LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Lisfaveen
(lisdexamfetamine dibesilate)

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Summary Public Assessment Report

Lisfaveen
lisdexamfetamine dibesilate, lisdexamfetamine, 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 Lisfaveen. 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 Lisfaveen 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.

Lisfaveen contains the active substance lisdexamfetamine which helps with your brain activity. It helps improve your attention, helps you concentrate and makes you less impulsive. Lisfaveen is a long acting medicine which works gradually over a 13 hour time period.

Lisfaveen 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 Lisfaveen.

You must talk to a doctor if you do not feel better or if you feel worse after one month of treatment. Lisfaveen is not recommended for all patients with ADHD and the decision to use this medicine is based on a thorough medical evaluation.

Lisfaveen is not used as a treatment for ADHD in children under 6 years of age because it is not known if it is safe or of benefit in such young people.

How does Lisfaveen work?

Lisfaveen improves the activity of certain parts of the brain which are under-active. The medicine can help improve attention, concentration and reduce impulsive behaviour.

The medicine is given as part of a treatment programme, which usually includes the following:
- psychological therapy
- educational therapy
- social therapy
- behavioural therapy
- occupational therapy

It is prescribed only by doctors who have experience in treating people with behaviour problems.

How is Lisfaveen 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 Lisfaveen 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 Lisfaveen?

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 Lisfaveen approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be similar 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 Lisfaveen?”

What measures are being taken to ensure the safe and effective use of Lisfaveen?
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:
  - Prescriber checklist, sections 1 and 2
  - Chart for monitoring therapy
  - Patient guide

  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.

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

Other information about Lisfaveen

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

This summary was last updated in 2026-06.