LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Dexfarm
(dexamfetamine sulfate)

SE/H/2344/01-03/DC

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Summary Public Assessment Report

Dexfarm
dexamfetamine sulfate

Tablet, 5 mg, 10 mg, 20 mg

This is a summary of the public assessment report (PAR) for Dexfarm. 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 Dexfarm 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 Attentin.

The product is used in the treatment of attention-deficit/hyperactivity disorder (ADHD).

- It is used in children and adolescents aged 6-17 years.
- It is not indicated in all children with ADHD.
- It is used only after when another medicine called methylphenidate was not sufficiently effective.
- It should be used as part of a treatment programme which typically includes psychological, educational and social measures.

How does Dexfarm work?
The product is a psychostimulant. It improves activity in parts of the brain. This medicine can help to improve attention span, concentration, and reduce impulsive behaviour.

How is Dexfarm used?
The pharmaceutical form is 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 Dexfarm have been shown in studies?
No additional studies were needed as the product is a generic medicine considered to be bioequivalent to the reference medicine, Attentin. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Dexfarm?
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 Dexfarm approved?
It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be therapeutically equivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Attentin, 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 Dexfarm?"

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

The additional risk minimisation measures (aRMM) material contains the following key elements:

- Physician educational material, including a prescriber checklist and a guide for healthcare professionals.
- A patient information pack, including a parent/carer guide.

For more details, please see the full PAR for Dexfarm on the following website: MRI - Home.

Other information about Dexfarm
The full PAR for Dexfarm can be found on the following website: MRI - Home. For more information about treatment with Dexfarm, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-03.