

Package Leaflet

Sinepar 200 mg/50 mg prolonged-release tablets

levodopa/carbidopa

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Sinepar is and what it is used for

Sinepar is a medicine that combines the aromatic amino acid carbidopa monohydrate (a decarboxylase inhibitor) with levodopa (a metabolic precursor of dopamine) in a prolonged-release tablet. It is used to treat the symptoms of Parkinson's disease.

Why you have been prescribed Sinepar?

Your doctor has prescribed Sinepar to treat the symptoms of Parkinson's disease.

Parkinson's disease is a chronic disease characterized by delayed and unstable movements, muscle stiffness and tremor. If left untreated, Parkinson's disease can make your daily routine difficult.

How Sinepar works in the treatment of Parkinson's disease?

Sinepar tablets slowly release the two active ingredients - levodopa and carbidopa.

It is believed that the symptoms of Parkinson's disease is caused by a lack of dopamine, a chemical normally produced in several areas of the brain. Dopamine transmits signals to the parts of the brain that control muscle movement. Thus, the reduced production of dopamine leads to difficulty in movement.

Levodopa compensates for the lack of dopamine in the brain, while carbidopa ensures the delivery of the required amount of levodopa in the brain. In most patients, this leads to an improvement in the symptoms of Parkinson's disease. The prolonged-release dosage form maintains a constant amount of levodopa in your body.

2. What you need to know before you take Sinepar

Do not take Sinepar:

- If you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6);
- If you have any unusual skin lumps or moles which have not been examined by your doctor, or if you have ever had skin cancer or melanoma;
- If you are taking certain medicines called 'MAOIs' (Monoamine Oxidase Inhibitors) used for depression (with the exception of MAO-B inhibitors, such as selegiline);
- If you have a narrow-angle glaucoma.

Warnings and precautions

Talk to your doctor or pharmacist before taking Sinepar.

Tell your doctor if you or your family/carer notices you are developing urges or cravings to behave in ways that are unusual for you or you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These behaviours are called impulse control disorders and can include addictive gambling, excessive eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings. Your doctor may need to review your treatments.

Tell your doctor if you have or have had any health problems such as:

- allergies;
- depression or mental disturbances;
- lung disease;
- heart disease;
- kidney problems;
- liver problems;
- hormonal problems;
- ulcer;
- glaucoma;
- seizures.

Tell your doctor if you have been treated with levodopa.

Children and adolescents

The safety and efficacy of Sinepar in infants and children have not been established and its use is not recommended in patients under 18 years of age.

Other medicines and Sinepar

Although Sinepar can be given with other medicines, there are exceptions. Your doctor may warn you about incompatibilities with some other medicines, such as:

- antihypertensive drugs (medicines that lower high blood pressure - nifedipine, propranolol, enalapril). Tell your doctor, as it will probably be necessary to change the dosage of the antihypertensive medicine;
- tricyclic antidepressants - taking them at the same time can cause hypertension (high blood pressure);
- medicines used in Parkinson's disease - anticholinergic drugs (detrusitol, akinestat), COMT inhibitors, MAO inhibitors, amantadine;
- iron and iron supplements;

- medicines for mental illness - neuroleptics (risperidone, phenothiazines, butyrophenones);
- medicines used to treat tuberculosis - isoniazid;
- antiepileptics - phenytoin;
- muscle relaxants - papaverine.

Your doctor and pharmacist have more detailed information about the medicines you should avoid during treatment with Sinepar.

Tell your doctor if you or your family/carer notice that you develop addictive symptoms leading to a strong desire for high doses of Sinepar and other medicines used to treat Parkinson's disease.

Tell your doctor about any medicines you are taking or intend to take, including medicines obtained without a prescription.

Pregnancy, breastfeeding and fertility

It is not clear exactly what effect Sinepar has on pregnancy.

Levodopa passed into human milk.

If you are pregnant or planning to become pregnant or breast-feeding, tell your doctor before starting treatment with Sinepar. He will assess the benefits of treatment and the possible risks.

Driving and using machines

The individual response to the tablets may vary. Some side effects that have been reported with Sinepar may affect the ability of some patients to drive or use machines (see section 4).

