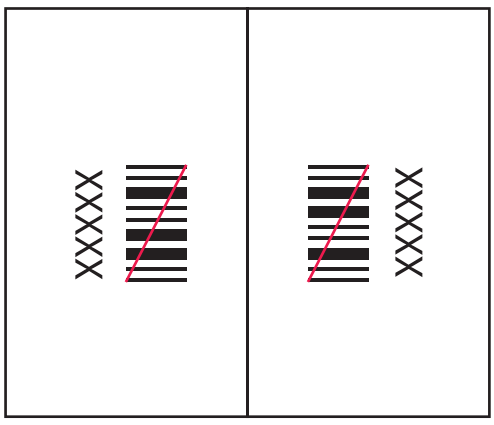


Celix Pharma

Package leaflet: Information for the patient

Safinamide 50 mg Film-coated Tablets
Safinamide 100 mg Film-coated Tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Safinamide Tablets are and what they are used for
2. What you need to know before you take Safinamide Tablets
3. How to take Safinamide Tablets
4. Possible side effects
5. How to store Safinamide Tablets
6. Contents of the pack and other information

1. What Safinamide Tablets are and what they are used for

Safinamide Tablets are 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. Safinamide Tablets are 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, Safinamide Tablets are 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 Safinamide Tablets

Do not take Safinamide Tablets
- If you are allergic to safinamide or any of the other ingredients of this medicine (listed in section 6).
- 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 Safinamide treatment before starting treatment with MAO inhibitors or pethidine.
- If you have been told that 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
Talk to your doctor before taking Safinamide Tablets
- If you have 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.
- Uncontrollable jerky movements may occur or worsen when Safinamide Tablets are used together with levodopa.

Children and adolescents
Safinamide Tablets are 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 Safinamide Tablets
Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.
Ask your doctor for advice before taking any of the following medicines together with Safinamide Tablets:
- 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 type 2 diabetes such as glyburide, metformin
- Medicines to treat virus infection such as aciclovir, ganciclovir

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

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

Breast Feeding
Safinamide is likely to be excreted in breast milk. Safinamide Tablets should not be used during breast-feeding.

Driving and using machines
Somnolence and dizziness may occur during safinamide treatment; you should be cautious about operating hazardous machines or driving, until you are reasonably certain that Safinamide Tablets do not affect you in any way. Ask your doctor for advice prior to driving or using machines.

Safinamide Tablets contains sodium
This medicine contains less than 1 mmol sodium (23 mg) tablet, that is to say essentially 'sodium free'.

3. How to take Safinamide Tablets

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

The recommended starting dose of Safinamide Tablets 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. Safinamide Tablets 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.

If you take more Safinamide Tablets than you should
If you have taken too many Safinamide Tablets, you may develop raised blood pressure, anxiety, confusion, forgetfulness, sleepiness, lightheadedness; feel sick or be sick; dilated pupils or develop involuntary jerky movements. Contact your doctor immediately and take the Safinamide Tablet pack with you.

If you forget to take Safinamide Tablets
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 Safinamide Tablets
Do not stop taking Safinamide Tablets without first talking to your doctor.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Seek medical advice in case of hypertensive crisis (very high blood pressure, collapse), neuroleptic malignant syndrome (confusion, sweating, muscle rigidity, hyperthermia, increase level of enzyme creatine kinase in your blood), serotonin syndrome (confusion, hypertension, muscle stiffness, hallucinations), and hypotension.

The following side effects have been reported in patients at a mid- to late-stage of Parkinson's disease (patients taking safinamide as add-on to levodopa alone or in combination with other medicines for Parkinson's disease):

Common (may affect up to 1 in 10 people):
insomnia, difficulty in performing voluntary movements, feeling sleepy, dizziness, headache, worsening of Parkinson's disease, clouding of the lens of the eye, fall in blood pressure when rising to a standing position, nausea, falling.

Uncommon (may affect up to 1 in 100 people):
urine 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, 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, difficulty in having sex in males, 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, liver function test abnormal, abnormal urine tests, blood pressure decreased, blood pressure increased, abnormal eye test, fracture of your foot.

Rare (may affect up to 1 in 1000 people):
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, drug effect decreased, drug intolerance, 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.

Reporting of side effects
If you get any 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 directly via the Yellow Card Scheme Website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Safinamide Tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Safinamide Tablets contain
- The active substance is safinamide. Each tablet contains 50 mg or 100 mg of safinamide (as methansulfonate).
- The other ingredients are:
- Tablet core: microcrystalline cellulose, crospovidone type A, colloidal silicon dioxide, sodium stearyl fumarate, ascorbic acid
- Tablet coating: hypromellose, macrogol (6000), MICA-Based pearlscent pigment (E555/E171), titanium dioxide (E171), iron oxide red (E172).

What Safinamide Tablets look like and contents of the pack
Safinamide 50 mg Film-coated Tablets are orange to copper, round, biconcave film-coated tablets (approximately 7 mm diameter) with metallic gloss, embossed with "50" on one side of the tablet.

Safinamide 100 mg Film-coated Tablets are orange to copper, round, biconcave film-coated tablets (approximately 9 mm diameter) with metallic gloss, embossed with "100" on one side of the tablet.

Safinamide Tablets are supplied in packs containing 10, 30 or 100 film-coated tablets.
Not all pack sizes may be marketed.

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If you are blind or partially sighted and require this leaflet in a different format, call 0800 669 6825 or contact medinfo@celixpharma.com.

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CEL20250062P

Company Name	Product Description	Celix / OLS	CCR No.
Celix Pharma	Safinamide 50 mg_100 mg Film-coated Tablets	Celix	-
	Version No.	Artwork Code	Artwork Creation Date: 12 November 2025
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Reviewed / Approved by	Component	Dimension	
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	Market	Font Size (Minimum)	
	UK	9pt	
		Font Type	
	Pharmacode	Helvetica Neue LT Pro	
Sign / Date	N/A		