

Summary Public Assessment Report

Alfuzosin Orion **(alfuzosin hydrochloride)**

SE/H/1572/02/DC

Summary Public Assessment Report

Alfuzosin Orion

(alfuzosin hydrochloride)

10 mg, prolonged-release tablets

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

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

What is Alfuzosin Orion and what is it used for?

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

Alfuzosin Orion belongs to a group of medicines called alpha-1-blockers. Alfuzosin is used to treat moderate to severe symptoms of Benign Prostatic Hyperplasia. This is a condition where the prostate gland enlarges (hyperplasia), but the growth in itself is not cancerous (it is benign). It is more common in older men.

How does Alfuzosin Orion work?

The prostate gland is situated under the bladder surrounding the urethra (the tube that takes your urine to the outside of the body). With age, the prostate gland may grow and press on the urethra making it smaller. This may cause problems with urination such as frequent urination and difficulty in passing urine.

Alfuzosin works by relaxing the prostate gland muscle. This reduces the narrowing of the urethra and so makes it easier to pass urine.

How is Alfuzosin Orion used?

The pharmaceutical form of Alfuzosin Orion is prolonged-release tablets 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 Alfuzosin Orion have been shown in studies?

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

What are the possible side effects of Alfuzosin Orion?

Because Alfuzosin 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 Alfuzosin Orion approved?

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

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

The marketing authorisation for Alfuzosin Orion was granted on 2016-06-16 in Sweden.

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

This summary was last updated in 201607.