LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Minalix
(lisdexamfetamine dimesilate)

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Summary Public Assessment Report

Minalix
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 Minalix. 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 Minalix 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.

The product is a part of a comprehensive treatment programme for 'attention deficit hyperactivity disorder' (ADHD)

- for children and young people between the ages of 6 and 18 who have previously taken a methylphenidate treatment that inadequately treated their 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 Minalix work?

The product 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. The product is a long acting medicine which works gradually over a 13 hour time period.

How is Minalix 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 Minalix 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. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Minalix?

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 Minalix 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, 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 Minalix?"

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

- **Additional risk minimisation measures (including educational material)**
  The educational material should contain the following key elements:

Draft key messages of the additional risk minimisation measures

- **Checklist 1: Prescriber checklist before prescribing lisdexamfetamine**
  The checklist is designed to support the prescriber in the appropriate initiation of lisdexamfetamine dimesylate in a child aged six years and above, or adults, with ADHD;
- **Checklist 2: Prescriber checklist for ongoing monitoring during lisdexamfetamine treatment** – The checklist is designed to support the prescriber in the ongoing monitoring of lisdexamfetamine dimesylate therapy in children aged six years and above, or in adults with ADHD;
- **Chart for ongoing monitoring during lisdexamfetamine treatment** - The chart is designed to support the prescriber in the ongoing monitoring of lisdexamfetamine therapy in children aged six years and above or in adults with ADHD.

Leaflet for patient use:
In addition to the checklists and chart above, there is also a leaflet provided for use by patients.

- *Potential for non-medical use and diversion of prescription stimulant medications leaflet*
  - Educational leaflet for use by patients and their parents/guardians

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

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

This summary was last updated in 2026-03.