

PARNIDO EXTENDED-RELEASE TABLETS

Paliperidone (3 mg, 6 mg, 9 mg)

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What Parnido is used for

Schizophrenia

Parnido belongs to the class of antipsychotic medicines and is used to treat schizophrenia in adults and adolescents 15 years of age and older. In addition, after symptoms have been relieved, Parnido is used to keep the disorder under control, i.e. to prevent its recurrence.

Schizophrenia is a disorder with symptoms such as hearing things, seeing or sensing things that are not there, mistaken beliefs, unusual suspiciousness, becoming withdrawn, incoherent speech, and reduced behavioral/emotional responses. People with this disorder may also feel depressed, anxious, guilty, or tense.

Schizoaffective Disorder

Parnido belongs to the class of antipsychotic medicines and is used to treat schizoaffective disorder in adults (18 years of age and older), used either alone or with other medicines that are also used to treat depression and/or other mood disorders. Parnido is not for treating people with schizoaffective disorder who are younger than 18 years old.

Schizoaffective disorder is a mental condition in which a person experiences a combination of schizophrenia symptoms (as listed above) in addition to mood disorder symptoms (feeling very high, feeling sad, feeling agitated, distracted, sleeplessness, talkativeness, losing interest in everyday activities, sleeping too much or too little, eating too much or too little, and recurrent thoughts of suicide).

How Parnido works

Parnido can help alleviate the symptoms of your disease and stop your symptoms from coming back.

Before you use Parnido

- When you must not use it

Do not take Parnido if you know that you are allergic (hypersensitive) to paliperidone, risperidone or any of the other ingredients of this medicine. Hypersensitivity can be recognized for instance by skin rash, itching, shortness of breath or swollen face. If any of these occur, contact your doctor right away.

- Before you start to use it

Elderly patients

Parnido has not been studied in elderly patients with dementia. However, elderly patients with dementia, who are treated with other similar types of medicine, may have an increased risk of stroke or death.

All patients

If you have any of the following conditions, talk to your doctor as he/she may want to adjust your dose or monitor you for a while.

- if you have Parkinson's disease or Dementia.
- if you have ever been diagnosed with a condition whose symptoms include high temperature and muscle stiffness (also known as Neuroleptic Malignant Syndrome).
- if you have ever experienced abnormal movements of the tongue or face (Tardive Dyskinesia).
- if you have or are at risk of having diabetes (e.g. being overweight or have family history of diabetes). Your doctor should check your blood sugar before you start taking Parnido and regularly during treatment.
- if you have heart disease or heart disease treatment that makes you prone to low blood pressure, or are prone to drop in blood pressure or feeling dizzy when you stand up from lying or sitting positions.
- if you have epilepsy.

- if you have or have had low white blood cell counts in your blood. Let your doctor know right away if you develop a fever or infection while being treated with Parnido.
- if you have a swallowing, stomach or intestinal disorder that reduces your ability to swallow or pass food through your digestive system.
- if you have diseases associated with diarrhea.
- if you have a loss of kidney function. Your doctor may reduce your dose of Parnido if your kidney function is reduced.
- if you have a loss of liver function.
- if you have prolonged and/or painful erection.
- if you have had problems with body temperature regulation.
- if you or someone else in your family has a history of blood clots. Blood clots in the lungs and legs have been seen in patients taking Parnido. Blood clots in the lungs can be fatal.

Weight gain has been seen in patients receiving antipsychotic medicines. Your doctor may monitor your body weight while you are being treated with Parnido. During an operation on the eye for cloudiness of the lens (cataract), the pupil (the black circle in the middle of your eye) may not increase in size as needed. Also, the iris (the colored part of the eye) may become floppy during surgery and that may lead to eye damage. If you are planning to have an operation on your eye, make sure you tell your eye doctor that you are taking this medicine.

Pregnancy

Tell your doctor if you are pregnant, think you may be pregnant or are planning for pregnancy.

You should not take Parnido during pregnancy unless this has been discussed with your doctor. Shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, or difficulty in feeding may occur in your newborn baby if you used Parnido in the last trimester of your pregnancy.

Breastfeeding

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Do not breastfeed while you are being treated with Parnido. Consult your doctor in that case.

Patients with kidney or liver impairment

Your doctor may adjust your dose of Parnido based upon your kidney function. Adjustment in dose based on liver impairment is typically not necessary.

