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EPAR summary for the public

Xadago

safinamide

This is a summary of the European public assessment report (EPAR) for Xadago. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Xadago.

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

What is Xadago and what is it used for?

Xadago is a medicine used to treat Parkinson's disease, a progressive brain disorder that causes shaking, slow movement and muscular stiffness. It is used in addition to levodopa (a medicine commonly used to treat the symptoms of Parkinson's disease) either alone or in combination with other medicines for Parkinson's, in patients with mid- to late-stage Parkinson's disease who are having 'motor fluctuations'. These fluctuations occur when the effect of levodopa wears off and the patient suddenly switches from being 'on' and able to move about to being 'off' and having difficulty moving about.

Xadago contains the active substance safinamide.

How is Xadago used?

Xadago is available as tablets (50 and 100 mg) and can only be obtained with a prescription. Treatment should be started at a dose of 50 mg a day and the doctor may increase the dose up to 100 mg a day based on patient's need.

For further information, see the package leaflet.



How does Xadago work?

In patients with Parkinson's disease, certain cells in the brain that produce dopamine die, and as dopamine is involved in controlling movement, the patient's movement worsens over time.

The active substance in Xadago, safinamide, is a 'monoamine oxidase-B (MAO-B) inhibitor'. It blocks the enzyme monoamine oxidase type B (which breaks down dopamine), thereby helping to restore dopamine levels in the brain and improving the patient's symptoms.

What benefits of Xadago have been shown in studies?

Xadago, as an add-on treatment to levodopa with or without other medicines for Parkinson's disease, has been compared with placebo (a dummy treatment) in two main studies involving 1,218 patients with late stage Parkinson's disease who experienced fluctuations. In both studies, 6 months treatment with Xadago increased the time during the day during which patients were 'on' and able to move by 30-60 minutes when compared with placebo. Another study showed maintenance of this effect for 24 months.

Xadago was also investigated as an add-on to treatment in 2 studies in patients with early Parkinson's disease without fluctuations, but these studies did not show a clear benefit and the company did not pursue this use as part of the application.

What are the risks associated with Xadago?

The most common side effects with Xadago (which may affect up to 1 in 10 people) are insomnia (difficulty sleeping), dyskinesia (difficulty controlling movement), somnolence (sleepiness), dizziness, headache, worsening of existing Parkinson's disease, cataract (clouding of the lens), orthostatic hypotension (drop in blood pressure when standing up), nausea (feeling sick) and falls. For the full list of all side effects reported with Xadago, see the package leaflet.

Xadago must not be used in patients with severe liver problems, in patients treated with pethidine or other MAO inhibiting medicines, or in patients with certain conditions affecting the eyes. For the full list of restrictions, see the package leaflet.

Why is Xadago approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Xadago's benefits are greater than its risks and recommended that it be approved for use in the EU. The Committee concluded that the effect of Xadago on the daily time that patients lived without motor symptoms was of clinical relevance, also taking into account the response reported in the literature for other Parkinson's medicines. This effect was also maintained in the long-term. Regarding safety, in overall it was considered acceptable.

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

A risk management plan has been developed to ensure that Xadago 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 Xadago, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the [summary of the risk management plan](#).

Other information about Xadago

The European Commission granted a marketing authorisation valid throughout the European Union for Xadago on 24 February 2015.

The full EPAR and risk management plan summary for Xadago can be found on the Agency's website: [ema.europa.eu/Find medicine/Human medicines/European public assessment reports](http://ema.europa.eu/Find%20medicine/Human%20medicines/European%20public%20assessment%20reports). For more information about treatment with Xadago, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2015.