1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

KETAZOL TABLET

Ketoconazole 200 mg

Read all of this leaflet carefully before you are start taking KETAZOL TABLET.

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

The active substance is ketoconazole.

The other ingredients are croscarmellose sodium, lactose monohydrate, magnesium

stearate, maize starch, microcrystalline cellulose, povidone, purified talc, sodium sulphite anhydrous.

Contains sugar: Lactose monohydrate 50,0 mg.

WHAT KETAZOL TABLET IS USED FOR

KETAZOL TABLET is used for the treatment of certain skin infections caused by fungi or yeasts. KETAZOL TABLET should only be used if other medicines are not well tolerated.

BEFORE YOU TAKE KETAZOL TABLET

Do not take KETAZOL TABLET if you:

- Are hypersensitive (allergic) to ketoconazole, or to any other antifungal medicines called imidazoles, or any of the other ingredients of KETAZOL TABLET.
- Have pre-existing liver disease or liver problems and abnormal levels of enzymes in your liver.
- Have disturbances in the rhythm of your heart called QT prolongation.
- Are taking certain medicines that may interact with KETAZOL TABLET (see Using other medicines with KETAZOL TABLET).
- Have fungal meningitis.
- Are pregnant.
- Are breastfeeding.

Not to be taken by children.

Take special care with KETAZOL TABLET

Special care should be taken with KETAZOL TABLET:

- If you have underlying liver disease, a history of liver disease or consume excessive quantities of alcohol. Liver problems can sometimes occur even with a short course of KETAZOL TABLET. Before you are given KETAZOL TABLET your doctor may check your liver by testing your blood. Your doctor may re-test your blood at frequent intervals during treatment.
- Serum cortisol levels may decrease when you are taking KETAZOL TABLET. Your adrenal function should therefore be monitored if you have borderline adrenal function and if you are under prolonged periods of stress.
- If you have low testosterone levels. Testosterone levels may decrease after taking KETAZOL TABLET, but the levels return to normal after 24 hours.
- If you have a problem with your heart rhythm, KETAZOL TABLET can make this worse or cause a heart rhythm problem. This problem can be worsened when mixed with other medicines that can also cause heart rhythm problems.
- If you experience any of the following symptoms, report to your medical practitioner immediately as you might be experiencing hepatitis: nausea, vomiting, fatigue, loss of appetite, yellowing of the skin and eyes, pain in the stomach or abdomen or dark urine.
- If you are taking medicines that will decrease the acidity or suppress the secretion of acid in your stomach (e.g. aluminium hydroxide, H_2-antagonists, proton pump inhibitors), KETAZOL TABLET will not be absorbed fully.
- If you have an autoimmune disease or inflammation.
- If you have porphyria.

Taking KETAZOL TABLET with food and drink

Take KETAZOL TABLET with a meal.

If you take an antacid medicine, take it two hours after taking KETAZOL TABLET. If you

take medicines for a stomach ulcer it may be better to take KETAZOL TABLET with a cola drink. Check with your doctor if you take any of these medicines.

Taking alcohol while on treatment with KETAZOL TABLET may cause nausea, headache, swelling of hands and feet, reddening of the face or neck. Alcohol should not be used while on this treatment.

Pregnancy and breastfeeding

You should not take KETAZOL TABLET if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, please consult your doctor, pharmacist or other healthcare provider for advice before taking KETAZOL TABLET.

Driving and using machinery

Since adverse reactions such as dizziness and drowsiness have been reported in patients taking KETAZOL TABLET, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that KETAZOL TABLET does not adversely affect your ability to do so (see POSSIBLE SIDE EFFECTS).

Important information about some of the ingredients in KETAZOL TABLET

KETAZOL TABLET contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking KETAZOL TABLET. Patients with the rare hereditary conditions of lactose intolerance should not take KETAZOL TABLET.

Taking other medicines with KETAZOL TABLET

Always tell your healthcare provider if you are taking any other medicines (this includes

complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- Antihistamine medicine or medicine used for allergies such as mizolastine and ebastine.
- Cardiac or heart rhythm medicine such as dofetilide, quinidine, disopyramide and digoxin.
- Gastric reflux medicine such as cisapride.
- Psychiatric, anti-anxiety and sleeping medicine such as pimozide, triazolam, alprazolam, midazolam, buspirone, aripiprazole, haloperidol, quetiapine and risperidone.
- Domperidone and aprepitant used in nausea and vomiting.
- Cholesterol lowering medicines such as simvastatin, atorvastatin and lovastatin.
- Ergotamine, methylergometrine and dihydroergotamine used for migraines.
- Oral anticoagulant and antiplatelet medicine (medicine that reduces the thickness of your blood or stops clot forming) such as warfarin, rivaroxaban and dabigatran.
- Medicines used in HIV treatment such as indinavir saquinavir/ ritonavir, maraviroc and nevirapine.
- Medicines used in treating cancer such as vinca alkaloids (vincristine and vinblastine), busulphan, docetaxel, sunitinib, dasatinib, lapatinib, nilotinib, erlotinib, irinotecan, bortezomib, imatinib, cabazitaxel and paclitaxel.
- High blood pressure medicine such as dihydropyridines, verapamil and felodipine.
- Immunosupressive medicine (medicine that reduces your immune system response) such as ciclosporin, tacrolimus, sirolimus (rapamycin), everolimus,

temsirolimus, budesonide, ciclesonide, dexamethasone, fluticasone and methylprednisolone.