- Taking other medicines and alcohol

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription. Note that some medicines may increase the levels of paliperidone in your blood, which may produce an increase in side effects resembling overdose of Parnido. (See *If you use too much (overdose)* below.)

Since Parnido can make you sleepy or drowsy, care should be taken when Parnido is taken with other medicines that can also cause sleepiness or drowsiness.

Since Parnido can lower blood pressure, care should be taken when this medicine is taken with other medicines that lower blood pressure.

Parnido can reduce the effect of medicines against Parkinson's disease and restless legs syndrome (e.g., levodopa).

Parnido should be used with caution with medicines that increase the activity of the central nervous system (psychostimulants such as methylphenidate).

Alcohol should be avoided when taking Parnido.

How to use Parnido

- How much to use

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

For adults (18 years of age and older) with schizophrenia: The usual dose is

6 mg once a day taken in the morning, but the dose may be increased or decreased by your doctor within the dose range of 3 mg to 12 mg once a day.

For adults (18 years of age and older) with schizoaffective disorder: The usual dose is 6 mg once a day taken in the morning, but the dose may be increased or decreased by your doctor within the dose range of 3 mg to 12 mg once a day.

Use in adolescents

The recommended starting dose for treating schizophrenia in adolescents 15 years and older is 3 mg once a day taken in the morning.

For adolescents weighing 51 kg or more the dose may be increased within the range of 6 mg to 12 mg once a day.

For adolescents weighing less than 51 kg the dose may be increased to 6 mg once a day.

Parnido is not approved for treating schizoaffective disorder in patients younger than 18 years of age.

Your doctor will decide how much to give you. The amount you take depends on how well the medicine works for you.

- When to use it

Parnido should be taken every morning with or without food. Parnido must be taken by mouth, swallowed whole with water or other liquids. It must not be chewed, broken, or crushed. The active ingredient, paliperidone, dissolves once swallowed and the tablet shell is passed out of the body as waste. Do not be alarmed if you notice what looks like the Parnido tablet in your stool.

- How long to use it

Continue using Parnido for as long as your doctor recommends.

- If you forget to use it

Do not take a double dose to make up for a forgotten dose. If you miss one dose, take your next dose on the day following the missed dose. If you miss two or more doses, contact your doctor.

- If you stop Parnido

You will lose the effects of the medicine. You should not stop this medicine unless told to do so by your doctor as your symptoms may return.

- If you use too much (overdose)

Contact your doctor right away. Patients who have taken too much paliperidone may experience the following symptoms: drowsiness or sleepiness, fast heart rate, low blood pressure, an abnormal electrocardiogram (electrical tracing of the heart), or slow or abnormal movements of the face, body, arms, or legs.

In overdose, one or more of the following signs may occur: reduced consciousness, drowsiness, sleepiness, excessive trembling, excessive muscle stiffness, fast beating heart, and low blood pressure. Cases of abnormal electrical conduction in the heart (QT prolongation) and convulsion have been reported. If you experience the above symptoms contact your doctor so you can be treated for taking too much Parnido.

Information for the Doctor in Case of Overdose

- Establish and maintain a clear airway if patient has lost consciousness.
- Inject sympathomimetic if blood pressure is low.
- ECG monitoring is required: consider transfer to hospital.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

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Tell all the doctors, dentists and pharmacists treating you that you are using Parnido.

Tell your doctor immediately if you become pregnant while using this medication.

- ***Things you must not do***

Do not stop using the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Parnido to anyone else, even if they have the same symptoms or condition as you.

- ***Things to be careful of***

Driving or operating machinery

Parnido might affect your alertness and may affect your vision. You are, therefore, advised not to drive or operate machines before you know how sensitive you are to Parnido.

Side effects

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

Uncommonly, a severe allergic reaction characterized by fever, swollen mouth, face, lip or tongue, shortness of breath, itching, skin rash and sometimes drop in blood pressure (amounting to an 'anaphylactic reaction') can occur. If this occurs, seek medical attention immediately.

