EMA/709842/2021
EMEA/H/C/000610

Noxafil (*posaconazole*)

An overview of Noxafil and why it is authorised in the EU

What is Noxafil and what is it used for?

Noxafil is an antifungal medicine that is used to treat adults and children from 2 years of age with the following fungal diseases:

- invasive aspergillosis (fungal infection caused by *Aspergillus*);
- fusariosis (fungal infection caused by *Fusarium*);
- chromoblastomycosis and mycetoma (long-term fungal infections of the skin or the tissue just below the skin, usually caused by fungal spores infecting wounds due to thorns or splinters);
- coccidioidomycosis (fungal infection of the lungs caused by breathing in spores).

For fusariosis, chromoblastomycosis and mycetoma and coccidioidomycosis, Noxafil is only used when treatments with other antifungal medicines (amphotericin B, itraconazole or fluconazole) have not worked or are not suitable.

Noxafil is also used in adults to treat fungal infections of the mouth and throat caused by *Candida* (thrush). It is used in patients whose thrush infection is severe or who have weakened immune systems, when medicines applied topically (directly on the thrush) are unlikely to work.

Noxafil is also used to prevent invasive fungal infections in patients from 2 years of age whose immune system is weakened because of treatments they are receiving for blood or bone marrow cancers or medicines used in haematopoietic stem cell transplantation (a transplant of cells that make blood cells).

Noxafil contains the active substance posaconazole.

How is Noxafil used?

Noxafil can only be obtained with a prescription, and treatment should be started by a doctor who has experience in managing fungal infections or in treating patients at high risk of invasive fungal infections.

Noxafil is available as an oral suspension (a liquid to be taken by mouth), as a concentrate for solution for infusion (drip) into a vein, as gastro-resistant tablets and as a gastro-resistant powder and solvent

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

for oral suspension. Gastro-resistant means that the medicine passes through the stomach without being broken down until it reaches the intestine.

The choice of dosage form and the dose and duration of treatment depend on the condition being treated and the patient's age, weight and response to treatment. Noxafil oral suspension, tablets, and powder and solvent for oral suspension have different dosages and should not be used interchangeably.

Patients treated with the solution for infusion should be switched to Noxafil tablets, oral suspension or powder and solvent for oral suspension as soon as the patient's condition allows it.

For additional information, see the package leaflet.

How does Noxafil work?

The active substance in Noxafil, posaconazole, is an antifungal medicine that belongs to the triazole group. It works by preventing the formation of ergosterol, which is an important part of fungal cell walls. Without ergosterol, the fungus dies or cannot spread. The list of fungi against which Noxafil is active can be found in the product information.

What benefits of Noxafil have been shown in studies?

Treatment of infection

One main study involved 238 patients with invasive fungal infections that did not respond to standard antifungal treatment and who were treated with Noxafil oral suspension. These results obtained with Noxafil were compared with those for other antifungal medicines from records of 218 patients. In this study, 42% of the patients with invasive aspergillosis taking Noxafil oral suspension had a successful response compared with 26% of patients receiving other antifungal medicines. Noxafil also successfully treated 11 of 18 patients (61%) who had proven or probable fusariosis, 9 of 11 patients (82%) with chromoblastomycosis or mycetoma, and 11 of 16 patients (69%) with coccidioidomycosis.

In the second main study involving 350 HIV-positive patients with oropharyngeal candidiasis, Noxafil oral suspension was as effective as the antifungal medicine fluconazole. For both medicines, after 14 days of treatment, oropharyngeal candidiasis either improved or was successfully cured in 92% of patients.

A third study involving 575 patients with proven, probable or possible invasive aspergillosis found that Noxafil given as an infusion into the vein or as tablets was at least as effective as the antifungal medicine voriconazole in reducing the risk of death. The results showed that 44 of 288 (15%) patients who received initial treatment with Noxafil died within 42 days of starting treatment compared with 59 of 287 (21%) of those who received initial treatment with voriconazole.

Prevention of infection

Two additional main studies investigated the ability of Noxafil oral suspension to prevent infections. In one of the studies, involving 600 stem cell transplant patients, Noxafil oral suspension was as effective as fluconazole in preventing an invasive fungal infection, with 5% of patients who took Noxafil developing an infection compared with 9% of those treated with fluconazole or itraconazole.

In the other study, involving 602 cancer patients, Noxafil was more effective than fluconazole or itraconazole, with 2% of patients developing an infection in the Noxafil group, and 8% in patients treated with fluconazole or itraconazole.

Children

The effectiveness of Noxafil in children is based on a study establishing whether the medicine is processed in the body similarly to adults. The study involved 115 children from 2 years of age with a weakened immune system who were given Noxafil either as a tablet or a powder and solvent for oral suspension. In these children, the level of Noxafil in the blood was similar to that considered safe and effective in adults. In addition, based on data on how Noxafil behaves in children with invasive aspergillosis when given as an infusion, a powder and solvent for oral suspension or a tablet, the medicine is expected to work in these children in the same way as it does in adults.

Another study involved 31 children from 2 to 17 years of age with possible, probable or confirmed invasive aspergillosis. After 6 or 12 weeks of treatment, around 68% and 77% of children, respectively, had a successful response to Noxafil, which was either complete (infection resolved) or partial (improvement of symptoms). The study did not compare Noxafil with another treatment or placebo (a dummy treatment).

What are the risks associated with Noxafil?

For the full list of all side effects and restrictions with Noxafil, see the package leaflet.

Side effects depend on the dosage form of the medicine being used.

The most common side effects with Noxafil include nausea (feeling sick), which can be serious. The other most common serious side effects include vomiting, diarrhoea, pyrexia (fever) and increased bilirubin in the blood (a sign of liver problems).

Noxafil must not be used together with any of the following medicines:

- ergotamine or dihydroergotamine (used to treat migraine),
- terfenadine, astemizole (used for allergy),
- cisapride (used for stomach problems),
- pimozide (used for treating mental illness),
- quinidine (used for irregular heartbeat),
- halofantrine (used to treat malaria),
- simvastatin, lovastatin or atorvastatin (used to lower cholesterol),
- venetoclax (when used for treating patients with chronic lymphocytic leukaemia, at the start of treatment and when the dose is being adjusted).

Further information is available in the package leaflet.

Why is Noxafil authorised in the EU?

Noxafil is effective at treating fungal infections in patients for whom therapeutic options are limited; it can also prevent certain infections in patients with a weakened immune system. The infections it can be used to treat or prevent can have serious outcomes, including death. Its side effects are considered manageable. The European Medicines Agency therefore decided that Noxafil's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Noxafil?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Noxafil have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Noxafil are continuously monitored. Suspected side effects reported with Noxafil are carefully evaluated and any necessary action taken to protect patients.

Other information about Noxafil

Noxafil received a marketing authorisation valid throughout the EU on 25 October 2005.

Further information on Noxafil can be found on the Agency's website: https://www.ema.europa.eu/en/medicines/human/EPAR/noxafil

This overview was last updated in 02-2026.