PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

Schedule 4

TRISPORAL 100 mg Capsules

Itraconazole

Contains sugar: each capsule contains 175.68 mg of sucrose.

Read all of this leaflet carefully before you are given TRISPORAL

- Keep this leaflet. You may need to read it again.
- TRISPORAL 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.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

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

1. What TRISPORAL is and what it is used for

TRISPORAL contains a medicine called itraconazole. This belongs to a group of medicines called 'antifungals'.

TRISPORAL is used for treating fungal infections of the vagina, skin, nails or internal organs.

2. What you need to know before you take TRISPORAL

Do not take TRISPORAL

- If you are hypersensitive (allergic) to itraconazole or any of the other ingredients of TRISPORAL (listed in section 6).
- if you are pregnant. If you are of childbearing age and could become pregnant, you should take adequate contraceptive precautions to make sure that you do not become pregnant while you are taking TRISPORAL. As TRISPORAL remains in the body for some time after you stop taking it, you should continue to use contraception until your next period after your treatment with TRISPORAL capsules is finished.
- if you have a condition called heart failure (also called congestive heart failure or CHF), TRISPORAL could make it worse. If your doctor decides that you need to take TRISPORAL even if you have this condition, be sure to get immediate medical help if you have shortness of breath, unexpected weight gain, swelling of the legs, unusual fatigue, or begin to wake up at night.

Also, do not use certain medicines if you are on TRISPORAL capsules. There are many medications that interact with TRISPORAL capsules. Please refer to the section "Other medicines and TRISPORAL".

Warnings and precautions

Tell your doctor, pharmacist or nurse before taking TRISPORAL, if:

- Always tell your doctor or pharmacist if you are taking any other medicine because taking some medicines together can be harmful.
- Tell your doctor if you know you have a liver problem. The dose of TRISPORAL capsules may have to be adjusted.

  Stop taking TRISPORAL capsules and see your doctor immediately should any of the following symptoms appear during the TRISPORAL treatment: lack of appetite, nausea, vomiting, tiredness, abdominal pain, yellow colour to skin or eyes, pale stools (bowel moments) or very dark urine.

  If you have to take TRISPORAL capsules your doctor may also ask you to have your blood checked regularly. The reason for this is to rule out liver disorders in timely fashion, since such disorders can occur very rarely.
- Tell your doctor if you have a heart problem. See or let your doctor know immediately if you develop shortness of breath, unexpected weight gain, swelling of the legs, unusual fatigue, or begin to wake up at night as these may be symptoms of heart failure.
- Tell your doctor if you have a kidney disorder. The dose of TRISPORAL may have to be adjusted.
- Tell your doctor or get medical assistance immediately if you have a severe allergic reaction (characterised by significant skin rash, itching, hives, difficulty breathing, and/or swollen face) whilst taking TRISPORAL capsules.
- Stop taking TRISPORAL capsules and tell your doctor immediately if you become oversensitive to sunlight.
- Stop taking TRISPORAL capsules and tell your doctor immediately if you experience a severe skin disorder such as widespread rash with peeling skin and blisters in the mouth, eyes and genitals, or a rash with small pustules or blisters.

- Stop taking TRISPORAL capsules and tell your doctor immediately if you develop any feelings of tingling, diminished sensation or weakness in your limbs, or other problems with the nerves in the arms or legs.
- If in the past you have had an allergic reaction to TRISPORAL or another antifungal, please discuss this with your doctor.
- Tell your doctor if you have cystic fibrosis before using TRISPORAL capsules.
- Tell your doctor if you have low white blood cell counts or HIV infection or have received an organ transplant. The dose of TRISPORAL capsules may have to be adapted.
- Stop taking TRISPORAL capsules and tell your doctor immediately if you experience any hearing loss symptoms. Patients taking TRISPORAL may develop temporary or permanent hearing loss and deafness.
- Tell your doctor if your vision gets blurry or you see double, if you hear ringing in your ears, if you lose the ability to control your urine or urinate much more than usual.
- Tell you doctor if you have pophyria.

Children and adolescents

Do not give TRISPORAL to children.

