

# NOXAFIL Concentrated injection

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## 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.

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### 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?

NOXAFIL is usually diluted and given as a slow infusion or “drip” injection into your vein (intravenously).

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?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• If you are about to start any other new medicine, tell your doctor that you are taking NOXAFIL.</li><li>• Remind any doctor, dentist or pharmacist you visit that you are being given NOXAFIL.</li><li>• If you need to have any blood tests, tell your</li></ul>
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	<p>doctor you are taking NOXAFIL. NOXAFIL may affect the results of some laboratory tests.</p>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• NOXAFIL should not be used during pregnancy or breastfeeding unless indicated by your doctor.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• NOXAFIL may cause dizziness, sleepiness, or blurred vision in some people</li> <li>• 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.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• NOXAFIL concentrated injection is stored in a refrigerator (at 2°C - 8°C) in the pharmacy or on the ward in a hospital. Once prepared, the product should be</li> </ul>

	<p>used immediately. If not used immediately it can be stored for up to 24 hours at 2°C - 8°C.</p>
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- NOXAFIL is for single use only and any unused solution should be discarded.

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, pharmacist or nurse immediately if you notice any of the following serious side effects: Swelling of the face, lips, mouth, throat or neck which may cause difficulty swallowing or breathing, nausea or vomiting, diarrhoea, yellowing of the 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 (signs of liver problems).

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® Concentrated Injection

**Active ingredient:** *Posaconazole*

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## 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 Concentrated Injection is used for:**

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- 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**.

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.

**NOXAFIL is only for use in adults (18 years of age and older).**

## **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?](#)

## **Pregnancy and breastfeeding**

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

NOXAFIL should not be used during pregnancy unless indicated by your doctor. Women who are of childbearing potential should use effective contraception while being given 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 being given NOXAFIL, contact your doctor straight away.**

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



NOXAFIL should not be given to 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 heartbeat)
- 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

### **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)

These medicines may be affected by NOXAFIL or may affect how well it works. You may need different amounts of these medicines 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?**

NOXAFIL concentrated injection will be diluted to the correct concentration by your pharmacist or nurse.

NOXAFIL is usually diluted and given as a slow infusion or 'drip' injection into your vein (intravenously).

The length of treatment may depend on the type of infection that you have and will be individually adapted for you by your doctor.

### **How much is given**

The usual dose is 300 mg twice a day on the first day, then 300 mg once a day, thereafter.

## **How long will I be given it?**

The length of treatment will depend on the type of infection you have and will be individually adapted for you by your doctor.

## **If a dose of NOXAFIL has been forgotten**

As you will be given this medicine under close medical supervision, it is unlikely that a dose would be missed. However, tell your doctor or pharmacist if you think that a dose has been forgotten.

## **If you use too much NOXAFIL**

As you will be given this medicine under close medical supervision, it is unlikely that you will be given too much. However, if you think that you have been given too much NOXAFIL, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre
- **(by calling 13 11 26)**, 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 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.

Tell all doctors, dentists and pharmacists who are treating you that you are being given NOXAFIL

### **Call your doctor straight away if you:**

- Have diarrhoea or vomiting
- If you become pregnant or plan to get pregnant whilst you are using NOXAFIL
- Do not feel well whilst you are using NOXAFIL, or after using NOXAFIL

**Remind any doctor, dentist, pharmacist or nurse you visit that you are being given NOXAFIL.**

## **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**

NOXAFIL concentrated injection is stored in a refrigerator (2 to 8°C) in the pharmacy or on the ward in a hospital.

Once prepared, the product should be used immediately. If not used immediately it can be stored for up to 24 hours at 2 to 8 degrees Celsius (in a refrigerator).

Keep it where young children cannot reach it.

## **When to discard your medicine**

NOXAFIL is for single use only and any unused solution should be discarded.

## **Getting rid of any unwanted medicine**

If you no longer need to be given 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 which is stated on the label. The expiry date refers to the last day of that month.

## 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
<ul style="list-style-type: none"><li>• Abnormal skin sensations, such as numbness, tingling, itching, creeping prickling or burning, rash, swelling, redness and tenderness along the vein in which NOXAFIL was given.</li><li>• Loss of appetite, stomach pain or upset stomach, passing wind, dry mouth, changes in</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<b>Less serious side effects</b>	<b>What to do</b>
<p>your taste, constipation, rectal discomfort</p> <ul style="list-style-type: none"> <li>• Feeling confused or weak, dizzy, tired or sleepy, headache</li> <li>• Raised blood pressure with a low potassium level (shown in blood test)</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• Swelling of the face, lips, mouth, throat or neck which may cause difficulty swallowing or breathing, rash, itchiness, hives</li> <li>• Nausea or vomiting, diarrhoea</li> <li>• Yellowing of the skin or whites of eyes, unusually dark urine or pale faeces, feeling sick for no reason, stomach problems, loss of appetite or unusual</li> </ul>	<p><b>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.</b></p>



<b>Serious side effects</b>	<b>What to do</b>
tiredness or weakness (signs of liver problems)	

**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](http://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**

<b>Active ingredient (main ingredient)</b>	posaconazole
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<b>Other ingredients (inactive ingredients)</b>	Sulfobutyl betadex sodium.  disodium edetate.  hydrochloric acid and sodium hydroxide for pH adjustment.  Water for Injections.
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**Do not take this medicine if you are allergic to any of these ingredients.**

## **What NOXAFIL Concentrated Injection looks like**

NOXAFIL Concentrated Injection is a clear, colourless to yellow liquid.

## **Who distributes NOXAFIL Concentrated Injection?**

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Road

Macquarie Park, NSW 2113, Australia

Australian Registration Number:

NOXAFIL Concentrated Injection - AUST R 218702

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