

SCHEDULING STATUS

S4

XADAGO 50 mg film-coated tablets

XADAGO 100 mg film-coated tablets

Safinamide

Sugar free

Read all of this leaflet carefully before you start taking XADAGO.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- XADAGO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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1. What XADAGO is and what it is used for

XADAGO contains the active substance safinamide. XADAGO 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. XADAGO is used for the treatment of Parkinson's disease in adults.

In mid- to late-stage patients experiencing sudden switches between being "ON" and able to move and being "OFF" and having difficulties moving about, XADAGO is added to a stable dose of the medicine called levodopa alone or in combination with other medicines for Parkinson's disease.

2. What you need to know before you take XADAGO

Do not take XADAGO:

- If you are hypersensitive (allergic) to safinamide or any of the other ingredients of XADAGO (listed in section 6 of this leaflet).
- If you have a history of an allergic reaction to safinamide. Signs of an allergic reaction to safinamide could include swelling of your tongue, mouth or trouble breathing. Ask your healthcare provider if you are not sure if you have had an allergic reaction to safinamide in the past.
- If you are taking any of the following medicines:
 - Monoamine oxidase (MAO) inhibitors such as selegiline, rasagiline, moclobemide, phenelzine, isocarboxazid, tranylcypromine (e.g. for treatment of Parkinson's disease or depression, or used for any other condition).
 - Pethidine (a strong pain killer)

You must wait at least 7 days after stopping XADAGO treatment before starting treatment with MAO inhibitors or pethidine.

- If you have severe liver problems.
- If you have an eye condition which might put you at risk of potential damage to your retina (the light sensitive layers at the back of your eyes), e.g. albinism (lack of pigment in your skin and eyes), retinal degeneration (loss of cells from light sensitive layer at the back of the eye), or uveitis (inflammation inside of the eye), inherited retinopathy (inherited disorders of the vision), or severe progressive diabetic retinopathy (a progressive decrease of the vision due to diabetes).

Warnings and precautions

Tell your doctor before taking XADAGO:

- If you have any liver problems.
- Patients and carers should be made aware that certain compulsive behaviours such as compulsions, obsessive thoughts, pathological gambling, increased libido, hypersexuality, impulsive behaviour and compulsive spending or buying have been reported with other medicines for Parkinson's disease (see section 4).
- Uncontrollable jerky movements may occur or worsen when XADAGO is used together with levodopa. Also, when using XADAGO together with levodopa, tell your doctor if you or your family/carers notice you are developing addiction-like symptoms leading to craving for large doses of levodopa and other medicines used to treat Parkinson's disease.

Children and adolescents

XADAGO is not recommended for use in children and adolescents, below 18 years old due to the lack of data on safety and efficacy in this population.

Other medicines and XADAGO

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Ask your doctor for advice before taking any of the following medicines together with XADAGO:

- Cold or cough remedies containing dextromethorphan, ephedrine or pseudoephedrine
- Medicines called selective serotonin reuptake inhibitors (SSRIs) typically used to treat anxiety disorders, and some personality disorders (e.g. fluoxetine or fluvoxamine)
- Medicines called serotonin-norepinephrine reuptake inhibitors (SNRIs), used in the treatment of major depression and other mood disorders, such as venlafaxine
- Medicines for high cholesterol such as rosuvastatin, pitavastatin, pravastatin
- Fluoroquinolone antibiotic such as ciprofloxacin
- Medicines that affect the immune system such as methotrexate
- Medicines to treat metastatic carcinoma such as topotecan
- Medicine to treat pain and inflammation such as diclofenac
- Medicines to treat fungal infections such as ketoconazole
- Medicines to treat type 2 diabetes such as glyburide, metformin
- Medicines to treat viral infection such as aciclovir, ganciclovir

XADAGO with food and drink

XADAGO may be taken with or without food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care provider for advice before taking XADAGO.

XADAGO should not be used during pregnancy or by women of childbearing potential not practicing adequate contraception.

XADAGO is likely to be excreted in breast milk. XADAGO should not be used during breastfeeding.

Driving and using machines

Somnolence and dizziness may occur during XADAGO treatment; you should be cautious about operating hazardous machines or driving, until you are reasonably certain that XADAGO does not affect you in any way.

Ask your doctor for advice prior to driving or using machines.

3. How to take XADAGO

Do not share any medicines prescribed for you with any other person.

Always take XADAGO exactly as your doctor has told you. Check with your doctor if you are not sure.

The recommended starting dose of XADAGO is one 50 mg tablet that may be increased to one 100 mg tablet, taken once daily preferably in the morning by mouth with water. XADAGO may be taken with or without food.

If you suffer from moderately reduced liver function, you should not take more than 50 mg a day; your doctor will advise if this applies to you.

Your doctor will tell you how long your treatment with XADAGO will last.

If you have the impression that the effect of XADAGO is too strong or too weak, tell your doctor or pharmacist.

If you take more XADAGO than you should

If you have taken too many XADAGO tablets, you may develop raised blood pressure, anxiety, confusion, forgetfulness, sleepiness, light-headedness; feel sick or be sick; dilated pupils or develop involuntary jerky movements. In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and your remaining tablets with you so the doctor can see what you have taken.

If you forget to take XADAGO

Do not take a double dose to make up for a forgotten dose. Skip the missed dose and take the next dose at the time you normally take it.