Other medicines and TRISPORAL

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

In particular, do not take the following list of medicines with TRISPORAL capsules and tell your doctor if you are taking any of these:

- • terfenadine, astemizole, mizolastine for allergy;

- bepridil, felodipine, nisoldipine, lercanidipine, ivabradine, ranolazine, eplerenone to treat angina (crushing chest pain) or high blood pressure;
- ticagrelor, to slow down blood clotting;
- cisapride; to treat certain digestive problems;
- simvistatin, lomitapide, lovastatin; which lower the cholesterol;
- midazolam (oral), triazolam; sleeping pills
- lurasidone, pimozide, sertindole; used for psychotic disorders
- levacetylmethadol, (levomethadyl), methadone; for severe pain or to manage addiction;
- halofantrine, to treat malaria;
- irinotecan, an anti-cancer medicine;
- dihydroergotamine or ergotamine (called ergot alkaloids); used in the treatment of migraine headaches;
- ergometrine (ergonovine) or methylergometrine (methylergonovine) (called ergot alkaloids); used to control bleeding and maintain uterine contraction after child birth;
- disopyramide, dronedarone, quinidine, dofetilide; to treat irregular heart beat rhythms;
- domperidone, to treat nausea and vomiting;
- isavuconazole; to treat fungal infections;
- naloxegol; to treat constipation caused by taking opioid painkillers;
- avanafil; to treat erectile dysfunction;
- dapoxetine; to treat premature ejaculation.
- colchicine, to treat gout;
- fesoteridine or solifenacin, when used to control irritated urinary bladder;
- telithromycin, an antibiotic;
- eliglustat, to treat Gaucher disease.

Wait at least 2 weeks after stopping TRISPORAL capsules before taking any of these medicines.

Medicines that are not recommended, because they can decrease the action of TRISPORAL capsules:

- carbamazepine, phenytoin, phenobarbital: to treat epilepsy:
- rifampicin. rifabutin, isoniazid; to treat tuberculosis:
- efavirenz, nevirapine; to treat HIV/AIDS.

You should therefore always inform your doctor if you are using any of these medicines so that the appropriate measures can be taken.

Wait at least 2 weeks after stopping these medicines before taking TRISPORAL capsules.

Medicines not recommended unless your doctor feels it is necessary:

- axitinib, bosutinib, carbazitaxel, cabozanitinib, ceritinib, cobimetinib, crizotinib,dabrafenib, dasatinib, docetaxel, ibrutinib, lapatanib, nilotinib, olaparib, pazopanib, regorafenib,sunitinib, trabectedin, trastuzumab emtansine, vinca alkaloids; used in the treatment of cancer;
- riociguat, sildenafil, tadalafil; when used to treat pulmonary hypertension (increased blood pressure in the blood vessels in the lungs);
- everolimus, rapamycin (also known as sirolimus); usually given after an organ transplant;
- bedaquiline; rifabutin; to treat tuberculosis;
- conivaptan, tolvaptan; to treat low blood sodium;
- apixaban, rivaroxaban; to slow down blood clotting;

- alfuzosin, sildosin; to treat benign prostatic enlargement;
- aliskiren, to treat hypertension;
- sildenafil, when used for pulmonary hypertension (increased blood pressure in the blood vessels in the lungs);
- carbamazepine, to treat epilepsy;
- colchicine, to treat gout;
- darifenacin, to treat urinary incontinence;
- everolimus, given after an organ transplant;
- fentanyl, a stong medicine to treat pain;
- vorapaxar; to treat heart attacks or strokes;
- salmeterol, to improve breathing;
- simeprevir, to treat hepatitis C;
- tamsulosin, to treat male prostate problems;
- vardenafil, to treat erectile dysfunction;
- *Saccharolmyces boulardii*; used to treat diarrhoea;
- lumacaftor/ ivacaftor; used to treat cystic fibrosis.

Wait at least 2 weeks after stopping TRISPORAL capsules before starting these medicines unless your doctor feels it is necessary to take.

