PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

HEXAL® FLUCONAZOLE 50 (capsules)

FLUCONAZOLE UNICORN 150 (capsules)

HEXAL® FLUCONAZOLE 200 (capsules)

Fluconazole

Each HEXAL FLUCONAZOLE 50 capsule contains sugar (lactose monohydrate 48,75 mg).

Each FLUCONAZOLE UNICORN 150 capsule contains sugar (lactose monohydrate 146,25 mg).

Each HEXAL FLUCONAZOLE 200 capsule contains sugar (lactose monohydrate 195,0 mg).

Read all of this leaflet carefully before you start taking HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN 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 HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN is and what it is used for
2. What you need to know before you take HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN
3. How to take HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN
4. Possible side effects
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1. What HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN is and what it is used for

HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN contains fluconazole which is an antifungal agent used to treat serious fungus infections that may occur in different parts of the body.

Your doctor has prescribed HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN for you to treat the specific fungal infection you have. HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN can be prescribed alone or in combination with other medicines.

2. What you need to know before you take HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN

Do not take HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN if:

- You are hypersensitive (allergic) to fluconazole or any of the other ingredients of HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN (listed in section 6).
- You are taking antihistamines called terfenadine or astemizole.
- You are taking a medicine called cisapride to increase your bowel movements.
- You are pregnant or breastfeeding.
- You should not take multiple doses if you have a serious kidney problem.

Warnings and precautions

Take special care with HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN:

Before taking this medication, tell your doctor if:

- You have kidney problems.
- You suffer from liver problems or start developing liver problems while taking this medicine. If you develop the following symptoms, you should speak to your doctor, as they may be signs of serious liver problems: feeling tired all the time, loss of appetite and weight loss (anorexia), feeling nauseous all the time, vomiting and jaundice (yellowing of the white of the eyes and skin).
- You are HIV positive.
- You have been diagnosed with any malignancies (cancer).
- You develop signs of ‘adrenal insufficiency’ where the adrenal glands do not produce adequate amounts of certain steroid hormones such as cortisol, which may present with the following

symptoms: chronic, or long lasting fatigue, muscle weakness, loss of appetite, weight loss, abdominal pain.

- You suffer from heart disease, including heart rhythm problems.
- You have abnormal levels of potassium, calcium or magnesium in your blood (seen in blood tests).
- You develop severe skin reactions (itching, reddening of the skin, rash, swelling, dry skin, abnormal odour, flaking and blistering of the skin).

Children and adolescents

Follow the dose prescribed by your doctor. The dose will be based on the child's weight in kilograms.

Other medicines and HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN

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

Please advise your doctor or health care provider if you are using any of the following products as these should not be taken with HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN (see section "Do not take HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN if"):

- Cisapride a medicine used to increase bowel movements.
- Antihistamines e.g. terfenadine and astemizole.
- Pimozide (used for treating mental illness).
- Quinidine (used for treating heart arrhythmia).
- Erythromycin (an antibiotic for treating infections).

HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN may interact with the following medicines, make sure your doctor knows if you are taking any of these medicines:

- Blood thinning agents e.g. warfarin.
- Medicines against epilepsy e.g. phenytoin, carbamazepine.
- Oral antidiabetic medicines such as chlorpropamide, glibenclamide, glipizide or tolbutamide.
- Theophylline (a medicine for asthma).

