LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Dexatin
(dexamfetamine sulfate)

SE/H/2484/01-03/MR

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Dexatin
dexamfetamine sulfate

Tablet, 5 mg, 10 mg, 20 mg

This is a summary of the public assessment report (PAR) for Dexatin. 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 Dexatin 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 ADHD (attention deficit hyperactivity disorder) when medicines containing methylphenidate are not sufficiently effective.
The product should be used by children and adolescents aged 6 to 17 years diagnosed with ADHD.

How does Dexatin work?

Dexatin contains the active substance dexamfetamine sulfate. Dexatin is a psychostimulant which improves the activity in parts of the brain. The medicinal product can help to improve attention span, concentration, and reduce impulsive behavior.

How is Dexatin used?

The pharmaceutical form is 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 Dexatin have been shown in studies?

As dexamfetamine sulfate is a well-known substance, and its use in the treatment of ADHD is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of dexamfetamine sulfate in the treatment of the above-mentioned indication.

What are the possible side effects from Dexatin?

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 Dexatin 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 Dexatin?”

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

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.

As part of the approval, the applicant has been requested to produce educational material prior to launch of the product.

Other information about Dexatin

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

This summary was last updated in YYYY-MM.
Infoga datum enligt när sPAR blir klar för publicering.