Applicant: MSD (Pty) Ltd
APPROVED PATIENT INFORMATION LEAFLET
NOXAFIL Tablet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

NOXAFIL® Tablet 100 mg

Posaconazole

NOXAFIL Tablets 100 mg are sugar free.

Read all of this leaflet carefully, before you start taking NOXAFIL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- NOXAFIL Tablets have been prescribed for you personally and you should not share your medicine with other people. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

What is in this leaflet

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

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1. What NOXAFIL is and what it is used for

NOXAFIL contains a medicine called posaconazole. This belongs to a group of medicines called "antifungals". NOXAFIL is used to prevent and treat many different fungal infections.

NOXAFIL works by killing or stopping the growth of some types of fungi that can cause infections.

NOXAFIL can be used to treat the following types of fungal infections in patients 13 years of age or older:

- Infections caused by fungi of the *Aspergillus* family that have not improved during treatment with the antifungal medicine's amphotericin B, itraconazole or voriconazole or when these
- infections of the mouth or throat area caused by fungi of the *Candida* family that have not improved during treatment with the antifungal medicine's amphotericin B, itraconazole or voriconazole, or when these medicines had to be stopped.
- Infections caused by fungi of the *Fusarium* family that have not improved during treatment of amphotericin B or other therapy, or when such therapy had to be stopped.
- Infections caused by fungi that cause the conditions known as zygomycosis, cryptococcosis, chromoblastomycosis and mycetoma, that have not improved during treatment with itraconazole or other therapy, or when such therapy had to be stopped.
- Infections caused by the condition known as coccidioidomycosis.
- NOXAFIL can be used to prevent fungal infections in patients whose immune systems may be weakened due to other medicines or diseases.

2. What you need to know before you take NOXAFIL

Do not take NOXAFIL if:

- you are hypersensitive (allergic) to posaconazole or to any of the other ingredients of NOXAFIL.
- you are taking medicines that contain ergot alkaloids (used to treat migraines). NOXAFIL can increase the blood levels of these medicines, which can lead to severe reductions in blood flow to some parts of the body and damage tissues.
- you are taking any of the following medicines. NOXAFIL can increase the blood levels of these medicines, which can lead to very serious disturbances in heart rhythm
  - terfenadine (used to treat allergies)
  - astemizole (used to treat allergies)
  - cisapride (used to treat stomach problems)
  - pimozide (used to treat symptoms of Tourette's disorder)
  - quinidine (used to treat abnormal heart rhythms).
- you are taking simvastatin, lovastatin, atorvastatin and some similar medicines (called HMG-CoA reductase inhibitors or statins) that are used to treat high cholesterol levels in the blood.
- you are pregnant or breastfeeding.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking NOXAFIL if you:

have had an allergic reaction to another antifungal medicine such

- as ketoconazole, fluconazole, itraconazole or voriconazole.

have or have ever had liver problems. You may need to have

- blood tests while you are taking this medicine.

develop severe diarrhoea or vomiting, as these conditions may

- limit the effectiveness of this medicine.

have an abnormal heart rhythm tracing (ECG) that shows a

- problem called long QTc interval.

have a weakness of the heart muscle or heart failure

- have a very slow heartbeat
- have heart rhythm disturbance
- have any problem with potassium, magnesium or calcium levels in your blood
- are taking vincristine, vinblastine and other "vinca alkaloids" (medicines used to treat cancer).
- are taking venetoclax (a medicine used to treat cancer).

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before taking NOXAFIL.

If you develop severe diarrhoea or vomiting (being sick) while taking NOXAFIL, talk to your doctor, pharmacist or nurse straight away, as this may stop it from working properly. See section 4 for more information.

Children

Children under the age of 13 must not use NOXAFIL, unless instructed to do so by a doctor.

Other medicines and NOXAFIL

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take NOXAFIL if you are taking any of the following:

- terfenadine (used to treat allergies)
- astemizole (used to treat allergies)
- cisapride (used to treat stomach problems)
- pimozide (used to treat symptoms of Tourette's and mental illness)
- halofantrine (used to treat malaria)
- quinidine (used to treat abnormal heart rhythms).

NOXAFIL can increase the amount of these medicines in the blood which may lead to very serious changes to your heart rhythm:

- any medicines that contain “ergot alkaloids” such as ergotamine or dihydroergotamine used to treat migraines. NOXAFIL can increase the amount of these medicines in the blood which may lead to a severe decrease in blood flow to your fingers or toes and could cause damage to them.
- a “statin” such as simvastatin, atorvastatin or lovastatin used to treat high cholesterol.

Do not take NOXAFIL if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Other medicines

Look at the list of medicines given above that must not be taken while you are taking NOXAFIL.

In addition to the medicines named above there are other medicines that carry a risk of rhythm problems that may be greater when they are taken with NOXAFIL. Please make sure you tell your doctor about all the medicines you are taking (prescribed or non-prescribed).

Certain medicines may increase the risk of side effects of NOXAFIL by increasing the amount of NOXAFIL in the blood.

The following medicines may decrease the effectiveness of NOXAFIL by decreasing the amount of NOXAFIL in the blood:

- rifabutin and rifampicin (used to treat certain infections). If you are already taking rifabutin, you will need a blood test and you will need to look out for some possible side effects of rifabutin.
- some medicines used to treat or prevent fits including phenytoin, carbamazepine, phenobarbital or primidone.
- efavirenz and fosamprenavir used to treat HIV infection.

