LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Hydroxyzine Orifarm
(hydroxyzine hydrochloride)

SE/H/1450/01-02/DC

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Summary Public Assessment Report

Hydroxyzine Orifarm
(hydroxyzine)

Film-coated tablet, 10 and 25 mg

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

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

What is Hydroxyzine Orifarm and what is it used for?

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

Hydroxyzine Orifarm is used in treatment of:
- 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 Orifarm work?

Hydroxyzine Orifarm 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 Orifarm used?

The pharmaceutical form of Hydroxyzine Orifarm 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 Orifarm have been shown in studies?

Because Hydroxyzine Orifarm 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 Orifarm?

Because Hydroxyzine Orifarm 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 Orifarm approved?

It was concluded that, in accordance with EU requirements, Hydroxyzine Orifarm 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 Orifarm?

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

The marketing authorisation for Hydroxyzine Orifarm was granted on 2015-10-22 in Sweden.

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

This summary was last updated in 2015-10.