LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Amitriptylin Abcur
(amitriptyline hydrochloride)

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Summary Public Assessment Report

Amitriptylin Abcur

(amitriptyline hydrochloride)

Film coated tablet 10 mg, 25 mg, 50 mg

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

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

What is Amitriptylin Abcur and what is it used for?

Amitriptylin Abcur is a 'generic medicine'. This means that Amitriptylin Abcur is similar to a 'reference medicine' already authorised in the European Union (EU) called Saroten.

Amitriptylin Abcur is used in the treatment of depression. The cause of depression is not fully understood, but it is known that there is a lower amount of certain substances that transmit impulses between nerve cells in the brain, called neurotransmitters.

How does Amitriptylin Abcur work?

Amitriptylin Abcur contains the active substance amitriptyline. It belongs to a group of medicines called tricyclic antidepressants (TCA).

Amitriptyline Abcur works by increasing the amount of neurotransmitters. Amitriptylin Abcur has antidepressant, sedative and anxiolytic properties.

How is Amitriptylin Abcur used?

The pharmaceutical form of Amitriptylin Abcur 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 Amitriptylin Abcur have been shown in studies?

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

What are the possible side effects of Amitriptylin Abcur?

Because Amitriptylin Abcur 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 Amitriptylin Abcur approved?

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

A risk management plan has been developed to ensure that Amitriptylin Abcur 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 Amitriptylin Abcur, 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 Amitriptylin Abcur

The marketing authorisation for Amitriptylin Abcur was granted on 2014-05-22 in Sweden.

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

This summary was last updated in 2017-03.