

Summary Public Assessment Report

Balidax (lisdexamfetamine dimesilate)

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Balidax
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 Balidax. 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 Balidax 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.

Balidax is used in the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents.

How does Balidax work?

Balidax contains the active substance lisdexamfetamine dimesylate which helps with your brain activity. It helps improve attention and concentration and reduces impulsivity. Balidax is a long acting medicine which works gradually over a 14 hour time period.

Balidax 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
- behavioural therapy
- occupational therapy
- social therapy

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

How is Balidax used?

The pharmaceutical form is hard capsules 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 Balidax have been shown in studies?

Because the product is a generic medicine, studies in patients 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 Balidax?

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 Balidax 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 Balidax?”

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

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.

The product has been authorised with the condition to provide additional measures to minimise the risk. These measures involve educational material containing of a prescriber checklist and charts for ongoing monitoring during the treatment, together with an educational leaflet for patient use.

Other information about Balidax

The full PAR for Balidax can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Balidax , please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in YYYY-MM.

Infoga datum enligt när sPAR blir klar för publicering.