- Antiretroviral medicines e.g. zidovudine, saquinavir.
- Ciclosporin, everolimus, sirolimus and tacrolimus, immunosuppressants used after organ transplants.
- Anti-anxiety medicines called benzodiazepines (e.g. midazolam, triazolam).
- Anti-TB medicine called rifabutin (HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN may also interact with the anti-TB medicine rifampicin by decreasing the blood level of this medicine, which could lead to ineffectiveness of this medicine).
- The diuretic (medicine that increases urination), hydrochlorothiazide increases the blood levels of HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN.
- Halofantrine (used for treating malaria).
- Amiodarone (used for treating uneven heartbeats ‘arrhythmias’).
- Alfentanil, fentanyl (used as anaesthetic).
- Amitriptyline, nortriptyline (used as anti-depressant).
- Amphotericin B, voriconazole (anti-fungal).
- Nifedipine, isradipine, amlodipine, verapamil, felodipine and losartan (high blood pressure medication).
- Celecoxib, flurbiprofen, naproxen, ibuprofen, lornoxicam, meloxicam, diclofenac (Non-Steroidal Anti-Inflammatory Drugs (NSAID)).
- Cyclophosphamide, vinca alkaloids (vincristine, vinblastine or similar medicines) used for treating cancer.
- Statins (atorvastatin, simvastatin and fluvastatin or similar medicines) used for reducing high blood cholesterol levels.
- Ibrutinib (used for treating blood cancer).
- Ivacaftor (used for treating cystic fibrosis).
- Olaparib (used for treating ovarian cancer).
- Methadone (used for pain).
- Prednisone (steroid).
- Tofacitinib (used for treating rheumatoid arthritis).
- Tolvaptan used to treat hyponatremia (low levels of sodium in your blood) or to slow kidney function decline.

- Vitamin A (nutritional supplement).

HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN with food, drink and alcohol

You can take this capsule before or after meals, the presence of food will not influence the absorption of the medicine. Do not chew, crack or open the capsule and swallow it whole.

Pregnancy, breastfeeding 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.

HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN should not be used during pregnancy or by women who plan to become pregnant.

An effective form of birth control should be used during treatment with this product.

HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN should not be used during breastfeeding.

Driving and using machines

HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN should not affect your ability to drive or use machinery, but you should refrain from driving or using machinery until you know how this medicine affects you as it may cause dizziness or seizures (fits).

HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN contains lactose

HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN contains lactose monohydrate. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN.

HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN contains lactose monohydrate, which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN

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

Always take HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN exactly as your doctor has told you. Check with your doctor if you are not sure.

If you have the impression that the effect of HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN is too strong or too weak, talk to your doctor or pharmacist.

Follow your doctor's advice. The capsules should be swallowed whole with a glass of water and should be taken the same time each day.

Cryptococcal meningitis:

***Adults*:** Initial dose is 400 mg on the first day; followed by 200 mg to 400 mg daily. Duration of therapy is usually 8 weeks.

***Children over 4 weeks of age*:** The medical practitioner will determine the correct dosage, depending on the severity of the infection.

Maintenance therapy to prevent reoccurrence of cryptococcal meningitis in patients with AIDS:

***Adults*:** 100 mg to 200 mg per day.

Candidiasis (thrush):

***Adults*:** Starting dose may differ from 50 mg to 400 mg daily depending on the type of candidiasis.

***Children over 4 weeks of age*:** The medical practitioner will determine the correct dosage.

Prevention of fungal infections in patients who receive chemotherapy and/or radiation therapy:

Adults: 50 mg to 400 mg daily depending on the patient's risk for developing fungal infections.

Children over 4 weeks of age: The medical practitioner will determine the correct dosage.

Fungal infections of the skin or nails:

***Adults*:** 150 mg administered as a single dose once a week.

If your kidney function is impaired your doctor may reduce your dosage.

If you take more HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and any remaining capsules with you, so that the doctor knows what the person has taken.

If you forget to take HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN

Take the missed dose as soon as possible. However, if it is almost time for you next dose, continue to take the next capsule at the usual time. Do not take a double dose.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you stop taking HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN

It is important to keep taking your medicine for as long as your doctor prescribes them. Do not stop taking your medicine without consulting your doctor first.

4. Possible side effects

HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN can have side effects.

