

NOXAFIL[®] Modified Release Tablets and Oral Suspension

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using NOXAFIL?

NOXAFIL contains the active ingredient posaconazole. Posaconazole is used to kill or stop the growth of fungi that can cause infections. For more information, see Section [1. Why am I using NOXAFIL?](#) in the full CMI.

2. What should I know before I use NOXAFIL?

Do not use if you have ever had an allergic reaction to posaconazole or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I use NOXAFIL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NOXAFIL and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use NOXAFIL?

Do not switch between taking NOXAFIL Modified Release Tablets and NOXAFIL Oral Suspension without talking to your doctor. Follow all directions given to you by your doctor and pharmacist carefully.

More instructions can be found in Section [4. How do I use NOXAFIL?](#) in the full CMI.

5. What should I know whilst using NOXAFIL?

Things you should do	- Remind any doctor, dentist or pharmacist you visit that you are using NOXAFIL. - If you are about to start any other new medicine, tell your doctor that you are taking NOXAFIL. - If you need to have any blood tests, tell your doctor you are taking NOXAFIL. NOXAFIL may affect the results of some laboratory tests.
Things you should not do	- Do not give NOXAFIL to anyone else, even if they have the same condition as you. - Do not use NOXAFIL to treat any other medical complaints unless your doctor tells you to.
Driving or using machines	- NOXAFIL may cause dizziness, sleepiness, or blurred vision in some people. - There have been side effects reported with NOXAFIL that may affect your ability to drive or operate machinery. Individual responses to NOXAFIL may vary. Be careful before you drive or use any machines or tools until you know how NOXAFIL affects you.
Looking after your medicine	- Store NOXAFIL Oral Suspension in a cool dry place where the temperature stays below 25°C - Store NOXAFIL Modified Release tablets below 30°C - Do not store NOXAFIL or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. - Keep NOXAFIL and all other medicines where children cannot reach them.

For more information, see Section [5. What should I know whilst using NOXAFIL?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor if you experience any of the following: loss of appetite, sleeplessness, headache, dizziness, sleepiness, tingling in fingers or toes, hot flushes, upset stomach, nausea, vomiting, stomach pain, diarrhoea, gas from stomach or bowel, dry mouth, altered sense of taste, dry skin, rash, itchiness, back pain, fever, raised blood pressure with a low potassium level.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

NOXAFIL[®] Modified Release Tablets and Oral Suspension

Active ingredient: *Posaconazole*

Consumer Medicine Information (CMI)

This leaflet provides important information about using NOXAFIL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using NOXAFIL.**

Where to find information in this leaflet:

- [1. Why am I using NOXAFIL?](#)
- [2. What should I know before I use NOXAFIL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use NOXAFIL?](#)
- [5. What should I know whilst using NOXAFIL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using NOXAFIL?

NOXAFIL contains the active ingredient posaconazole.

NOXAFIL is a medicine that belongs to the triazole group of antifungals. Noxafil is used to kill or stop the growth of fungi that can cause infections.

NOXAFIL Modified Release Tablets and Oral Suspension are used for:

- The treatment of invasive aspergillosis, a fungal infection caused by a fungus called **aspergillus**
- The treatment of other serious fungal infections called **fusariosis, zygomycosis, chromoblastomycosis and mycetoma.**

NOXAFIL Oral Suspension is also used to treat superficial fungal infections of the mouth and throat called oropharyngeal candidiasis.

These types of fungal infections usually occur in some patients who may have lowered resistance to infection due to poor immunity.

Treatment of these serious fungal infections with NOXAFIL is usually reserved for patients who do not respond to or cannot tolerate other medicines used to treat these types of fungal infections.

NOXAFIL is also used to treat coccidioidomycosis, a rare and serious fungal infection.

NOXAFIL is also used to prevent fungal infections, such as yeasts and moulds, from occurring in patients who are at high-risk of developing these infections.

Your doctor may have prescribed NOXAFIL for another reason.

Ask your doctor if you have any questions about why NOXAFIL has been prescribed for you.

This medicine is available only with a doctor's prescription

2. What should I know before I use NOXAFIL?

Warnings

Do not use NOXAFIL if:

you are allergic to posaconazole (or any other triazole antifungal medicines) or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include skin rash, itching, hives, shortness of breath, difficulty breathing, swelling of the face, tongue or other parts of the body.

Check with your doctor if you:

have any allergies to any other medicines, including other antifungal medicines such as:

- itraconazole (Sporanox[®])
- fluconazole (Diflucan[®])
- voriconazole (Vfend[®])
- ketoconazole (Nizoral[®])

or any other substances such as foods, preservatives or dyes.

have or have ever had any other health problems/ medical conditions including:

- any kidney problems
- any liver problems
- any heart problems
- any problems with potassium, magnesium, or calcium levels in your blood.

