg.

Flucoric 150 Capsules: Each capsule contains fluconazole 150 mg.

Flucoric 200 Capsules: Each capsule contains fluconazole 200 mg.

The other ingredients are:

Flucoric Capsules:

- colloidal anhydrous silica
- lactose monohydrate
- magnesium stearate
- maize starch
- sodium lauryl sulphate

Capsule shell – cap (Blue, opaque) – Flucoric 50 / 100 / 150 Capsules)

- Patent Blue (CI No. 42051) - (Flucoric 50 / 100 /150 Capsules)
- Phloxine B - (Flucoric 100 Capsules)
- Titanium dioxide (CI No. 77891) – (Flucoric 50 / 100 / 150 Capsules)
- Gelatin. – (Flucoric 50 / 100 / 150 Capsules)

Capsule shell – cap Purple, opaque (Flucoric 200 Capsules)

- Patent Blue (CI No. 42051)
- Phloxine B
- Titanium dioxide (CI No. 77891)
- Gelatin

Capsule Body (White, opaque) Flucoric 50 / 100 / 200 Capsules)

- Titanium dioxide (CI No. 77891)
- Gelatin

Capsule Body (Blue, opaque) - (Flucoric 150 Capsules)

- Patent Blue (CI No. 42051)
- Titanium dioxide (CI No. 77891)

- Gelatin

Composition of the printing ink (Flucoric 50 / 100 / 150 / 200 Capsules)

- Shell USNF
- Dehydrated alcohol USP
- isopropyl alcohol USP
- Butyl alcohol NF
- Propylene glycol USP
- Purified water USP
- Black iron oxide (CI No. 77499)

What FLUCORIC looks like and contents of the pack

Flucoric 50 Capsules

Blue/white hard gelatin, self locked capsules of size '4' imprinted with 'RANBAXY' in black edible ink on both cap and body containing white to off-white powder.

Flucoric 100 Capsules

Blue/white hard gelatin, self locked capsules of size '2' imprinted with 'RANBAXY' in black edible ink on both cap and body containing white to off-white powder.

Flucoric 150 Capsules

Blue/blue hard gelatin, self locked capsules of size '1' imprinted with 'RANBAXY' in black edible ink on both cap and body containing white to off-white powder.

Flucoric 200 Capsules

Purple/white hard gelatin, self locked capsules of size '0' imprinted with 'RANBAXY' in black edible ink on both cap and body containing white to off-white powder.

Contents of the pack:**Flucoric 50 Capsules**

Cartons containing blister strips consisting of white, opaque PVC (PVdC coated) film with an aluminium foil backing containing 14 capsules each.

Flucoric 100 Capsules

Cartons containing blister strips consisting of white, opaque PVC (PVdC coated) film with an aluminium foil backing containing 14 capsules each.

Flucoric 150 Capsules

Cartons containing blister strips consisting of white, opaque PVC (PVdC coated) film with an aluminium foil backing containing 1 or 4 capsules each.

Flucoric 200 Capsules

Cartons containing blister strips consisting of white, opaque PVC (PVdC coated) film with an aluminium foil backing containing 28 capsules each.

Holder of Certificate of Registration

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