Sinepar may cause drowsiness and sudden episodes of falling asleep. Therefore, avoid driving or do activities where reduced attention may put you or others at risk of injury or death (eg, working with machines) until such recurring episodes and drowsiness are controlled.

3. How to take Sinepar

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The dosage of Sinepar can be different and the doctor will determine it, depending on the stage of the disease and your tolerance to treatment.

For the slow and gradual release of the active ingredients of Sinepar, do not crush or chew the tablets.

For best results, take Sinepar every day. It is very important that you follow your doctor's recommendations about when and how much of the product to take.

Tell your doctor promptly about any changes in your condition, especially if you have nausea or abnormal movements, since this may require changes in your prescription. Do not stop taking this medicine suddenly unless your doctor tells you to.

If you take more Sinepar than you should.

If you make a mistake and take a lot of tablets, contact your doctor immediately for timely qualified medical care.

If you forget to take Sinepar.

Try to take the tablets as your doctor has told you. Do not take a double dose to make up for a forgotten tablet. Just take the next tablet as usual.

If you stop taking Sinepar.

Do not stop treatment or reduce the dose without consulting your doctor. This can lead to muscle stiffness, fever and mental changes.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Sinepar can cause side effects, although not everybody gets them.

If you notice any of the following side effects, please tell your doctor immediately or visit the emergency department of the nearest hospital:

- Fever and serious deterioration of your general condition;
- Allergic reactions: swelling of the face, hands, feet, lips, tongue or throat, or difficulty breathing or swallowing.

This is a very serious but rare side effect. Urgent medical attention or hospitalization may be required.

Serious side effects

Common side effects (may affect up to 1 in 10 people)

- depression with (rarely) suicidal tendencies.

Uncommon side effects (may affect up to 1 in 100 people)

- psychotic disorders with delusions (crazy thoughts) and paranoia (mania for persecution).

Rare side effects

- Muscle stiffness, heavy sweating (neuroleptic malignant syndrome);
- Swelling of the face, lips and tongue, which may cause airway obstruction.

Not known (frequency cannot be estimated from the available data)

- Irregular heartbeat;
- Severe illness due to low red blood cell count (anemia), which may cause fatigue, headache, shortness of breath, dizziness, paleness illness due to white blood cell deficiency (leukopenia);
- Bleeding from the skin and mucous membranes and bruising due to changes in the blood (too few platelets);
- Eye muscle spasms with staring upward gaze;
- Spontaneous bleeding from the skin and/or mucous membranes, joint pain and swelling, often with severe stomach pain and bleeding (Enoch-Schönlein purpura);
- Skin cancer. Contact your doctor immediately if new scars appear on your body or birthmarks increase or change in any way.;
- Persistent abnormal erection of the penis.

Unserious side effects

Very common side effects (may affect up to or more than 1 in 10 people)

- Unusual involuntary movements;
- Urinary tract infections.

Common to very common side effects (may affect 1 in 10 people to more than 1 in 100 people)

- Hallucinations;
- Heartbeat;
- Dizziness;
- Nausea, dry mouth, which may increase the risk of tooth decay;
- Confusion.

Common side effects (may affect up to 1 in 10 people)

- Involuntary and unintentional movements, manifested as throwing, throwing and sudden twitching movements;
- Unusual fatigue and drowsiness. Very rarely extreme drowsiness during the day and sudden twitching;
- Difficulty breathing. In some people, it can become a serious side effect;
- Dizziness and possible loss of consciousness when changing body position from lying to sitting or from sitting to standing due to low blood pressure;
- Alternating periods of over-expressed movements with complete stiffness;
- Headache;
- Burning sensation, tingling of the skin;
- Very slow twisting movements;
- Diarrhea, vomiting, constipation, digestive problems;
- Muscle spasms;
- Loss of appetite;
- Chest pain;
- Fainting and weakness;
- Unusual dreams, insomnia.

Uncommon side effects (may affect up to 1 in 100 people)

- Weight loss;
- Fainting;
- Involuntary body movements;
- Decreased mental acuity;
- Stomachache;
- Hives;
- Tendency to fall, unusual gait;
- Motor arousal;
- Increased sexuality;
- Uncontrollable urge to gamble.

