LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Abbonate
(tranylcypromine sulfate)

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Summary Public Assessment Report

Abbonate
tranylcypromine sulfate, tranylcypromine

Film-coated tablet, 20 mg

This is a summary of the public assessment report (PAR) for Abbonate. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Abbonate and what is it used for?
The product is a medicine with 'well-established use'. This means that the medicinal use of the active substance of the product is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

The product is used in the treatment of severe depressive episodes in adults with major depressive disorder where appropriate standard treatment with two antidepressants (including tricyclic antidepressants) supplemented with for example lithium, did not have a sufficient effect.

How does Abbonate work?
Abbonate contains the active substance tranylcypromine which belongs to a group of antidepressants known as monoamin oxidas inhibitors (MAOIs).

How is Abbonate used?

The pharmaceutical form 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 in Sweden.

What benefits of Abbonate have been shown in studies?

As *tranylcypromine sulfate* is a well-known substance, and its use in the treatment of *For the treatment of severe depressive episodes in adults with treatment resistant major depressive disorder where adequate treatment with two standard antidepressants (including tricyclic antidepressants) and augmentation with, e.g. lithium, yielded an insufficient treatment response.* is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of *tranylcypromine sulfate* in the treatment of the above-mentioned indication.

What are the possible side effects from Abbonate?

For the full list of side effects, see section 4 of the package leaflet.

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

Why is Abbonate approved?
The Swedish Medical Products Agency decided that the benefits are greater than its risks and recommended that it can be approved for use.

The product has been authorised with the condition to perform further studies and/or to provide additional measures to minimise the risk. See section below “What measures are being taken to ensure the safe and effective use of Abbonate?”

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

A risk management plan has been developed to ensure that the product 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, 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.

Educational materials are also obligations for this medical product as measures to ensure a safe and effective use of Abbonate.

Other information about Abbonate

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

This summary was last updated in 2024-04.