

PALIDONE 9

*Paliperidone Extended
Release Tablets USP 9 mg*

Consumer Medicine Information

What is in this leaflet?

This leaflet contains answers to some common questions about Palidone 9. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risk of you using this medicine against the benefits he/she expects it will have for you. If you have any concerns about using this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine. You may need to read it again.

What does Palidone 9 look like? (Dosage Form)

Brown colour round shape biconvex film coated extended release tablet, with one side break line and other side plain.

Is this oral or injectable? (Route of Administration)

It is to be consumed orally, swallowed with water. Do not chew the tablet.

Ingredients / Content / Volume:

Each film coated extended release tablet contains:
Paliperidone USP.... 9 mg
Excipients Q.S.
Colour: Red Oxide of Iron

How to store Palidone 9? (Storage temperature & conditions)

Store in a cool and dry place at temperature below 30°C. Keep medicine away from children.

What other ingredients are in this medicine beside the active one? (Declaration of Excipients)

Sodium Lauryl Sulphate BP, M.C.C.P 102 BP, HPMC K 100M IH, HPMC k 4M IH, Ethyl Cellulose BP, Lactose BP, P.V.P.K 30 BP, Fumed Silica IH, Magnesium Stearate BP, Plasticised Cellulose Colour Coat TiO₂ (FC4S-I) (White Sol.) IH, Isopropyl Alcohol BP, Methylene Dichloride BP, Red Oxide of Iron IH.

Do I need a prescription to get this medicine? (Dispensing Condition)

Yes, Prescription Medication Only.

What age group is this medicine suitable for? (Age Indication)

Initial dose is 3 mg, and maximum dose is 12 mg / day.

Children: 12 to 17 years

Adults: 18 years and above

The dose can be given from 3 mg – 12 mg once a day that may be adjusted depending on the severity of the patient or as directed by the physician.

What Palidone 9 is used for? (Indications)

Palidone 9 Extended-Release Tablets are indicated for the acute treatment of schizoaffective disorder as monotherapy, for the acute treatment of

schizoaffective disorder as an adjunct to mood stabilizers and/or antidepressants.

How should I take this medicine? (Method of Use)

It is to be consumed orally, swallowed with water. Do not chew the tablet.

What is the dosage schedule and dose duration?

Initial dose is 3 mg and maximum dose is 12 mg / day. Your doctor will decide The dose depending on your condition and other factors such as weight and your response to the medicine.

Children: 12 to 17 years

Adults: 18 years and above

The dose can be given from 3 mg – 12 mg once a day that may be adjusted depending on the severity of the patient or as directed by the physician. If you are unsure or having trouble remembering the dose, speak to your doctor or pharmacist.

What are the signs of an Overdose?

Observed signs and symptoms included extrapyramidal symptoms and gait unsteadiness. Other potential signs and symptoms include those resulting from an exaggeration of paliperidone's known pharmacological effects, i.e., drowsiness and somnolence, tachycardia and hypotension, and QT prolongation. Torsade de pointes and ventricular

fibrillation have been reported in a patient in the setting of overdose.

What should I do immediately if someone has Overdosed? (Overdose Management):

There is no specific antidote to paliperidone, therefore, appropriate supportive measures should be instituted, and close medical supervision and monitoring should continue until the patient recovers. Consideration should be given to the extended-release nature of the product when assessing treatment needs and recovery. Multiple drug involvement should also be considered.

In case of acute overdose, establish and maintain an airway and ensure adequate oxygenation and ventilation. Administration of activated charcoal together with a laxative should be considered. Cardiovascular monitoring should commence immediately, including continuous electrocardiographic monitoring for possible arrhythmias. Hypotension and circulatory collapse should be treated with appropriate measures, such as intravenous fluids and/or sympathomimetic agents. In cases of severe extrapyramidal symptoms, anticholinergic medication should be administered.

Warning & Precaution:
Is there anything I should be careful about while taking this medicine?

Before starting treatment with Palidone 9, tell your doctor if you have:

- Not recommended for use in patients (especially elderly) with dementia related psychosis and increased incidence of cerebrovascular adverse reactions including (eg: stroke, transient ischemic attack, including fatalities).
- If you have Parkinson's disease or dementia, or diagnosed with a condition whose symptoms include high temperature and muscle stiffness (also known as Neuroleptic Malignant Syndrome).
- If you have ever experienced abnormal movement of the tongue or face. (Tardive Dyskinesia).
- If you have heart disease or heart disease treatment that makes you prone to low blood pressure.
- Caution needed for patients having history of seizure or epilepsy.
- Closely supervise high risk patients (Suicidal Patients)
- Patients with schizoaffective disorder treated with this medicine should be carefully monitored for a potential shift from maniac to depressive symptoms.

Who should not take this medicine? (Contraindications)

If allergic or hypersensitivity to Paliperidone, and lactose intolerant patients.

Does this medicine interact with any other drugs I'm taking? Drug Interactions:

Paliperidone may interact with CNS depressants, alcohol, QT-prolonging drugs, antihypertensives, dopamine agonists, and enzyme inducers such as carbamazepine.

Concomitant use may require caution or dose adjustment.

Is it safe during pregnancy or breast feeding?

Consult your doctor if you are pregnant, or planning to have a baby or during breast feeding, before consuming Palidone 9.

Is it safe to drive or operate machine using this medicine?

Paliperidone may cause dizziness, drowsiness, or visual disturbances. Patients should be advised not to drive or operate machinery until they know how the medicine affects them.

If I am Lactose Intolerant?

Inform your doctor if you are lactose intolerant as Palidone 9 contains lactose monohydrate.

How does this medicine work? (Pharmacological Information)

Paliperidone is an atypical antipsychotic that works by balancing dopamine and serotonin levels in the brain. This helps improve symptoms of schizophrenia and related conditions. The extended-release tablet provides steady action

throughout the day with once-daily dosing.

The extended-release formulation allows for a controlled release of the medicine over 24 hours, providing consistent therapeutic levels with once-daily dosing.

What Side Effects can this medicine cause?

Common side effects: Tell your doctor if you notice any of the following:

- Staying asleep or less alert
 - Restlessness & Headache
 - Change in appetite and weight
 - Mood swings, irritability, depression, anxiety
 - Dystonia & dyskinesia
 - Tremor and blurry vision
 - Low blood pressure on standing, may feel fainting.
- Consult your doctor if you experience blood clots in the veins (especially in the legs), chest pain, difficulty in breathing, experience sudden change of mental state, sudden weakness or numbness of your face, arms or legs, slurred speech (even for a short time), prolonged and painful erection, involuntary rhythmic movements of the tongue, mouth and face, allergic reactions and high fever.

How does the packaging of this medicine look like?

There are 10 tablets in one strip and 3 such strips in a box with leaflet.

**Manufacturer & Product License Holder:
Rhombus Pharma Pvt Ltd.**

Survey No 807/002, Near
Ethrico Industries,
Lakshmanpura, Ta: Kadi,
Dist: Mehsana 382165.
Gujarat. India

Marketing Authorisation Holder:

**ELR Pharmaceuticals
FZCO**

Premises No. 22584,
Building A2, DSO-IFZA,
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