LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

# Summary Public Assessment Report

# Dilida
# (lisdexamfetamine dimesilate)

# SE/H/2722/001-006/DC

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# Summary Public Assessment Report

Dilida,
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 Dilida. 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 Dilida 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 Dilida 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 Dilida 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 Dilida 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 Dilida?**

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 Dilida 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 Dilida?"

**What measures are being taken to ensure the safe and effective use of Dilida?**
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:

  - 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.

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

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

This summary was last updated in 2026-04.