Medicines that may require a dose change (for either TRISPORAL capsules or the other medicine)

- ciprofloxacin, clarithromycin, erythromycin, telithromycin; antibiotics
- delamanid, used to treat tuberculosis;
- trimetrexate; used to treat pneumonia in patients with immune system problems;

- bosentan, digoxin, nadolol, and certain calcium-channel blockers including verapamil; that act on the heart or blood vessels;
- guanfacine; used to treat attention deficit hyperactivity disorder;
- diltiazem; used to treat hypertension;
- coumarins (e.g. warfarin), cilostazol, dabigatran; that slow down blood clotting;
- methylprednisolone, budesonide, ciclesonide, fluticasone or dexamethasone, medicines given by mouth, injection or inhalation for conditions such as inflammations, asthma, and allergies;
- ciclosporine, tacrolimus, temsirolimus, which are usually given after an organ transplant;
- cobicistat, boosted elvitegravir, tenofovir disoproxil fumerate (TDF), maraviroc, and protease inhibitors: indinavir, ritonavir, ritonavir-boosted darunavir, ritonavir-boosted fosamprenavir, saquinavir; used in the treatment of HIV/AIDS;
- dienogest, ulipristal; used as contraceptives;
- boosted asunaprevir, boceprevir, daclatasvir, vaniprevir,telaprevir, used in the treatment of hepatitis C virus;
- bortezomib, brentuximab vedotin, busulphan, erlotinib, gefitinib, idelalisib, imatinib, ixabepilone, nintedanib, panobinstat, ponatinib, ruxolitinib, sonidegib, vandetanib; used in the treatment of cancer;
- buspirone, perospirone, ramelteon, midazolam IV, alprazolam, brotizolam; for anxiety or to help you sleep (tranquilliser);
- alfentanil, buprenorphine, oxycodone; sufentanil; certain strong medicines to treat pain;
- repaglinide, saxagliptin; to treat diabetes;
- aripiprazole, cariprazine, haloperidol, quetiapine, risperidone; to treat psychosis;

- suvorexant, zopiclone; to treat insomnia;
- aprepitant, netupitant; certain medicines to treat nausea and vomiting during cancer treatment;
- loperamide; to treat diarrhoea;
- fesoterodine, imidafenacin, oxybutynin, solifenacin, tolterodine; to control irritated urinary bladder;
- dutasteride; used to treat benign prostatic enlargement;
- sildenafil, tadalafil, udenafil; to treat erectile dysfunction;
- praziquantel, to treat fluke and tapeworms;
- bilastine, ebastine, rupatadine; for allergy;
- reboxetine, venlafaxine; to treat depression and anxiety;
- atorvastatin, to lower cholesterol;
- meloxicam, to treat joint inflammation and pain;
- cinacalcet, to treat over active parathyroid;
- mozavaptan, to treat low blood sodium;
- alitretinoin (oral formulation), to treat eczema;
- cabergoline; to treat Parkinson's disease;
- cannabinoids; to treat nausea and vomiting, weight loss for patients with immune system problems and muscle spasms in patients with multiple sclerosis;
- eletriptan, to treat migraine headaches;
- telithromycin, to treat pneumonia;
- ivacaftor; to treat cystic fibrosis;
- elbasvir, grazoprevir, glecaprevir, pibrentasvir, ombitasvir, paritaprevir, ritonavir, dasabuvir, to treat hepatitis C.

Tell your doctor if you are using any of these medicines.

There must be sufficient stomach acid to ensure that TRISPORAL capsules are properly absorbed by the body. Therefore, medicines that neutralise stomach acid should be taken at least 2 hours before TRISPORAL capsules or should not be taken sooner than 2 hours after TRISPORAL capsules. For the same reason, if you take medicines that stop the production of stomach acid, you should take your TRISPORAL capsules with a non-diet cola beverage. If in doubt, consult your doctor or pharmacist.

Tell your doctor before taking, or if you are already taking any of the above. They may need to alter the dose of TRISPORAL capsules or your other medicine.

TRISPORAL with food, drink and alcohol

- Always take TRISPORAL immediately after a complete meal, because it is very well taken up by the body in this way.
- Swallow the capsule whole with water.

Pregnancy and Breastfeeding

Do not use TRISPORAL during pregnancy or while breastfeeding your infant. (Refer to 'What you need to know before you take TRISPORAL, above.)

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 healthcare professional for advice before taking TRISPORAL.

Driving and using machines

TRISPORAL can sometimes cause dizziness, blurred/double vision or hearing loss. If you have these symptoms, do not drive or use machines.

TRISPORAL contains sugar (sucrose).

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

TRISPORAL capsules contain sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus or if you are intolerant to sucrose.

3. How to take TRISPORAL

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

Always take TRISPORAL exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

How much TRISPORAL you will need to take and how long will depend on the type of fungus and the place of infection. Your doctor or pharmacist will tell you exactly how to use TRISPORAL.

