

Summary Public Assessment Report

Hydroxyzine Orion (hydroxyzine hydrochloride)

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(hydroxyzine hydrochloride)

film-coated tablets 10 mg, 25 mg

This is a summary of the public assessment report (PAR) for Hydroxyzine Orion. It explains how Hydroxyzine Orion 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 Hydroxyzine Orion.

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

What is Hydroxyzine Orion and what is it used for?

Hydroxyzine Orion is a ‘generic medicine’. This means that Hydroxyzine Orion is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Atarax.

Hydroxyzine Orion is used to treat:

- anxiety in adults where no other medication is suitable
- hives and itching caused by allergic reactions in adults, adolescents and children of 5 years and above.

How does Hydroxyzine Orion work?

Hydroxyzine Orion belongs to a group of medicines called sedating antihistamines. It suppresses certain functions in the brain without creating a habit. It also blocks histamine, a substance found in body tissues, which is responsible for allergic reactions.

How is Hydroxyzine Orion used?

The pharmaceutical form of Hydroxyzine Orion is film-coated tablet for oral 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.

What benefits of Hydroxyzine Orion have been shown in studies?

Because Hydroxyzine Orion is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Atarax. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Hydroxyzine Orion?

Because Hydroxyzine Orion 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 restrictions, see the package leaflet.

Why is Hydroxyzine Orion approved?

It was concluded that, in accordance with EU requirements, Hydroxyzine Orion has been shown to have comparable quality and to be bioequivalent to the reference medicine Atarax. Therefore, the Medical Products Agency in Sweden decided that, as for Atarax, 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 Hydroxyzine Orion?

A risk management plan has been developed to ensure that Hydroxyzine Orion 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 Hydroxyzine Orion, 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 Hydroxyzine Orion

The marketing authorisation for Hydroxyzine Orion was granted on 2016-11-11 in Sweden.

The full PAR for Hydroxyzine Orion can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Hydroxyzine Orion, please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2016-11.