

Summary Public Assessment Report

Methylphenidate Orion (methylphenidate hydrochloride)

SE/H/1917/01/DC

SE/H/1917/04/DC

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Methylphenidate Orion
methylphenidate hydrochloride

Prolonged-release tablets, 18 mg and 54 mg.

This is a summary of the public assessment report (PAR) for Methylphenidate Orion. It explains how Methylphenidate Orion was assessed to reach an opinion in favour of granting a marketing authorisation and its recommendations on the conditions of its use. It is not intended to provide practical advice on how to use Methylphenidate Orion.

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

What is Methylphenidate Orion and what is it used for?

Methylphenidate Orion is a 'generic medicine'. This means that Methylphenidate Orion is similar to a 'reference medicine' already authorised in the European Union (EU) called Concerta.

Methylphenidate Orion is used to treat 'attention deficit hyperactivity disorder' (ADHD)

- in children and young people between the ages of 6 and 18
- only after trying treatments which do not involve medicines, such as counselling and behavioural therapy.

How does Methylphenidate Orion work?

Methylphenidate Orion 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 treating children or young people's behaviour problems. Although there is no cure for ADHD, it can be managed using treatment programmes.

How is Methylphenidate Orion used?

The pharmaceutical form of Methylphenidate Orion is prolonged-release tablets 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 Methylphenidate Orion have been shown in studies?

Because Methylphenidate Orion is a generic medicine, studies in patients have been limited to studies performed 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 of Methylphenidate Orion?

Because Methylphenidate Orion 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 restrictions, see the package leaflet.

Why is Methylphenidate Orion approved?

It was concluded that, in accordance with EU requirements, Methylphenidate Orion has been shown to have comparable quality and to be bioequivalent to the reference medicine Concerta. Therefore, the Medical Products Agency in Sweden decided that, Methylphenidate Orion has the benefits that 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 Methylphenidate Orion?

A risk management plan has been developed to ensure that Methylphenidate Orion 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 Methylphenidate Orion, 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 Methylphenidate Orion

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

This summary was last updated in 2023-02.