- Strong pain medicine such as methadone, buprenorphine, alfentanil, fentanyl and oxycodone.
- Medicine to treat epilepsy or fits such as carbamazepine and phenytoin.
- Medicine to treat high blood sugar such as repaglinide and saxapliptin.
- Medicine to treat certain types of infections such as rifabutin, rifampicin, isoniazid, telithromycin, clarithromycin and praziquantel.
- Medicine causing an increased passing of urine (water tablets) such as eplerenone.
- Medicine to open up your airways or chest such as salmeterol.
- Medicine used to treat bladder diseases such as fesoterodine, tolterodine and solifenacin.
- Medicine used to treat erectile dysfunction such as sildenafil, tadalafil and vardenafil.
- Medicine used to treat gout such as colchicine.
- Medicine that mimics the action of calcium in the body such as cinacalcet.
- Medicine used to treat malaria such as halofantrine.

HOW TO TAKE KETAZOL TABLET

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

Always take KETAZOL TABLET exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The dose of KETAZOL TABLET depends on the condition you have.

For chronic and recurrent vaginal candidiasis the usual dose is 2 tablets (400mg) once a day with a meal for 5 days.

All other indications:

The usual dose is one tablet (200 mg) once a day with a meal. Continue with the treatment until at least one week after the symptoms have disappeared and your doctor advises you that all cultures have become negative.

Your doctor will tell you how long your treatment with KETAZOL TABLET will last. Treatment can be for a long period depending on the condition being treated.

If you have the impression that the effect of KETAZOL TABLET is too strong or too weak, tell your doctor or pharmacist.

If you take more KETAZOL TABLET than you should

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

If you forget to take or miss a dose of KETAZOL TABLET

Take the missed dose as soon as you remember if within a few hours after missing a dose. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS

KETAZOL TABLET can have side effects.

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

If any of the following happens, stop taking KETAZOL TABLET and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to KETAZOL TABLET. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Chronic fatigue (unusually tired), muscle weakness, loss of appetite, weight loss and stomach pain. These signs and symptoms are associated with adrenocortical insufficiency.
- Chronic nausea, vomiting, stomach pain, unusually dark urine, light stools yellowing of the whites of the eyes and skin (jaundice). These signs and symptoms are associated with hepatitis, hepatic toxicity, cirrhosis (scarring of the liver) and liver failure.
- Changes in the way your heart beats, for example, if you notice it beating faster.

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

Tell your doctor if you notice any of the following:

The following side effects have been frequently reported:

- Nausea and vomiting and diarrhoea
- Increased enzymes in your liver
- Abnormal liver laboratory test results

The following side effects have been reported less frequently:

- Increased bleeding or bruising (due to lowering of blood platelets)
- Headache
- Dizziness
- Sleepiness
- Sudden decrease in blood pressure when standing up
- Hair loss
- Redness of the skin usually due to medicine use
- Loss of male sexual ability
- Decreased number of sperm (low sperm count)
- Lack of energy, weakness, tiredness
- Fever and chills

The following side effects have been reported but the frequency is unknown:

- Deceased testosterone concentration in your blood that lasts for a short time
- Alcohol intolerance
- Increased appetite
- Increased lipid levels

- Inability to sleep
- Nervousness
- Numbness, tingling, pins and needles
- Sensitivity to light
- Reversible, increased pressure in the brain
- Nose bleeds
- Heartburn and indigestion
- Constipation
- Dry mouth
- Lack of taste
- Wind or gas (flatulence)
- Tongue discolouration
- Muscle pain
- Joint pain
- Erectile dysfunction
- Menstrual disorders
- Breast enlargement in men
- No sperm count in the semen of men
- Hot flushes
- General feeling of being unwell
- A non-permanent decrease in testosterone levels

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: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of KETAZOL TABLET.

STORAGE AND DISPOSING OF KETAZOL TABLET

Store at or below 25 °C in a dry place.

Protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

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

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF KETAZOL TABLET

10, 30 and 100 tablets are packed in a polyvinyl chloride/polyvinylidenechloride blister strips.

The blister strips are packed into an outer cardboard carton together with a leaflet.

100 tablets are packed in a white polypropylene securitainer with a white low-density

polyethylene snap on cap, together with a white foam insert and a silica gel sachet and a leaflet.

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF KETAZOL TABLET

A round, white tablet with bevelled edges, bisected on one side.

REGISTRATION NUMBER

33/20.2.2/0309

NAME AND ADDRESS OF REGISTRATION HOLDER

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION

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Namibia: NS2 04/20.2.2/0036

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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