LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Elvanse Vuxen
(lisdexamfetamine dimesilate)

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lisdexamfetamine dimesilate

Capsule, hard, 20 mg, 40 mg, 60 mg

This is a summary of the public assessment report (PAR) for Elvanse Vuxen. 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 Elvanse Vuxen and what is it used for?

Elvanse Vuxen is a treatment for 'attention deficit hyperactivity disorder' (ADHD) in adults.

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

For children and adolescents aged 6 to 17 years, another product containing lisdexamfetamine dimesylate is available. Lisdexamfetamine dimesylate 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 Elvanse Vuxen work?

Elvanse Vuxen 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 Elvanse Vuxen 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 Elvanse Vuxen have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that the product is effective as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in adults.

Elvanse Vuxen is not indicated in all adult patients and the decision to use the medicinal product must take into consideration the profile of the patient, including a thorough assessment of the severity and chronicity of the patient's symptoms, the potential for abuse, misuse or diversion and clinical response to any previous pharmacotherapies for the treatment of ADHD.

Treatment must be under the supervision of a specialist in behavioural disorders. Diagnosis should be based on a complete history and evaluation of the patient according to current DSM criteria or ICD guidelines. Diagnosis cannot be made solely on the presence of one or more symptom. In adults, the presence of symptoms of ADHD that were pre-existing in childhood is required and should be confirmed retrospectively (according to the patient's medical record or, if not available, through appropriate and structured instruments or interviews). Based on clinical judgment, patients should have ADHD of at least moderate severity as indicated by at least moderate functional impairment in two or more settings (for example, social, academic, and/or occupational functioning), affecting several aspects of an individual's life.

The specific aetiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use of medical and specialised psychological, educational, and social resources.

A comprehensive treatment programme typically includes psychological, educational, behavioural, occupational and social measures as well as pharmacotherapy and is aimed at stabilising the adult patient with a behavioural syndrome characterised by symptoms which may include chronic history of short attention span, distractibility, impulsivity and hyperactivity.

What are the possible side effects from Elvanse Vuxen?

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 Elvanse Vuxen approved?

The Swedish Medical Products Agency decided that 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 Elvanse Vuxen?"

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

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 prescriber checklists and chart for ongoing monitoring during the treatment, together with an educational leaflet for patient use.

Other information about Elvanse Vuxen

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

This summary was last updated in 2023-05.