



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2016
EMA/425762/2016

EMA warns that Noxafil tablets and oral suspension have different doses and are not interchangeable

Prescriptions should indicate which dose form is intended

Product information for Noxafil (posaconazole) is to be updated to strengthen warnings that the two dose forms given by mouth cannot be simply interchanged at the same dose. Noxafil, a medicine for serious fungal infections, is available by mouth as tablets (100 mg) and oral suspension (40 mg/ml), but the recommended doses for the two forms are different.

Some patients have mistakenly received oral solution instead of tablets, leading to underdosing and to a potential lack of effect. Similarly, there are reports of patients given tablets instead of oral solution, leading to overdosage and side effects.

The product information is therefore to be updated to strengthen existing warnings that the two forms cannot be simply interchanged, and the packaging will also be changed to distinguish the two forms more clearly and to carry a warning statement that they should not be substituted for one another without adjusting the dose.

Healthcare professionals will also receive a letter in the coming weeks reminding them of the problem. Prescribers are advised to make clear which form is intended when they write a prescription, and pharmacists should ensure that the correct form is dispensed.

Information for patients

- Noxafil is a medicine used to treat serious infections caused by fungi, when other medicines cannot be used or are not effective. It contains the active substance posaconazole.
- When the medicine is given by mouth, it can be given either as tablets or a liquid, but the dose needed when using the tablets (how much and how often) is different from the one needed when using the liquid.
- The usual dose of tablets is three tablets (300 mg) twice a day on the first day, then 300 mg once a day. Doses of the liquid (200 mg, one 5-ml spoonful) are taken three or four times a day.
- There have been cases where patients were provided with the wrong form of the medicine, and so took the wrong dose, resulting either in side effects or in the medicine not being effective.



- Patients should not switch between taking Noxafil tablets and Noxafil oral suspension without talking to their doctor or pharmacist first as it may result in a decreased effectiveness or an increased risk of side effects.
- Patients who have any concerns about their medicine should speak to their pharmacist or the prescriber.

Information for healthcare professionals

- Noxafil tablets and oral suspension are not interchangeable due to the differences between these two formulations in the frequency of dosing, administration with food and plasma drug concentration achieved. The recommended oral dosage is 300 mg once a day with the tablets (after a loading dose of 300 mg twice daily on day 1) and 200 mg three to four times a day (600 to 800 mg daily) with the oral suspension.
- Medication errors have been reported following erroneous switching, resulting in over- or underdosage and consequent dose-related toxicity or lack of efficacy.
- It is important that the dosage form as well as the relevant dose be specified on the prescription, and that pharmacists ensure the correct oral dosage form is dispensed.
- The SmPC and patient information leaflet for Noxafil are being updated to strengthen warnings about the differences between the two formulations, and the outer cartons will be revised to further differentiate the two and to include a warning statement that they cannot be simply substituted without adjusting the dose.

More about the medicine

Noxafil is an antifungal medicine containing the active substance posaconazole, a member of the group of triazole antifungals. It is available as a solution for infusion (drip) into a vein, but also as tablets and oral suspension for use by mouth. It is used when other medicines do not work or cannot be given, to treat adults with the serious fungal infections invasive aspergillosis, fusariosis, chromoblastomycosis, mycetoma, or coccidioidomycosis. It is also used in patients with weakened immune systems (such as transplant patients) to treat thrush (fungal infection of the throat or mouth due to *Candida*) or prevent invasive fungal infections.

More information about Noxafil can be found on the Agency's website: ema.europa.eu/Find_medicine.

More about the procedure

This review was conducted by EMA's Committee for Medicinal Products for Human Use (CHMP) in the context of a procedure known as a 'type II variation'. The CHMP opinion will now be sent to the European Commission for a legally binding decision applicable in all EU Member States.

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