LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Solifenacin Orion
(solifenacin succinate)

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Summary Public Assessment Report

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solifenacin succinate

Film-coated tablet 5 mg and 10 mg

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

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

What is Solifenacin Orion and what is it used for?

Solifenacin Orion is a 'generic medicine'. This means that Solifenacin Orion is similar to a 'reference medicine' already authorised in the European Union (EU) called Vesicare.

Solifenacin Orion is used to treat the symptoms of a condition called overactive bladder. These symptoms include: having a strong, sudden urge to urinate without prior warning, having to urinate frequently or wetting yourself because you could not get to the bathroom in time.

How does Solifenacin Orion work?

The active substance of Solifenacin Orion, solifenacin succinate, belongs to the group called anticholinergics. These medicines are used to reduce the activity of an overactive bladder. This enables you to wait longer before having to go to the bathroom and increases the amount of urine that can be held by your bladder.

How is Solifenacin Orion used?

The pharmaceutical form of Solifenacin 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 Solifenacin Orion have been shown in studies?

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

What are the possible side effects of Solifenacin Orion?

Because Solifenacin 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 Solifenacin Orion approved?

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

A risk management plan has been developed to ensure that Solifenacin 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 Solifenacin 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 Solifenacin Orion

The marketing authorisation for Solifenacin Orion was granted on 2017-02-07 in Sweden.

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

This summary was last updated in 2017-02.