

Summary Public Assessment Report

Lisdexamfetamine FrostPharma (lisdexamfetamine dimesilate, lisdexamfetamine, dexamfetamine)

SE/H/2587/01

This module reflects the scientific discussion for the approval of Lisdexamfetamine FrostPharma. The Summary Public Assessment Report was written in 03-2024 by the previous RMS MT after initial procedure MT/H/0619/001. RMS transfer from MT to SE was completed 2024-03-27.

Summary Public Assessment Report

Generics

Lisdexamfetamine Aristo 10mg/ml oral solution

**Lisdexamfetamine FrostPharma 10mg/ml oral
solution**

Lisdexamfetamine Adalvo 10mg/ml oral solution

Lisdexamfetamine dimesylate

MT/H/0618/001/DC

MT/H/0619/001/DC

MT/H/0620/001/DC

Date: 21.03.2024

Summary Public Assessment Report

Generics

Lisdexamfetamine Aristo 10mg/ml oral solution
Lisdexamfetamine FrostPharma 10mg/ml oral solution
Lisdexamfetamine Adalvo 10mg/ml oral solution

This is a summary of the public assessment report (PAR) for Lisdexamfetamine dimesylate 10mg/ml oral solution. It explains how Lisdexamfetamine dimesylate 10mg/ml oral solution was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Lisdexamfetamine dimesylate 10mg/ml oral solution.

For practical information about using Lisdexamfetamine dimesylate, patients should read the package leaflet or contact their doctor or pharmacist.

What is Lisdexamfetamine dimesylate 10mg/ml oral solution and what is it used for?

Lisdexamfetamine dimesylate is a ‘hybrid generic medicine’. This means that it is similar to a reference medicine containing the same active substance but is available as different pharmaceutical form.

The company has provided additional own data to demonstrate the safety and efficacy of Lisdexamfetamine dimesylate regarding this difference from the reference medicine.

The reference medicine for Lisdexamfetamine dimesylate 10mg/ml oral solution is Elvanse 70mg capsules.

Lisdexamfetamine dimesylate 10mg/ml oral solution is a treatment for ‘attention deficit hyperactivity disorder’ (ADHD). It is used:

- in children and young people between the ages of 6 and 18 who have previously taken a methylphenidate treatment that inadequately treated their ADHD. You may continue to take this medicine into adulthood if your doctor thinks you are benefiting from treatment.

How does Lisdexamfetamine dimesylate 10mg/ml oral solution work?

It 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. This medicine is a long acting medicine which works gradually over a 13 hour time period.

How is Lisdexamfetamine dimesylate 10mg/ml oral solution used?

The pharmaceutical form of Lisdexamfetamine dimesylate is oral solution and the route of administration is oral.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a special prescription.

What benefits of Lisdexamfetamine dimesylate 10mg/ml oral solution have been shown in studies?

Because Lisdexametamine dimesylate 10mg/ml oral solution is a hybrid application of Elvanse 70mg capsules, clinical studies have been provided for Lisdexametamine dimesylate 10mg/ml oral solution to show efficacy for the difference of Lisdexametamine dimesylate 10mg/ml oral solution from the reference product Elvanse 70mg capsules.

What are the possible side effects from Lisdexametamine dimesylate 10mg/ml oral solution?

The most common side effects with Lisdexamfetamine dimesylate (which may affect more than 1 in 10 people) are:

- uneven heartbeat (palpitations)
- chest pain (may be a sign of heart problems)

For the full list of all side effects reported with Lisdexamfetamine dimesylate, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Lisdexamfetamine dimesylate 10mg/ml oral solution approved?

The Malta Medicines Authority decided that Lisdexamfetamine dimesylate 10mg/ml oral solution's benefits are greater than its risks and recommended that it be approved for use.

A risk management plan has been developed to ensure that Lisdexamfetamine dimesylate 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 for Lisdexamfetamine dimesylate, 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.

What measures are being taken to ensure the safe and effective use of is Lisdexamfetamine dimesylate 10mg/ml oral solution?

A risk management plan has been developed to ensure that is Lisdexamfetamine dimesylate 10mg/ml oral solution 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 for is Lisdexamfetamine dimesylate 10mg/ml oral solution, 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.

Other information about Lisdexamfetamine dimesylate 10mg/ml oral solution

The marketing authorisation for Lisdexamfetamine dimesylate 10mg / ml oral solution was granted on 8th February 2024.

The full PAR for Lisdexamfetamine dimesylate can be found on the website. For more information about treatment with Lisdexamfetamine dimesylate, read the package leaflet (link)or contact your doctor or pharmacist.

This summary was last updated in 03-2024.