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

If any of the following happens, stop taking HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Skin rash, hives or itching skin
- Fever and chills
- Severe skin reactions that causes blistering, peeling or loosening of skin (this can affect the mouth and tongue)
- Difficulty in swallowing
- Unusual tiredness or weakness
- Swelling of face, arms, hands, lower legs or feet

These are all very serious side effects. If you have them, you may have had a serious reaction to HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Diarrhoea
- Headache
- Rash
- Increases in blood tests of liver function
- Nausea
- Vomiting
- Stomach pain

Less frequent side effects:

- Reduction in red blood cells, which can make skin pale and cause weakness or breathlessness
- Allergic reaction
- Decreased appetite
- Low blood potassium
- Blood chemistry changes (high blood levels of cholesterol, fats)
- Dizziness
- Fits
- Sensation of tingling, pricking or numbness
- Shaking
- Sleeping problems
- Feeling drowsy
- Muscle pain
- Tiredness
- Lower than normal white blood cells that help defend against infections and blood cells that help to stop bleeding
- Sensation of your head spinning (vertigo)
- Red or purple discoloration of the skin, which may be caused by low platelet count, other blood cell changes
- Change in heart rate or rhythm
- Constipation
- Difficult digestion
- Liver damage and yellowing of the skin and eyes (jaundice)
- Liver failure
- Wind
- Unusual or unpleasant taste in mouth
- Dry mouth
- Temporary hair loss
- Increased sweating
- General feeling of being unwell
- Fever
- Abnormal electrocardiogram (ECG) (the ability of your heart to conduct electricity)

The frequency of the following side effects are unknown:

- 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) (Drug Reaction or rash with Eosinophilia and Systemic Symptoms (DRESS))

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 HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN. Suspected side effects can also be reported directly to the HCR (Holder of the Registration Certificate) via Patientsafety.sacg@novartis.com.

5. How to store HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN

Store at or below 25 ºC. Do not remove the blisters from the outer container until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use the capsules after the expiry date printed on the carton or label.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN contains:

Each HEXAL FLUCONAZOLE 50 capsule contains 50 mg fluconazole.

Each FLUCONAZOLE UNICORN 150 capsule contains 150 mg fluconazole.

Each HEXAL FLUCONAZOLE 200 capsule contains 200 mg fluconazole.

Inactive ingredients of HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN:

Anhydrous colloidal silica, hard gelatin capsule*****, lactose monohydrate, magnesium stearate, maize starch, sodium lauryl sulfate.

****Hard Gelatin capsule composed of:*** Gelatin, indigo carmine FD&C Blue 2**, Ponceau 4 R***, titanium dioxide.

***available in HEXAL FLUCONAZOLE 50 and HEXAL FLUCONAZOLE 200 only*

****available in HEXAL FLUCONAZOLE 200 only.*

Imprinting ink (all capsules):

Black iron oxide (E 172), propylene glycol (E 1520), shellac.

What HEXAL FLUCONAZOLE / FLUCONAZOLE UNICORN looks like and contents of the pack

HEXAL FLUCONAZOLE 50: Hard gelatin capsules, snap-fit closure, turquoise cap / white body with the imprint FC50, containing a white odourless powder.

FLUCONAZOLE UNICORN 150: Hard gelatin capsules, snap-fit closure, white cap / white body, with the imprint FC150, containing a white odourless powder.

HEXAL FLUCONAZOLE 200: Hard gelatin capsules, snap-fit closure, purple cap / white body, with the imprint FC200, containing a white odourless powder.

HEXAL FLUCONAZOLE 50: White, opaque PVC/Aluminium blister strips containing 14 capsules.

FLUCONAZOLE UNICORN 150: White, opaque PVC/Aluminium blister strips containing 1 or 4 capsules.

HEXAL FLUCONAZOLE 200: White, opaque PVC/Aluminium blister strips containing 28 or 30 capsules.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1], Waterfall 5-Ir, Magwa Crescent West, Waterfall City, Jukskei View, 2090

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HEXAL FLUCONAZOLE 200: 36/20.2.2/0266

[1]Company Reg. No.: 1990/001979/07