Follow your doctor's advice if any blood tests to check on your kidney or liver are recommended

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Children

NOXAFIL is not recommended for children below the age of 13 years.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

NOXAFIL should not be taken during pregnancy unless indicated by your doctor. Women who are of childbearing potential should use effective contraception while taking NOXAFIL and for 2 weeks after completing treatment.

Once you have finished taking NOXAFIL, continue using contraception until your next period.

Your doctor will discuss the possible risks and benefits to you and your unborn baby.

If you become pregnant while you are taking NOXAFIL, tell your doctor immediately.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

NOXAFIL should not be taken by breastfeeding women. It is possible that the active ingredient, posaconazole, may be passed into the breast milk. Your doctor can discuss the risks and benefits involved.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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

- certain medicines used to treat allergy or hay fever (terfenadine or astemizole)
- cisapride (a medicine used to treat certain stomach problems)
- pimozide (a medicine used to treat certain mental disorders)
- quinidine (a medicine used to treat irregular heart beat)
- ergotamine and dihydroergotamine, which are medicines used to treat migraine
- halofantrine (a medicine used to treat malaria)
- simvastatin, lovastatin, atorvastatin or similar medicines (called HMG-CoA reductase inhibitors or statins) that are used to treat high cholesterol levels.
- rivaroxaban or apixaban (medicines used to thin the blood)

Some medicines may interfere with NOXAFIL and affect how it works.

Some medicines may increase the risk of side effects of NOXAFIL by increasing the amount of posaconazole in the blood. Similarly, some medicines may decrease the effectiveness of NOXAFIL by decreasing the amount of posaconazole in the blood.

Medicines that can decrease the effectiveness of NOXAFIL are:

- rifabutin (used to treat tuberculosis)
- phenytoin (used to treat fits or convulsions)
- efavirenz and fosamprenavir (used to treat HIV infection)
- medicines used to decrease stomach acid such as cimetidine, ranitidine and omeprazole
- flucloxacillin (antibiotic used against bacterial infections).

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

- vincristine, vinblastine and other vinca alkaloids (used to treat cancer)

- cyclosporine, tacrolimus and sirolimus (used to treat certain immune system problems or to prevent organ transplant rejection)
- rifabutin (used to treat certain infections)
- midazolam and other benzodiazepine medicines (used as sedatives or muscle relaxants)
- calcium channel blockers, such as diltiazem, nifedipine and verapamil (used in certain heart conditions and to treat high blood pressure)
- digoxin (used to treat certain heart conditions)
- sulfonylureas such as glipizide (used to treat diabetes)
- medicines used to treat HIV called protease inhibitors (including atazanavir which is given with ritonavir) and non- nucleoside reverse transcriptase inhibitors
- venetoclax (used to treat certain blood cancers)
- all-trans retinoic acid (ATRA) or tretinoin (used to treat certain blood cancers)

These medicines may be affected by NOXAFIL or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NOXAFIL.

4. How do I use NOXAFIL?

Do not switch between taking NOXAFIL Modified Release Tablets and NOXAFIL Oral Suspension without talking to your doctor.

Follow all directions given to you by your doctor and pharmacist carefully.

This information may differ from the information contained in this leaflet.

If you do not understand the instructions on the box / bottle label, ask your doctor or pharmacist for help.

NOXAFIL Oral Suspension:

How much NOXAFIL Oral Suspension to take

Treatment of invasive fungal infections:

These types of fungal infections include: aspergillosis, coccidioidomycosis, fusariosis, zygomycosis, chromoblastomycosis and mycetoma

The usual dose for adults is 10 mL twice a day.

Treatment of oropharyngeal candidiasis:

The usual dose for adults is 5 mL once on the first day, then take 2.5mL once daily for 13 days.

Prevention of invasive fungal infections:

The usual dose for adults is 5 mL three times a day.

A measuring spoon is supplied with the medicine.

The dose may vary from one patient to another. Your doctor may recommend a different dose depending on your condition.

How to take NOXAFIL Oral Suspension

Shake the bottle well before use.

You should take NOXAFIL Oral Suspension with a meal or a nutritional supplement. Taking this medication with food containing fat will improve absorption.

Directions for opening the bottle

- NOXAFIL Oral Suspension comes with a child-resistant cap. It can be opened by pushing down on the plastic screw cap while turning it anti-clockwise.

NOXAFIL Modified Release Tablets:

How many NOXAFIL Modified Release Tablets to take

For treatment and prevention of invasive fungal infections:

The usual dose is three tablets twice a day on the first day, then three tablets once a day, thereafter.

The dose may vary from one patient to another. Your doctor may recommend a different dose depending on your condition.

How to take NOXAFIL Modified Release Tablets

Swallow the tablet whole with some water.

Do not crush, chew, break or dissolve the tablet.

NOXAFIL modified release tablets may be taken with or without food.

