LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Metylfenidat Amdipharm (methylphenidate hydrochloride)

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Summary Public Assessment Report

Metylfenidat Amdipharm
methylphenidate hydrochloride

Modified-release capsule, hard, 40 mg

This is a summary of the public assessment report (PAR) for Metylfenidat Amdipharm. 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 Metylfenidat Amdipharm and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Equasym Depot.

The product is used in the treatment of 'Attention Deficit Hyperactivity Disorder' (ADHD).

- It is used in children and adolescents between the ages of 6 and 18 years.
- It is used only after treatments which do not involve medicine, such as counselling and behavioural therapy, have been insufficient.

How does Metylfenidat Amdipharm work?

Metylfenidat Amdipharm contains the active substance methylphenidate.

Metylfenidat Amdipharm improves the activity of certain parts of the brain which are under-active. The medicine can help improve attention span and concentration, and reduce impulsive behaviour.

The medicine is given as part of a treatment programme, which usually includes psychological, educational and social therapy.

Using treatment programmes as well as medicine helps to manage ADHD.

Treatment must only be initiated by, and used under the supervision of a doctor specialised in the treatment of ADHD, such as an expert paediatrician or a child and adolescent psychiatrist. Careful examination and monitoring during treatment by a specialist doctor is required.

How is Metylfenidat Amdipharm used?

The pharmaceutical form is Modified-release capsule, hard, 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 Metylfenidat Amdipharm have been shown in studies?

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

What are the possible side effects from Metylfenidat Amdipharm?

Because the product 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 Metylfenidat Amdipharm approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Equasym Depot, 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 Metylfenidat Amdipharm?”

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

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.

Other information about Metylfenidat Amdipharm

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

This summary was last updated in 2023-02.