LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Prilect
(escitalopram oxalate)

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Prilect
(escitalopram oxalate)

oral drops, solution 20 mg/ml

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

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

What is Prilect and what is it used for?

Prilect is used in the treatment of depression (major depressive episodes) and anxiety disorders (such as panic disorder with or without agoraphobia, social anxiety disorder, generalised anxiety disorder and obsessive-compulsive disorder) in adults above 18 years of age.

How does Prilect work?

Prilect contains the active substance escitalopram. Prilect belongs to a group of antidepressants called selective serotonin reuptake inhibitors (SSRIs). These medicines act on the serotonin-system in the brain by increasing the serotonin level. Disturbances in the serotonin-system are considered an important factor in the development of depression and related diseases.

It may take a couple of weeks before you start to feel better. Continue to take Prilect even if it takes some time before you feel any improvement in your condition.

How is Prilect used?

The pharmaceutical form of Prilect is oral drops, solution.

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 Prilect have been shown in studies?

Prilect oral drops, solution 20 mg/ml is a different strength and pharmaceutical form compared to the already approved medicinal product Prilect film-coated tablets. The company’s own data on efficacy and safety studies previously approved for the Prilect film-coated tabelts is applicable for Prilect oral drops, solution 20 mg/ml as well. Therefore, it is considered that Prilect oral drops, solution 20 mg/ml is effective in treating depression and anxiety disorders in adults above 18 years of age.

What are the possible side effects of Prilect?

For the full list of all side effects reported with Prilect, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Prilect approved?

The effect of Prilect oral drops, solution 20 mg/ml, in the treatment of depression and anxiety disorders in adults above 18 years of age was considered to be the same as the effect of the previously approved Prilect film-coated tablets. Therefore, the Medical Products Agency in Sweden decided that Prilect's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Prilect?

A risk management plan has been developed to ensure that Prilect 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 Prilect, 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 Prilect

The marketing authorisation for Prilect was granted on 2007-03-02 in Sweden.

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

This summary was last updated in 2015-01.