COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Summary Public Assessment Report

Generics

Posaconazol Tillomed 40 mg/ml oral suspension

(posaconazole)

NL/H/4956/001/DC

Date: 26 October 2020

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Active substance: posaconazole

This is a summary of the public assessment report (PAR) for Posaconazol Tillomed. It explains how this medicine was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Posaconazol Tillomed.

For practical information about using this medicine, patients should read the package leaflet or contact their doctor or pharmacist.

What is Posaconazol Tillomed and what is it used for?
Posaconazol Tillomed is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Noxafil.

Posaconazol Tillomed can be used in adults to treat the following types of fungal infections when other antifungal medicines have not worked or you have had to stop taking them:

- infections caused by fungi of the *Aspergillus* family that have not improved during treatment with the anti-fungal medicines amphotericin B or itraconazole or when these medicines have had to be stopped;
- 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.
- infections in the mouth or throat area (known as "thrush") caused by fungi called *Candida*, which were not previously treated.

This medicine can also be used to prevent fungal infections in adults 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).

How does this medicine work?
Posaconazol Tillomed 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.

How is this medicine used?
The pharmaceutical form of Posaconazol Tillomed is an oral suspension. Whenever possible, the oral suspension should be taken during or immediately after food or a nutritional drink.

The medicine can only be obtained with a prescription.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

How has this medicine been studied?
Because Posaconazol Tillomed is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Noxafil. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of this medicine?
Because Posaconazol Tillomed is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be bioequivalent to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for the reference medicine called Noxafil, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Posaconazol Tillomed, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about this medicine
In the Netherlands, the marketing authorisation for Posaconazol Tillomed was granted on 23 September 2020.

The full PAR for this medicine can be found on the website http://mri.cts-mrp.eu/Human/. For more information about treatment with Posaconazol Tillomed, read the package leaflet (https://mri.cts-mrp.eu/Human/Downloads/NL_H_4956_001_FinalPI_2of2.pdf) or contact your doctor or pharmacist.

This summary was last updated in October 2020.