NOXAFIL may possibly increase the risk of side effects of some other medicines by increasing the amount of these medicines in the blood.

These medicines include:

- vincristine, vinblastine and other “vinca alkaloids” (used to treat cancer)
- venetoclax (used to treat cancer)
- ciclosporin (used during or after transplant surgery)

- tacrolimus and sirolimus (used during or after transplant surgery)
- rifabutin (used to treat certain infections)
- medicines used to treat HIV called protease inhibitors (including lopinavir and atazanavir, which are given with ritonavir)
- midazolam, triazolam, alprazolam or other “benzodiazepines” (used as sedatives or muscle relaxants)
- diltiazem, verapamil, nifedipine, nisoldipine or other “calcium channel blockers” (used to treat high blood pressure)
- digoxin (used to treat heart failure)
- glipizide or other “sulfonylureas” (used to treat high blood sugar).

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking NOXAFIL.

Pregnancy and breastfeeding

Tell your doctor if you are or think you are pregnant before you start to take NOXAFIL. Do not take NOXAFIL if you are pregnant.

If you are a woman who could become pregnant you should use effective contraception while you are taking this medicine. If you become pregnant while you are taking NOXAFIL, contact your doctor straight away.

Do not breastfeed while taking NOXAFIL. This is because small amounts may pass into breast milk.

Driving and using machinery

You may feel dizzy, sleepy or have blurred vision while taking NOXAFIL, which may affect your ability to drive or use tools or machines. If this happens, do not drive or use any tools or machines and contact your doctor.

3. How to take NOXAFIL

Do not switch between taking NOXAFIL Tablets and NOXAFIL Oral Suspension without talking to your doctor or pharmacist because it may result in a lack of efficacy or an increased risk of adverse reactions.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will monitor your response and condition to determine how long NOXAFIL needs to be given and whether any change is needed to your daily dose.

How much to take

The usual dose is 300 mg (three 100 mg tablets) twice a day on the first day, then 300 mg (three 100 mg tablets) once a day, thereafter.

The length of treatment may depend on the type of infection that you have and may be individually adapted for you by your doctor. Do not adapt your dose yourself before consulting your doctor or change your treatment regimen.

- Swallow the tablet whole with some water.
- Do not crush, chew, break or dissolve the tablet.
- Tablets may be taken with or without food.

If you take more NOXAFIL than you should

If you think that you may have taken too much NOXAFIL, talk to a doctor or go to the hospital straight away.

If you forget to take NOXAFIL

- If you forget a dose, take it as soon as you remember it.
- However, if it is almost time for your next dose, skip the missed dose and go back to your regular schedule.
- Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Not all side effects reported for NOXAFIL are included in this leaflet.

Should your general health worsen of if you experience any untoward effects while taking NOXAFIL, please consult your healthcare provider for advice.

NOXAFIL Tablets can have side effects although not everybody gets them.

Serious side effects

Tell your doctor, pharmacist or nurse straight away if you notice any of the following serious side effects, you may need urgent medical treatment:

- nausea or vomit (feeling or being sick), diarrhoea
- signs of liver problems, these include yellowing of your skin or whites of the eyes, unusually dark urine or pale faeces, feeling sick for no reason, stomach problems, loss of appetite or
- unusual tiredness or weakness, an increase in liver enzymes shown up in blood tests
- allergic reaction.

Other side effects

Tell your doctor, pharmacist or nurse if you notice any of the following side effects:

Common side effects (occurring in at least 1 in 100 patients) are:

- a decrease in white blood cells (that can include the risk of infections)
- loss of appetite, electrolyte imbalance, low calcium
- headache, dizziness, numbness or tingling, sleepiness
- stomach pain, diarrhoea, upset stomach, wind, dry mouth, feeling or being sick, vomiting, constipation
- liver function tests that are higher than normal (including AST, ALT, alkaline phosphatase, GGT and bilirubin)
- rash, itching
- weakness, tiredness, fever.

Other side effects that were related to treatment of NOXAFIL during clinical trials were: altered concentration of other medicinal products, increased liver enzymes, nausea, rash and vomiting, excess bilirubin in the blood.

Uncommon and rare treatment related adverse events that were reported during clinical trials include: inability of the adrenal gland to function normally, allergic and/or hypersensitivity reactions.

Some patients have also reported feeling confused after taking NOXAFIL, the frequency of this is not known.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions 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 NOXAFIL Tablets.

5. How to store NOXAFIL

Store all medicines out of the reach of children.

Store at or below 30 °C.

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

Return all unused medicine to your pharmacist. Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

What NOXAFIL Tablet 100 mg contains

The active substance is 100 mg posaconazole per tablet.

The other ingredients are hypromellose succinate; microcrystalline cellulose; hydroxypropyl cellulose; silicone dioxide; croscarmellose sodium; magnesium stearate; Opadry® II yellow which consists of polyvinyl alcohol; macrogol and titanium.

6. Contents of the pack and other information

Available in PVC/Aclar/Al blister packs of 24 or 96 tablets.

Not all pack sizes may be marketed.

Yellow coated capsule shaped tablets debossed with “100” on one side.

Holder of Certificate of Registration

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This leaflet was revised in

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October 2024

Registration number

50/20.3/1111