LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Phenilic
(methylphenidate hydrochloride)

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Summary Public Assessment Report

Phenilic
methylphenidate hydrochloride

Prolonged-release tablet, 18 mg, 27 mg, 36 mg, 54 mg

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

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

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

Phenilic is used to treat 'attention deficit hyperactivity disorder' (ADHD).

- It is used in children and young people between the ages of 6 and 18.
- It is used only after trying treatments which do not involve medicines. Such as counselling and behavioural therapy.
- It is not for use as a treatment for ADHD in children under 6 years of age or for the initiation of treatment in adults.

How does Phenilic work?

Phenilic improves the activity of certain parts of the brain which are under-active. The medicine can help improve attention (attention span), concentration and reduce impulsive behaviour. The medicine is given as part of a treatment programme, which usually includes:
- psychological
- educational and
- social therapy

It is prescribed only by doctors who have experience in children or young people's behaviour problems. Although there is no cure for ADHD, it can be managed using treatment programmes.

How is Phenilic used?

The pharmaceutical form of Phenilic is prolonged-release 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 Phenilic have been shown in studies?

Because Phenilic is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Concerta.

Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Phenilic?

Because Phenilic is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

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 Phenilic approved?

It was concluded that, in accordance with EU requirements, Phenilic has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine Concerta. Therefore, the Swedish Medical Products Agency decided that, as for Concerta, the benefits are greater than its risks and recommended that it can be approved for use.

Phenilic 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 Phenilic?”

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

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

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

This summary was last updated in 2023-03.