Package leaflet: Information for the user

Noxafil® 100 mg gastro-resistant tablets
posaconazole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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

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". It is used to prevent and treat many different fungal infections.

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

Noxafil can be used in adults and children from 2 years of age weighing more than 40 kg to treat the following types of fungal infections:
- infections caused by fungi of the *Aspergillus* family;
- infections caused by fungi of the *Fusarium* family that have not improved during treatment with amphotericin B or when amphotericin B has had to be stopped;
- infections caused by fungi that cause the conditions known as "chromoblastomycosis" and "mycetoma" that have not improved during treatment with itraconazole or when itraconazole has had to be stopped;
- infections caused by a fungus called *Coccidioides* that have not improved during treatment with one or more of amphotericin B, itraconazole or fluconazole or when these medicines have had to be stopped.

This medicine can also be used to prevent fungal infections in adults and children from 2 years of age weighing more than 40 kg who are at high-risk of getting a fungal infection, such as:
- patients who have a weak immune system due to having chemotherapy for "acute myelogenous leukaemia" (AML) or "myelodysplastic syndromes" (MDS)
- patients having "high-dose immunosuppressive therapy" after "hematopoietic stem cell transplant" (HSCT).

2. What you need to know before you take Noxafil

Do not take Noxafil
- if you are allergic to posaconazole or any of the other ingredients of this medicine (listed in section 6).

- if you are taking: terfenadine, astemizole, cisapride, pimozide, halofantrine, quinidine, any medicines that contain “ergot alkaloids” such as ergotamine or dihydroergotamine, or a “statin” such as simvastatin, atorvastatin or lovastatin.
- if you have just started taking venetoclax or your venetoclax dose is being slowly increased for treatment of chronic lymphocytic leukaemia (CLL).

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 Noxafil.

See “Other medicines and Noxafil” below for more information including information on other medicines which may interact with Noxafil.

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).

You should avoid sun exposure while being treated. It is important to cover sun exposed areas of skin with protective clothing and use sunscreen with a high sun protection factor (SPF), as an increased sensitivity of skin to the sun’s UV rays may occur.

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
Noxafil should not be given to children younger than 2 years of age.

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.
- venetoclax when used at the start of the treatment of a type of cancer, chronic lymphocytic leukaemia (CLL).

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.
- phenytoin, carbamazepine, phenobarbital or primidone (used to treat or prevent fits).
- efavirenz and fosamprenavir used to treat HIV infection.
- flucloxacillin (antibiotic used against bacterial infections).

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)
- all-trans retinoic acid (ATRA), also called tretinoin (used to treat certain blood cancers).

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

Pregnancy and breast-feeding

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 unless you are told to by your doctor.
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 breast-feed while taking Noxafil. This is because small amounts may pass into breast milk.

Driving and using machines
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.

Noxafil contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Noxafil

Do not switch between 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.

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.

Taking this medicine
- 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

Like all medicines, this medicine can cause 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: the following may affect up to 1 in 10 people
- a change in the salt level in your blood shown in blood tests - signs include feeling confused or weak
- abnormal skin sensations, such as numbness, tingling, itching, creeping, pricking or burning
- headache
- low potassium levels – shown up in blood tests
- low magnesium levels – shown up in blood tests
- high blood pressure
- loss of appetite, stomach pain or upset stomach, passing wind, dry mouth, changes in your taste
- heartburn (a burning sensation in the chest rising up to the throat)
- low levels of "neutrophils" a type of white blood cell (neutropenia) –this can make you more likely to get infections and be shown up in blood tests
- fever
- feeling weak, dizzy, tired or sleepy
- rash
- itching
- constipation
- rectal discomfort

