

Summary Public Assessment Report

Mometasone furoate/Olopatadine Glenmark (mometasone furoate, olopatadine hydrochloride)

SE/H/2538/01/DC

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mometasone furoate, olopatadine hydrochloride

Nasal spray, suspension, 25 mikrogram/dos + 600 mikrogram/dos

This is a summary of the public assessment report (PAR) for Mometasone furoate/Olopatadine Glenmark. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Mometasone furoate/Olopatadine Glenmark and what is it used for?

This medicine is the same as Ryaltris, which is already authorised. The company that makes Ryaltris has agreed that its scientific data can be used as a basis for the grant of identical licence for Mometasone furoate/Olopatadine Glenmark (so called informed consent).

The product is used to treat the symptoms of moderate to severe seasonal allergic rhinitis (also called hay fever) and perennial rhinitis in adults and adolescents 12 years of age or older.

Seasonal allergic rhinitis (hay fever) is an allergic reaction which occurs at certain times of the year and is caused by breathing in pollen from trees, grasses, weeds and also moulds and fungal spores. Perennial rhinitis occurs throughout the year and symptoms can be caused by a sensitivity to a variety of things including house dust mite, animal hair (or dander), feathers and certain foods.

The product relieves the symptoms of allergies, like runny nose, sneezing and itchy or blocked nose.

How does Mometasone furoate/Olopatadine Glenmark work?

The product contains two active substances: mometasone furoate and olopatadine.

- Mometasone furoate belongs to a group of medicines called corticosteroids (steroids) which reduce inflammation, often found in allergic rhinitis.
- Olopatadine belongs to a group of medicines called antihistamines. Antihistamines work by preventing the effects of substances such as histamine that the body produces as part of an allergic reaction – thus reducing symptoms of allergic rhinitis.

How is Mometasone furoate/Olopatadine Glenmark used?

The pharmaceutical form is Nasal Spray, suspension for nasal use.

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

The medicine can only be obtained with a prescription in Sweden.

What benefits of Mometasone furoate/Olopatadine Glenmark have been shown in studies?

The product is considered identical to previously authorised Ryaltris, with the same benefits and risks. No new studies have been provided, but reference is made to the studies for Ryaltris.

What are the possible side effects from Mometasone furoate/Olopatadine Glenmark?

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Mometasone furoate/Olopatadine Glenmark approved?

The Swedish Medical Products Agency decided that the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Mometasone furoate/Olopatadine Glenmark?

A risk management plan has been developed to ensure that the product 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, 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 Mometasone furoate/Olopatadine Glenmark

The full PAR for Mometasone furoate/Olopatadine Glenmark can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Mometasone furoate/Olopatadine Glenmark, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2024-11.