Prescribing Information
Xadago▼ 50 and 100 mg film-coated tablets

Consult Summary of Product Characteristics before prescribing.

Legal Category: POM

Marketing Authorisation number and basic NHS cost: EU/1/14/984/001-005, EU/1/14/984/006 £69 for 30 tablets.

Presentation: Each film-coated tablet contains safinamide methansulfonate equivalent to 50 or 100mg mg safinamide.

Uses: Xadago is indicated for the treatment of adult patients with idiopathic Parkinson's disease (PD) as add-on therapy to a stable dose of Levodopa (L-dopa) alone or in combination with other PD medicinal products in mid-to late-stage fluctuating patients.

Dosage and administration:
Treatment with Xadago should be started at 50 mg per day. This daily dose may be increased to 100 mg/day on the basis of individual clinical need. If a dose is missed the next dose should be taken at the usual time the next day.

Method of administration
Xadago is for oral administration. It should be taken with water. It may be taken with or without food.

Special populations:
Paediatric population: The safety and efficacy of safinamide in children and adolescents under 18 years of age have not been established.
Elderly: No change in dose is required for elderly patients. Experience of use of safinamide in patients over 75 years of age is limited.
Hepatic impairment: Caution should be exercised when initiating treatment with Xadago in patients with moderate hepatic impairment. The lower dose of 50 mg/day is recommended for patients with moderate hepatic impairment. It is contraindicated in severe hepatic impairment.
Renal impairment*:* No change in dose is required for patients with renal impairment.
Women of childbearing potential: Xadago should not be given to women of childbearing potential unless adequate contraception is practiced.
Pregnancy: Women of childbearing potential should be advised not to become pregnant during safinamide therapy. Xadago should not be given during pregnancy.
Breast-feeding: Xadago is expected to be excreted in breast milk. A risk for the breast-fed child cannot be excluded. Xadago should not be given to breast-feeding women.

Warnings and Precautions:
Xadago may be used with selective serotonin re-uptake inhibitors (SSRIs) at the lowest effective dose, with caution for serotoninergic symptoms. The concomitant use of Xadago and fluoxetine or fluvoxamine should be avoided, or if concomitant treatment is necessary these medicinal products should be used at low doses. A washout period corresponding to 5 half-lives of the SSRI used previously should be considered prior to initiating treatment with Xadago.

At least 7 days must elapse between discontinuation of Xadago and initiation of treatment with MAO inhibitors or pethidine.

Impulse control disorders can occur in patients treated with dopamine agonists and/or dopaminergic treatments. Patients and carers should be made aware of the behavioural symptoms of ICDs that were observed in patients treated with MAO-inhibitors, including cases of compulsions, obsessive thoughts, pathological gambling, increased libido, hypersexuality, impulsive behaviour and compulsive spending or buying.

Safinamide used as an adjunct to levodopa may potentiate the side effects of levodopa, and pre-existing dyskinesia may be exacerbated, requiring a decrease of levodopa.

Xadago has no or negligible influence on the ability to drive and use machines.

Contraindications:
Hypersensitivity to the active substance or to any of the excipients. Concomitant treatment with other monoamine oxidase (MAO) inhibitors or with pethidine. Use in patients with severe hepatic impairment. Xadago should not be administered to patients with ophthalmological history that would put them at increased risk for potential retinal effects e.g. in patients with albinism, retinal degeneration, uveitis, inherited retinopathy or severe progressive diabetic retinopathy.

Interactions:
Concomitant administration of dextromethorphan or sympathomimetics such as ephedrine or pseudoephedrine, requires caution.
Serious adverse reactions have been reported with the concomitant use of selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic/tetracyclic antidepressants and MAO inhibitors. In view of the selective and reversible MAO-B inhibitory activity of safinamide, antidepressants may be administered but used at the lowest doses necessary.

Xadago can be used safely without any dietary tyramine restrictions.

Side Effects:
Consult the summary of product characteristics for other side effects.
Serious adverse reactions are known to occur with the concomitant use of SSRIs, SNRIs, tricyclic/tetracyclic antidepressants and MAO inhibitors, such as hypertensive crisis, neuroleptic malignant syndrome, serotonin syndrome, and hypotension.

Other serious adverse reactions include bronchopneumonia, basal cell carcinoma, leukopenia, delirium, suicidal ideation, glaucoma, diabetic retinopathy, eye haemorrhage, keratitis, papilloedema, hallucination, depression, compulsions, delirium, suicidal ideation, impulse disorders, myocardial infarction, hyperkalaemia, peptic ulcer, upper gastrointestinal haemorrhage, hyperbilirubinaemia, ankylosing spondylitis, electrocardiogram QT prolonged and fat embolism, photosensitivity.

Common undesirable effects include insomnia, dyskinesia, somnolence, dizziness, headache, Parkinson's Disease, cataract, orthostatic hypotension, nausea and fall.

Further information is available from:
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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Profile Pharma Ltd. at profile.drugsafety@ZambonGroup.com or telephone: +44 (0) 800 0288 942