Skin infections: With skin infections, the lesions will disappear a few weeks after the end of the treatment with TRISPORAL capsules. This is typical of fungal patches: the medicine kills the fungus itself, but the lesion disappears together with regrowth of healthy skin.

Nail infections: Nail lesions disappear only 6 to 9 months after the end of treatment with TRISPORAL capsules since TRISPORAL kills only the fungus. That nail still needs to grow back after this and regrowth takes many months. So do not worry if you notice no improvement during your treatment. TRISPORAL will remain in your nail for several months to kill the

fungus. You should therefore only stop treatment as prescribed by your doctor, even though you do not see any improvement.

If you take more TRISPORAL than you should:

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

If you forget to take TRISPORAL:

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

4. Possible side effects

TRISPORAL can have side effects.

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

- Hypersensitivity to TRISPORAL capsules can occur. It can be recognised, for instance, by skin rash, itching, hives, shortness of breath or difficulty breathing, and/ or swollen face. Uncommonly, diminished sensation in the limbs, a tingling sensation in the limbs, or other problems with the nerves in the arms or legs can occur. Very rarely, an oversensitivity to sunlight or a severe skin disorder (widespread rash with peeling skin and blisters in the mouth, eyes and genitals, or rash with small pustules or blisters) can occur.
- You may experience one or more of the following symptoms that may be related to heart failure: shortness of breath, unexpected weight gain, swelling of the legs, unusual fatigue, or begin to wake up at night.

- One or more of the following symptoms that may be related to liver disorders may appear: lack of appetite, nausea, vomiting, tiredness, abdominal pain, jaundice, very dark urine, and pale stools.
- Your vision could get blurry or you could see double. You could hear a ringing in your ears. You could lose the ability to control your urine or urinate much more than usual. You may experience temporary or permanent hearing loss.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- *Stomach ache, nausea*
- *Headache*

Less frequent side effects:

- upset stomach, diarrhoea, vomiting, constipation, or excessive gas in stomach
- shortness of breath, cough, fluid in the lungs, altered voice, inflammation of the sinuses, inflammation of the nose, upper respiratory tract infection
- menstrual disorder, erectile dysfunction
- dizziness, confusion, tremor, sleepiness, fatigue, chills
- muscle weakness or pain, painful joints, pain, chest pain, swelling, generalised swelling
- inflammation of the pancreas
- unpleasant taste
- fever

- excessive sweating
- hair loss
- increase in heart rate, increase in blood pressure, decrease in blood pressure, or heart failure may also occur
- changes in laboratory tests may occur such as decrease in granulocytes, decrease in white blood cells, decrease in platelets, decrease in blood magnesium, decrease in blood potassium, increase in blood potassium, increase in blood sugar, increase in blood creatine phosphokinase, increase in liver enzymes, increase in blood bilirubin, increase in blood triglycerides, or increase in blood urea
- your vision could get blurry or you could see double
- you could hear ringing in your ears
- you could lose the ability to control your urine or urinate much more than usual
- you may experience temporary or permanent hearing loss]

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

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 “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 TRISPORAL.

5 How to store TRISPORAL

- Store in a dry place at or below 25° C. Protect from light.
- Do not use TRISPORAL after the expiry date which is stated on the blisters and the carton. The expiry date refers to the last day of the month.
- Store all medicines out of reach of children.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6 Contents of the pack and other information

What TRISPORAL contains:

- The active substance is itraconazole.
- Each TRISPORAL capsule contains 100 mg of itraconazole in a pellet formulation.
- The other ingredients are: hypromellose, macrogol, and sugar spheres (composed of maize starch, purified water and sucrose).

  The capsule itself is composed of erythrosine sodium, gelatin, indigotin disulphonate sodium and titanium dioxide.

What TRISPORAL looks like and contents of the pack

TRISPORAL 100 mg capsules are pink and blue capsules containing white to faintly cream-coloured beads (pellets).

Carton containing one or more blister strips of 4, 7 or 14 capsules each.

Holder of certificate of registration

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This leaflet was revised in

To be advised

Registration number

TRISPORAL capsules: A39/20.2.2/0617

Access to the corresponding Professional Information

Included in the carton, accompanying this patient information leaflet.