LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Dexamfetamine Afortas (dexamfetamine sulfate)

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Summary Public Assessment Report

Dexamfetamine Afortas
dexamfetamine, dexamfetamine sulfate

Tablet, 5 mg, 10 mg, 20 mg

This is a summary of the public assessment report (PAR) for Dexamfetamine Afortas. 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 Dexamfetamine Afortas 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 belongs to a group of medicinal products called Pharmacotherapeutic: Psychoanaleptics; psychostimulants, agents used for ADHD and nootropics; centrally acting sympathomimetics

How does Dexamfetamine Afortas work?
Dexamfetamine is a sympathomimetic amine with a central stimulant and anorectic activity.

How is Dexamfetamine Afortas 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 Dexamfetamine Afortas 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 Dexamfetamine Afortas?
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 restrictions, see the package leaflet.

Why is Dexamfetamine Afortas approved?
It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and bioequivalent 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.

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

In each Member State the Marketing Authorisation Holder (MAH) will agree about the content and format of the educational programme, including communication media, distribution modalities, and any other aspects of the programme, with the National Competent Authority.
The educational programme is aimed to address the importance of and to give tools for continuous monitoring of important identified risks.
The MAH shall ensure that in each Member State where Dexamfetamine Afortas is marketed, all healthcare
professionals and carer who are expected to prescribe, dispense and use Dexamfetamine Afortas have access to/are provided with the following educational package:

- Physician educational material
- Patient information pack

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

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

This summary was last updated in 2026-03.