If you stop taking XADAGO

Do not stop taking XADAGO without first talking to your doctor.

4. Possible side effects

XADAGO can have side effects.

Not all side effects reported for XADAGO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking XADAGO, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking XADAGO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, tongue and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to XADAGO. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- hypertensive crisis (very high blood pressure, collapse)
- neuroleptic malignant syndrome (confusion, sweating, muscle stiffness, higher than normal body temperature, increase level of enzyme creatine kinase in your blood)
- serotonin syndrome (confusion, hypertension, muscle stiffness, hallucinations), and
- hypotension (low blood pressure).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Side effects that may occur frequently:

- insomnia
- difficulty in performing voluntary movements
- feeling sleepy
- dizziness
- headache

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- worsening of Parkinson's disease
- clouding of the lens of the eye
- fall in blood pressure when rising to a standing position
- nausea

Side effects that may occur less frequently:

- urinary tract infection
- skin cancer
- low iron in your blood, low white cell count, red blood cell abnormality
- decreased appetite, high fat in blood, increased appetite, high blood sugar
- seeing things that are not there, feeling sad, abnormal dreams, fear and worry, confusional state, mood swings, increased interest in sex, abnormal thinking and perception, restlessness, sleep disorder
- numbness, unsteadiness, loss of sensation, sustained abnormal muscle contraction, head discomfort, difficulty in speaking, fainting, memory impairment
- blurring of vision, blind spot, double vision, aversion to light, disorders of the light sensitive layer at the back of your eye, redness of the eyes, increased pressure in the eye
- sensation of room spinning
- feeling of heart beating, fast heartbeat, irregular heartbeat, slowed heartbeat
- high blood pressure, low blood pressure, varicose veins (veins that have become large and twisted)
- cough, difficult breathing, runny nose
- constipation, heartburn, vomiting, dry mouth, diarrhoea, abdominal pain, burning stomach, wind, feeling full, drooling, mouth ulcer
- sweating, itching, sensitive to light, redness of the skin
- back pain, joint pain, cramps, stiffness, pain in legs or arms, muscle weakness, sensation of heaviness
- increased urination at night, pain upon urination
- the inability to get or keep an erection in men (erectile dysfunction)
- fatigue, feeling weak, unsteady walking, swelling of your feet, pain, feeling hot
- weight loss, weight gain, abnormal blood tests, high fat in your blood, increased sugar in your blood, abnormal ECG, abnormal liver function tests, abnormal urine tests, decreased blood pressure, increased blood pressure, abnormal eye test
- fracture of your foot

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Other side effects that may also occur:

- pneumonia, skin infection, sore throat, nasal allergy, tooth infection, viral infection
- non-cancerous skin conditions/growth
- white blood cell abnormalities
- severe loss of weight and weakness, increased potassium in blood
- uncontrollable urges, clouding of consciousness, disorientation, wrong perception of images, reduced interest in sex, thoughts that you cannot get rid of, feeling that someone is out to get you, premature ejaculation, uncontrollable urge to sleep, fear of social situations, thoughts of suicide
- clumsiness, easily distracted, loss of taste, weak/slow reflexes, radiating pain in the legs, continuous desire to move your legs, feeling sleepy
- eye abnormalities, progressive diminution of vision due to diabetes, increased tears, night blindness, cross eyed
- heart attack
- tightening/narrowing of blood vessel, severe high blood pressure
- tightening of the chest, difficulty in speaking, difficulty in/painful swallowing
- peptic ulcer, retching, stomach bleeding
- jaundice
- loss of hair, blister, skin allergy, skin conditions, bruising, scaly skin, night sweats, pain of skin, discolouration of the skin, psoriasis, flaky skin
- inflammation of spinal joints due to an autoimmune disorder, pain in your sides, swelling of joints, musculoskeletal pain, muscular pain, neck pain, joint pain, cyst in the joint
- uncontrollable urge to urinate, increased urination, passing of pus cells in urine, urinary hesitation
- prostate problem, breast pain
- feeling cold, feeling unwell, fever, dryness of skin, eye and mouth
- abnormal blood tests, heart murmur, abnormal heart tests
- bruising/swelling after injury, blood vessel blockage due to fat, head injury, mouth injury, skeletal injury
- gambling
 - hypersensitivity

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of XADAGO.

5. How to store XADAGO

- Store at or below 30 °C.
- Keep blister strips in carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What XADAGO contains

The active substance is safinamide. Each tablet contains 50 mg or 100 mg of safinamide (as methanesulfonate).

The other ingredients are:

- Tablet core: microcrystalline cellulose, crospovidone type A, magnesium stearate, silica colloidal anhydrous.
- Tablet coating: hypromellose, macrogol (6000), titanium dioxide (E171), iron oxide red (E172), mica (E555).

What XADAGO looks like and contents of the pack

XADAGO 50 mg are orange to copper, round, biconcave film-coated tablets of 7 mm diameter with metallic gloss, embossed with “50” on one side of the tablet.

XADAGO 100 mg are orange to copper, round, biconcave film-coated tablets 9 mm diameter with metallic gloss, embossed with “100” on one side of the tablet.

XADAGO is available in PVC/PVDC/Aluminium blister packs of 14, 28, 30, 90 or 100 tablets. Not all pack sizes may be marketed.

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Holder of certificate of registration

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand 1685

South Africa

Customer Care: 0860 ADCOCK / 232625

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