Summary Public Assessment Report

Generics

Dutasterid/Tamsulozín Xantis

Dutasteride/tamsulosin hydrochloride

SK/H/0201/001/DC

Date: November 2019

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Dutasteride/tamsulosin hydrochloride
Hard capsules
0,5mg/0,4 mg

This is a summary of the public assessment report (PAR) for Dutasterid/Tamsulozín Xantis. It explains how Dutasterid/Tamsulozín Xantis 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 Dutasterid/Tamsulozín Xantis.

For practical information about using Dutasterid/Tamsulozín Xantis, patients should read the package leaflet or contact their doctor or pharmacist.

What is Dutasterid/Tamsulozín Xantis and what is it used for?

Dutasterid/Tamsulozín Xantis is a 'generic medicine'. This means that Dutasterid/Tamsulozín Xantis is similar to a 'reference medicine' already authorised in the European Union (EU) called Duodart 0,5 mg/ 0,4 mg tvrdé kapsuly.

Dutasterid/Tamsulozín Xantis is used to treat men with an enlarged prostate *(benign prostatic hyperplasia)* - a non-cancerous growth of the prostate gland, caused by producing too much of a hormone called dihydrotestosterone.

How does Dutasterid/Tamsulozín Xantis work?

Dutasterid/Tamsulozín Xantis is a combination of two different medicines called dutasteride and tamsulosin. Dutasteride belongs to a group of medicines called *5-alpha reductase inhibitors* and tamsulosin belongs to a group of medicines called *alpha-blockers*. Dutasteride lowers the production of a hormone called dihydrotestosterone, which helps to shrink the prostate and relieve the symptoms. This will reduce the risk of acute urinary retention and the need for surgery. Tamsulosin acts by relaxing the muscles in your prostate gland, making it easier to pass urine and rapidly improving your symptoms.

How is Dutasterid/Tamsulozín Xantis used?

The pharmaceutical form of Dutasterid/Tamsulozín Xantis is hard capsule and the route of administration is oral.

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

The recommended dose is one capsule taken once a day, 30 minutes after the same meal each day.
Swallow the capsules whole with water. Do not chew or open the capsule. Contact with the contents of the capsules may make your mouth or throat sore.

The medicine can only be obtained with a prescription.

What benefits of Dutasterid/Tamsulozín Xantis have been shown in studies?

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

What are the possible side effects of Dutasterid/Tamsulozín Xantis?

Because Dutasterid/Tamsulozín Xantis 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 Dutasterid/Tamsulozín Xantis approved?

It was concluded that, in accordance with EU requirements, Dutasterid/Tamsulozín Xantis has been shown to have comparable quality and to be bioequivalent/be comparable to Duodart. Therefore, the State Institute for Drug Control decided that, as for Duodart, 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 Dutasterid/Tamsulozín Xantis?

A risk management plan has been developed to ensure that Dutasterid/Tamsulozín Xantis 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 Dutasterid/Tamsulozín Xantis, 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 Dutasterid/Tamsulozín Xantis

The marketing authorisation for Dutasterid/Tamsulozín Xantis was granted on 29 July 2019.

The full PAR for Dutasterid/Tamsulozín Xantis can be found on the http://www.sukl.sk/. For more information about treatment with Dutasterid/Tamsulozín Xantis, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 11-2019.