LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Fexofenadin Cipla
(fexofenadine hydrochloride)

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(fexofenadine hydrochloride)

Film-coated tablet; 120 mg and 180 mg

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

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

What is Fexofenadin Cipla and what is it used for?
Fexofenadin Cipla is a 'generic medicine'. This means that Fexofenadin Cipla is similar to a 'reference medicine' already authorised in the European Union (EU) called Telfast.

Fexofenadin Cipla 120 mg is used in adults and adolescents of 12 years and older to relieve the symptoms that occur with hay fever (seasonal allergic rhinitis) such as sneezing, itchy, runny or blocked nose and itchy, red and watery eyes.

Fexofenadin Cipla 180 mg is used in adults and adolescents of 12 years and older to relieve the symptoms that occur with long term allergic skin reactions (chronic idiopathic urticaria) such as itching, swelling and rashes.

How does Fexofenadin Cipla work?
Fexofenadin Cipla contains fexofenadine hydrochloride, which is an antihistamine.

How is Fexofenadin Cipla used?
The pharmaceutical form of Fexofenadin Cipla 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 Fexofenadin Cipla have been shown in studies?
Because Fexofenadin Cipla is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Telfast. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Fexofenadin Cipla?
Because Fexofenadin Cipla 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 Fexofenadin Cipla approved?
It was concluded that, in accordance with EU requirements, Fexofenadin Cipla has been shown to have comparable quality and to be bioequivalent to the reference medicine Telfast. Therefore, the Medical Products Agency in Sweden decided that, as for Telfast, 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 Fexofenadin Cipla?
A risk management plan has been developed to ensure that Fexofenadin Cipla 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 Fexofenadin Cipla, 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 Fexofenadin Cipla
The marketing authorisation for Fexofenadin Cipla was granted on 2014-12-12 in Sweden.

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

This summary was last updated in 2014-12.