

Summary Public Assessment Report

Safinamid ELPEN **(safinamide)**

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safinamide

Film-coated tablet, 50 mg, 100 mg

This is a summary of the public assessment report (PAR) for Safinamid ELPEN. 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 Safinamid ELPEN 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 Xadago.

The product is used in the treatment of Parkinson's disease in adults

How does Safinamid ELPEN work?

The product is a medicine that contains the active substance safinamide. It acts to increase the level of a substance called dopamine in the brain, which is involved in the control of movement and is present in reduced amounts in the brain of patients with Parkinson's disease

How is Safinamid ELPEN used?

The pharmaceutical form is film-coated tablet 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 Safinamid ELPEN 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, Xadago. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Safinamid ELPEN?

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 Safinamid ELPEN 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 Xadago, the benefits are greater than its risks and recommended that it can be approved for use.

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

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.

Other information about Safinamid ELPEN

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

This summary was last updated in 2025-12.