LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Lisdexamfetamin Hexal
(lisdexamfetamine dimesilate)

SE/H/2728/001-006/DC

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Summary Public Assessment Report

Lisdexamfetamin Hexal
lisdexamfetamine dimesilate

Capsule, hard, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 70 mg

This is a summary of the public assessment report (PAR) for Lisdexamfetamin Hexal. 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 Lisdexamfetamin Hexal 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 Elvanse Adult.

The product is a part of a comprehensive treatment programme for 'attention deficit hyperactivity disorder' (ADHD)
- for adults who have had ADHD since childhood. If you have not been treated for ADHD before, the doctor will check if you have had ADHD since childhood before prescribing the product.

How does Lisdexamfetamin Hexal work?

Lisdexamfetamin Hexal contains the active substance lisdexamfetamine dimesylate which helps with your brain activity. It helps improve your attention, helps you concentrate and makes you less impulsive. Lisdexamfetamin Hexal is a long acting medicine which works gradually over a 14 hour time period.

How is Lisdexamfetamin Hexal used?
The pharmaceutical form is capsule, hard 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 Lisdexamfetamin Hexal have been shown in studies?

Because the product is a generic medicine, studies have been limited to tests to determine that it is bioequivalent to the reference medicine, Elvanse Adult. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Lisdexamfetamin Hexal?

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 Lisdexamfetamin Hexal 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 Elvanse Adult, 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 Lisdexamfetamin Hexal?"

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

Below is described the educational material for the product.

Physician educational materials:

- The Summary of Product Characteristics
- Checklist 1: Prescriber checklist before prescribing lisdexamfetamine dimesylate
- Checklist 2: Prescriber checklist for ongoing monitoring during lisdexamfetamine dimesylate treatment
- Chart for ongoing monitoring during lisdexamfetamine dimesylate treatment
- Potential for non-medical use and diversion of prescription stimulant medications leaflet .

Education material components:

- **Checklist 1: Prescriber checklist before prescribing lisdexamfetamine dimesylate.**

The checklist is designed to support the prescriber in the appropriate initiation of lisdexamfetamine dimesylate in an adult (in countries with approval for the adult use) with attention-deficit/hyperactivity disorder (ADHD).

- **Checklist 2: Prescriber checklist for ongoing monitoring during lisdexamfetamine dimesylate treatment**

The checklist is designed to support the prescriber in the ongoing monitoring of lisdexamfetamine dimesylate therapy in adults (in countries with approval for the adult use) with ADHD.

- **Chart for ongoing monitoring during lisdexamfetamine dimesylate treatment**

The chart is designed to support you in the ongoing monitoring of lisdexamfetamine dimesylate therapy in adult (in countries with approval for the adult use) with ADHD.

In addition to the checklists and chart above, there is also a leaflet provided for use by patients, which is made available in countries where the health authorities have accepted it.

- **Potential for non-medical use and diversion of prescription stimulant medications leaflet:**

Educational leaflet for use by HCPs, patients and their parents/guardians.

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

This summary was last updated in 2026-03.