Rare side effects (may affect up to 1 in 1,000 people)

- Anxiety, disorientation;
- Blurred vision;
- Dark saliva, dark urine;
- Itching, hair loss, rash, dark sweat, redness;
- Fatigue.

Not known (frequency cannot be estimated from the available data)

- Skin cancer. Contact your doctor immediately if new scars appear or birthmarks increase/change in any way;
- Difficulty urinating, possible cessation of urination. In some people, it can become a serious side effect;

- Inflammation of a vein with pain and swelling of the vein. In some people, it can become a serious side effect. Talk to your doctor;
- High blood pressure. Talk to your doctor. High blood pressure requires treatment. Too high blood pressure is a serious condition;
- Increased volume of body fluids;
- Weight gain;
- Weakening of memory;
- Bitter taste;
- Increased trembling of the hands, unsteady movements;
- Pupil contraction, drooping eyelid and narrowing of the eye slit (Horner's syndrome);
- Stiffness;
- A sense of excitement;
- Double vision, dilated pupils, eyelid spasms;
- Hoarseness of voice, special way of breathing, hiccups;
- Increased salivation, difficulty swallowing, gas, burning sensation of the tongue;
- Urinary incontinence;
- Increased sweating, hot flashes;
- Muscle spasms, spasms of the masticatory muscles;
- Fatigue;
- Feeling weak;
- Euphoria;
- Gritting teeth.
- A strong desire for large doses of Sinepar in excess of what is needed to control motor symptoms is known as dopamine dysregulation syndrome. Some patients experience severe abnormal involuntary movements (dyskinesia), mood swings or other side effects after taking large doses of Sinepar.

You may experience the following side effects:

Inability to resist the impulse to perform an action that could be harmful and may include:

- Strong impulse for excessive gambling despite serious personal and family consequences;
- Altered or increased sexual interest and behavior that is disturbing to others, such as increased sexual desire;
- Uncontrollable excessive shopping or spending;
- Overeating (eating large amounts of food for a short period of time) or an irresistible tendency to eat (consuming more than the normal amount of food and more than necessary to satisfy hunger).

If you notice any of these behaviors, tell your doctor. He will consider ways to reduce or deal with the symptoms.

In addition, Sinepar may cause side effects that you would not normally experience. These are changes in some laboratory results, e.g. indicators of liver function, kidney function, increase in blood glucose.

Your doctor or pharmacist has a complete list of side effects. Some of them can be serious. If you get unusual symptoms, tell your doctor or seek medical help immediately.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system of Bulgarian Drug

Agency. By reporting side effects, you can help to get more information about the safety of this medicine.

Contacts:

Bulgarian Drug Agency.
Bulgaria
8 Damyan Gruev Str.,
1303 Sofia Tel.: +35
928903417 website:
www.bda.bg

5. How to store Sinepar

Keep out of the sight and reach of children.

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

Do not store above 25 °C.

Store in the original package.

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

6. Contents of the pack and other information

What Sinepar contains:

- The active substances are: levodopa and carbidopa (as carbidopa monohydrate). Each tablet contains 200 mg levodopa and 50 mg carbidopa.
- The other ingredients are: hydroxypropyl methylcellulose (Pharmacoat 603), hydroxypropyl methylcellulose (Methocel 50LV), colloidal anhydrous silica, fumaric acid, sodium stearyl fumarate, quinoline yellow (E104), hydroxypropyl methylcellulose (Pharmacoat 606), macrogol 6000, yellow iron oxide (E172), red iron oxide (E172), titanium dioxide (E171)

What Sinepar looks like and contents of the pack

Sinepar prolonged-release tablets are orange-brown, round tablets.

One carton contains 10 blisters of 10 prolonged-release tablets and a patient leaflet.

Marketing Authorization Holder and Manufacturer:

Tchaikapharma High Quality Medicines Inc
1 G. M. Dimitrov Blvd
Sofia 1172, Bulgaria
tel.: +359 2 962 54 54
Fax: +359 2 9603 703
e-mail: info@tchaikapharma.com

For any information about this medicine, please contact the local representative of the Marketing Authorization Holder..

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