

Summary Public Assessment Report

Metylfenidat Medical Valley (methylphenidate hydrochloride)

SE/H/1993/05/DC

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methylphenidate hydrochloride

Prolonged-release tablet, 45 mg

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

The product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance and is available as prolonged-release tablet.

The reference medicine for the product is Concerta.

The company has provided additional own data to demonstrate the safety and efficacy of the product regarding this difference from the reference medicine.

Metylfenidat Medical Valley is used to treat 'attention deficit hyperactivity disorder' (ADHD).

- It is used in children aged 6 years and over and in adults.
- It is used only after trying treatments which do not involve medicines, such as counselling and behavioural therapy.

Metylfenidat Medical Valley is not for use as a treatment for ADHD in children under 6 years of age.

How does Metylfenidat Medical Valley work?

Metylfenidat Medical Valley 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, adolescents or adults with behaviour problems. If you are an adult and have not been treated before, the specialist will carry out tests to confirm that you have had ADHD since childhood. Although there is no cure for ADHD, it can be managed using treatment programmes.

How is Metylfenidat Medical Valley used?

The pharmaceutical form 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 Metylfenidat Medical Valley have been shown in studies?

Because the product is a hybrid application, clinical studies have been provided to show efficacy for the difference from the reference product Concerta.

What are the possible side effects from Metylfenidat Medical Valley?

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 Medical Valley 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 Concerta, the benefits 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 Metylfenidat Medical Valley?

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.

For more details, please see the full PAR for Metylfenidat Medical Valley on the following website: [MRI - Home](#).

Other information about Metylfenidat Medical Valley

The full PAR for Metylfenidat Medical Valley can be found on the following website: [MRI - Home](#). For more information about treatment with Metylfenidat Medical Valley, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-05.