How long to use NOXAFIL Oral Suspension and Modified Release Tablets

Your doctor will advise how long you should take NOXAFIL.

Continue taking NOXAFIL for the length of time that your doctor recommends.

If you forget to use NOXAFIL

Take the dose you missed as soon as you remember, then continue to take it as you normally would.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

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

If you have taken too much NOXAFIL (overdose)

If you think that you have used too much NOXAFIL you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia) or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know whilst using NOXAFIL?

Things you should do

Always follow your doctor's instructions carefully.

If you are a woman of childbearing age, talk to your doctor about the need for effective contraception. Once you have finished taking NOXAFIL, continue using contraception until your next period.

If you become pregnant while you are taking NOXAFIL, tell your doctor immediately.

If you are about to start any other new medicine, tell your doctor that you are taking NOXAFIL.

If you need to have any blood tests, tell your doctor you are taking NOXAFIL. NOXAFIL may affect the results of some laboratory tests.

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.

Tell all doctors, dentists and pharmacists who are treating you that you are taking NOXAFIL.

Call your doctor straight away if you:

- Have diarrhoea or vomiting
- If you become pregnant or plan to get pregnant while you are taking NOXAFIL.
- Do not feel well whilst you are using NOXAFIL, or after using NOXAFIL
- Remind any doctor, dentist or pharmacist you visit that you are using NOXAFIL.

Remind any doctor, dentist or pharmacist you visit that you are using NOXAFIL.

Things you should not do

- Do not give NOXAFIL to anyone else, even if they have the same condition as you.
- Do not use NOXAFIL to treat any other medical complaints unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how NOXAFIL affects you.

You may feel dizzy, sleepy, or have blurred vision whilst being given 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.

Looking after your medicine

Do not take NOXAFIL if the packaging is torn or shows signs of tampering.

Do not take NOXAFIL if the expiry date (EXP) printed on the pack has passed.

NOXAFIL Oral Suspension

Keep NOXAFIL Oral Suspension in the bottle until it is time to take it.

Keep NOXAFIL Oral Suspension in a cool dry place where the temperature stays below 25°C.

Do not freeze NOXAFIL Oral Suspension.

Protect NOXAFIL Oral Suspension from light.

NOXAFIL Modified Release Tablets

Store NOXAFIL Modified Release Tablets below 30°C.

Store in original container.

Follow the instructions in the carton on how to take care of your medicine properly.

Store NOXAFIL in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor tells you to stop taking NOXAFIL, or if it has passed the expiry date, ask your pharmacist what to do with any leftover medicine.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• Loss of appetite, upset stomach, nausea, vomiting, stomach pain, diarrhoea, gas from stomach or bowel, dry mouth, altered sense of taste • Sleeplessness, headache, dizziness, sleepiness, tingling in fingers or toes • Hot flushes • Raised blood pressure with a low potassium level (shown in blood test) • Dry skin, rash, itchiness • Back pain • Fever	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
• Rash, itchiness, hives • Swelling of the face, lips, mouth, throat or neck which may cause difficulty swallowing or breathing • Tingling or numbness of the hands or feet, or muscle weakness	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What NOXAFIL contains

Active ingredient (main ingredient)	Posaconazole
Other ingredients (inactive ingredients)	polysorbate 80 simethicone sodium benzoate sodium citrate dihydrate citric acid monohydrate glycerol xanthan gum liquid glucose titanium dioxide artificial cherry flavouring purified water

NOXAFIL Oral Suspension does not contain lactose, gluten, tartrazine or any other azo dyes.

What NOXAFIL Modified Oral Release Tablets contains

Active ingredient (main ingredient)	Posaconazole
Other ingredients (inactive ingredients)	hypromellose acetate succinate microcrystalline cellulose hydroxypropylcellulose silicon dioxide croscarmellose sodium magnesium stearate polyvinyl alcohol Macrogol 3350 titanium dioxide purified talc iron oxide yellow

Do not take this medicine if you are allergic to any of these ingredients.

What NOXAFIL Oral Suspension looks like

NOXAFIL Oral Suspension (AUST R 115556) is a white liquid.

It is supplied in an amber glass bottle with a child-resistant cap. Each bottle contains 105 mL of suspension. A measuring spoon graduated to measure 2.5 mL and 5 mL is included with each bottle.

What NOXAFIL Modified Release Tablets looks like

NOXAFIL Tablets (AUST R 216283) are yellow-coated, capsule-shaped tablets with “100” marking on one side.

NOXAFIL tablets are available in blister packs of 24 or 96 tablets.

Who distributes NOXAFIL

Merck Sharp & Dohme (Australia) Pty Limited
Level 1, Building A, 26 Talavera Rd
Macquarie Park NSW, 2113, Australia

Australian Registration Numbers:

NOXAFIL Oral Suspension - AUST R 115556

NOXAFIL Modified Release Tablet - AUST R 216283

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