Uncommon: the following may affect up to 1 in 100 people
- anaemia - signs include headaches, feeling tired or dizzy, being short of breath or looking pale and a low level of haemoglobin shown up in blood tests
- low level of platelets (thrombocytopenia) shown in blood tests – this may lead to bleeding
- low level of "leukocytes" a type of white blood cell (leukopenia) shown in blood tests – this can make you more likely to get infections
- high level of "eosinophils" a type of white blood cell (eosinophilia) – this can happen if you have inflammation
- inflammation of the blood vessels
- heart rhythm problems
- fits (convulsions)
- nerve damage (neuropathy)
- abnormal heart rhythm – shown up on a heart trace (ECG), palpitations, slow or fast heartbeat, high or low blood pressure
- low blood pressure
- inflammation of the pancreas (pancreatitis) – this may cause severe stomach pain
- oxygen supply to the spleen is interrupted (splenic infarction) - this may cause severe stomach pain
- severe kidney problems – signs include passing more or less urine, that is a different colour than usual
- high blood levels of creatinine – shown in blood tests
- cough, hiccups
- nose bleeds
- severe sharp chest pain when breathing in (pleuritic pain)
- swelling of lymph glands (lymphadenopathy)
- reduced feeling of sensitivity especially on the skin
- tremor
- high or low blood sugar levels
- blurred vision, sensitivity to light
- hair loss (alopecia)
- mouth ulcers

- shivering, feeling generally unwell
- pain, back or neck pain, pain in arms or legs
- water retention (oedema)
- menstrual problems (abnormal vaginal bleeding)
- inability to sleep (insomnia)
- being completely or partially unable to talk
- swelling of the mouth
- abnormal dreams, or difficulty sleeping
- problems with co-ordination or balance
- mucosal inflammation
- stuffy nose
- difficulty breathing
- chest discomfort
- feeling bloated
- mild to severe nausea, vomiting, cramps and diarrhoea, usually caused by a virus, stomach pain
- belching
- feeling jittery

Rare: the following may affect up to 1 in 1 000 people

- pneumonia – signs include feeling short of breath and producing discoloured phlegm
- high blood pressure in the blood vessels in the lungs (pulmonary hypertension) this can cause serious damage to your lungs and heart
- blood problems such as unusual blood clotting or prolonged bleeding
- severe allergic reactions, including widespread blistering rash and skin peeling
- mental problems such as hearing voices or seeing things that are not there
- fainting
- having problems thinking or talking, having jerking movements, especially in your hands that you cannot control
- stroke – signs include pain, weakness, numbness, or tingling in the limbs
- having a blind or dark spot in your field of vision
- heart failure or heart attack which could lead to the heart stopping beating and death, heart rhythm problems, with sudden death
- blood clots in your legs (deep vein thrombosis) – signs include intense pain or swelling of the legs
- blood clots in your lungs (pulmonary embolism) – signs include feeling short of breath or pain while breathing
- bleeding into your stomach or gut – signs include vomiting blood or passing blood in your stool
- a blockage in your gut (intestinal obstruction) especially in the "ileum". The blockage will prevent the contents of your intestine from passing through to the lower bowel – signs include feeling bloated, vomiting, severe constipation, loss of appetite, and cramps
- "haemolytic uraemic syndrome" when red blood cells breakup (haemolysis) which may happen with or without kidney failure
- "pancytopenia" low level of all blood cells (red and white blood cells and platelets) shown in blood tests
- large purple discolourations on the skin (thrombotic thrombocytopenic purpura)
- swelling of the face or tongue
- depression
- double vision
- breast pain
- adrenal glands not working properly – this may cause weakness, tiredness, loss of appetite, skin discolouration
- pituitary gland not working properly – this may cause low blood levels of some hormones that affect the function of the male or female sex organs
- hearing problems

- pseudoaldosteronism, which results in high blood pressure with a low potassium level (shown in blood test)

Not known: frequency cannot be estimated from the available data
- some patients have also reported feeling confused after taking Noxafil.
- redness of the skin

Tell your doctor, pharmacist or nurse if you notice any of the side effects listed above.

Reporting of side effects
If you get any 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 directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Noxafil

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Noxafil contains
- The active substance in Noxafil is posaconazole. Each tablet contains 100 mg of posaconazole.
- The other ingredients are: hypromellose acetate succinate; cellulose, microcrystalline; hydroxypropylcellulose (E463); silica dental type; croscarmellose sodium; magnesium stearate, polyvinyl alcohol, macrogol 3350, titanium dioxide (E171), talc, iron oxide yellow (E172).

What Noxafil looks like and contents of the pack
Noxafil gastro-resistant tablets are yellow-coated and capsule-shaped, debossed “100” on one side packaged in a blister in cartons of 24 (2x12) or 96 (8x12) tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Merck Sharp & Dohme (UK) Limited, 120 Moorgate, London, EC2M 6UR, United Kingdom.

Manufacturer: Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands.

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