In elderly patients with dementia, medicines in the same group as Parnido have been associated with side effects including sudden weakness or numbness of the face, arms, or legs, instances of slurred speech, or blurred vision. These symptoms may be associated with stroke. If any of these occur, even for a short period of time, seek medical attention immediately.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

Talk to your doctor or pharmacist if you experience:

- increase in blood sugar level and/or symptoms of high blood sugar (e.g. increased hunger, and frequent urination)
- unpleasant leg sensations and an intense urge to move the legs (restless legs syndrome)
- trouble breathing during sleep (sleep apnoea)
- difficulty or inability to pass urine (urinary retention)

Very common: may affect more than 1 in 10 people

- difficulty falling or staying asleep
- parkinsonism: This condition may include slow or impaired movement, sensation of stiffness or tightness of the muscles (making your movements jerky), and sometimes even a sensation of movement "freezing up" and then restarting. Other signs of parkinsonism include a slow shuffling walk, a tremor while at rest, increased saliva and/or drooling, and a loss of expression on the face
- restlessness
- feeling sleepy or less alert
- headache

Common side effects: may affect up to 1 in 10 people

- infection of the chest (bronchitis), common cold symptoms, sinus infection, urinary tract infection, feeling like you have the flu
- weight gain, increased appetite, weight loss, decreased appetite
- elated mood (mania), irritability, depression, anxiety
- dystonia: This is a condition involving slow or sustained involuntary contraction of muscles. While it can involve any part of the body (and may result in abnormal posture), dystonia often involves muscles of the face,

including abnormal movements of the eyes, mouth, tongue or jaw.

- dizziness
- dyskinesia: This is a condition involving involuntary muscle movements, and can include repetitive, spastic or writhing movements, or twitching.
- tremor (shaking)
- blurry vision
- an interruption in conduction between the upper and lower parts of the heart, abnormal electrical conduction of the heart, prolongation of the QT interval from your heart, slow heart rate, rapid heart rate
- low blood pressure upon standing (consequently, some people taking Parnido may feel faint, dizzy, or may pass out when they stand up or sit up suddenly), high blood pressure
- sore throat, cough, stuffy nose
- abdominal pain, abdominal discomfort, vomiting, nausea, constipation, diarrhoea, indigestion, dry mouth, toothache
- increased liver transaminases in your blood
- itching, rash
- bone or muscle ache, back pain, joint pain
- loss of menstrual periods
- fever, weakness, fatigue (tiredness)

Additional side effects in adolescents

Adolescents generally experienced side effects that were similar to those seen in adults except the following side effects were seen more commonly:

- feeling sleepy or less alert
- parkinsonism: This condition may include slow or impaired movement, sensation of stiffness or tightness of the muscles (making your movements jerky), and sometimes even a sensation of movement "freezing up" and then restarting. Other signs of parkinsonism include a slow shuffling walk, a tremor while at rest, increased saliva and/or drooling, and a loss of expression on the face
- weight gain
- common cold symptoms
- restlessness
- tremor (shaking)

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- stomach pain
- leaking milk from the breasts in girls
- breast swelling in boys
- acne
- problems with speech
- stomach or intestinal infection
- nose bleeds
- ear infection
- high blood triglycerides (a fat)
- sensation of spinning (vertigo)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Parnido

- **Storage**
Keep out of the sight and reach of children.
Do not use Parnido after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.
Store below 30 °C.
Store in the original package in order to protect from moisture.
- **Disposal**
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- **What it looks like**
3 mg: White to greyish white round biconvex film-coated tablets with possible uneven surface and imprinted with mark P3 on one side of the tablet.
6 mg: Brownish yellow, round, biconvex, film-coated tablets with possible uneven surface and imprinted with mark P6 on one side of the tablet.
9 mg: Off-pink, round, biconvex, film-coated tablets with possible uneven

surface and imprinted with mark P9 on one side of the tablet.

Blister pack: 28 extended-release tablet, in a box.

- Ingredients

- Active ingredient
3 mg: Each extended-release tablet contains 3 mg paliperidone.
6 mg: Each extended-release tablet contains 6 mg paliperidone.
9 mg: Each extended-release tablet contains 9 mg paliperidone.

- Inactive ingredients
Tablet core: macrogol, butylhydroxytoluene (E321), povidone K30, sodium chloride, cellulose, microcrystalline, magnesium stearate, ferric oxide, red (E172), hydroxypropylcellulose, cellulose acetate
Coating: hypromellose, titanium dioxide (E171), talc, propylene glycol, ferric oxide yellow, (E172) – *only for 6 mg tablets*, ferric oxide, red (E172) – *only for 9 mg tablets*
Printing ink: shellac, ferric oxide, black (E172), propylene glycol

MAL number(s):

MAL*****
MAL*****
MAL*****

Manufacturer

KRKA, d.d., Novo mesto,
Šmarješka cesta 6,
8501 Novo mesto,
Slovenia

Product Registration Holder

PAHANG PHARMACY SDN. BHD.
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