

**Ropinirole Cas No. : 91374-21-9**

This medication is used to treat Parkinson's disease. It helps replace the brain chemical called dopamine, which is low in Parkinson's disease. It is also used to treat RLS (Restless Legs Syndrome).

Active Pharmaceuticals Ingredients Manufacturers

## Taj Pharmaceuticals Ltd.

### Ropinirole

**CAS No. : 91374-21-9**


#### Synonyms

4-(2-Dipropylaminoethyl)-1,3-dihydroindol-2-one

#### Ropinirole,

4-(2-Dipropylaminoethyl)-1,3-dihydroindol-2-one,

#### Chemical data

Molecular Formula C<sub>16</sub>H<sub>24</sub>N<sub>2</sub>O

Molecular Weight 260.37

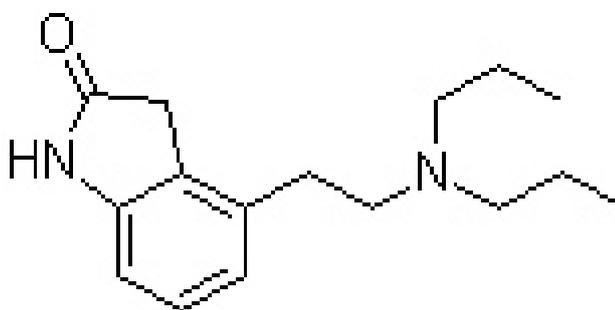
CAS Registry Number 91374-21-9

#### Pharmacokinetic data

Bioavailability 50%

Metabolism hepatic (CYP1A2)

Half life 5-6 hours



#### DOSAGE

Take this medication as prescribed. Do not increase your dose or take it more often than directed. Do not stop taking this medication without your doctor's approval. Stopping this drug suddenly may cause you to experience unwanted side effects. Dosing is based on your condition and this drug's side effects. It may take a few weeks for this medication to take effect.

Ropinirole comes as a tablet and an extended-release (long-acting) tablet to take by mouth. Ropinirole may be taken with food to prevent stomach upset. When ropinirole is used to treat Parkinson's disease, the regular tablet is usually taken three times a day and the extended-release tablet is taken once daily. When ropinirole is used to treat Restless Legs Syndrome, the regular tablet is usually taken once a day, 1 to 3 hours before bedtime. Ropinirole extended-release tablets are not used to treat Restless Legs Syndrome. Take ropinirole at around the same time(s) every day. Follow the directions on your prescription label carefully and ask your doctor or pharmacist to explain any part you do not understand. Take ropinirole exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the extended-release tablets whole; do not split, chew, or crush them.

If you stop taking ropinirole for any reason, do not start to take the medication again without talking to your doctor.

#### SIDE EFFECTS

Nausea, dizziness, drowsiness, trouble sleeping, constipation, unusual weakness, stomach upset and pain, headache or dry mouth may occur.

If these effects persist or worsen, notify your doctor promptly. To relieve dry mouth, suck on (sugarless) hard candy or ice chips, chew (sugarless) gum, drink water or use saliva substitute.

Report promptly: hallucinations, difficulty moving or walking, difficulty breathing. Unlikely but report promptly: confusion, restlessness, leg or foot swelling, fainting, twitching, chest pain, unusually fast or slow heartbeat.

Very unlikely but report promptly: muscle pain, vision problems, fever, severe muscle stiffness, sudden irresistible urge to sleep. If you notice other effects not listed above, contact your doctor.



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**All medicines may cause side effects most common** side effects : Confusion; constipation; diarrhea; dizziness; drowsiness; fatigue; headache; increased sweating; indigestion; leg swelling; lightheadedness; nausea; sore throat; stomach pain; sweating; vision problems; vomiting; weakness.

Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); blood in the urine; chest pain; confusion; difficulty sleeping; fainting; falling asleep during the daytime; hallucinations; impotence; nightmares; numbness or tingling of the skin; pounding in the chest; slow or irregular heartbeat; sudden, severe drowsiness or falling asleep during normal daily activities; swelling of the arms or legs; worsening of muscle coordination.

### PRECAUTIONS

Tell your doctor if you have a history of: heart disease or heart arrhythmias (abnormal rhythms), hallucinations, mental confusion, difficulty walking, any allergies, kidney problems, liver disease, low blood pressure. To avoid dizziness and lightheadedness when rising from a seated or lying position, get up slowly. Use caution when performing tasks requiring mental alertness such as driving or using machinery. Limit alcohol use because it may intensify the drowsiness and dizziness effects of this drug. This drug should be used only when clearly needed during pregnancy.

#### Before taking ropinirole,

tell your doctor and pharmacist if you are allergic to ropinirole, any other medications, or any of the ingredients in ropinirole tablets or extended-release tablets. Ask your doctor or pharmacist for a list of ingredients in ropinirole regular or extended-release tablets.

tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: antidepressants ('mood elevators'); antipsychotics (medications for mental illness); cimetidine (Tagamet, Tagamet HB); fluoroquinolone antibiotics such as ciprofloxacin (Cipro), and norfloxacin (Noroxin); fluvoxamine (Luvox); hormone replacement therapy and hormonal contraceptives (birth control pill, patches, rings, and injections); insulin; lansoprazole (Prevacid); levodopa (in Sinemet, in Stalevo); medications for anxiety and seizures; medications that cause drowsiness; metoclopramide (Reglan); mexiletine (Mexitil); modafinil (Provigil); nafcillin; omeprazole (Prilosec, Zegerid); sedatives; sleeping pills; and tranquilizers. Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Be sure to tell your doctor or pharmacist if you stop taking any medications while you are taking ropinirole.

tell your doctor if you have ever had an urge to gamble that was difficult to control and if you have or have ever had unexpected daytime sleepiness or a sleep disorder other than restless legs syndrome; high or low blood pressure; a psychotic disorder (mental illness that causes abnormal thinking or perceptions); or heart, liver, or kidney disease. remember that alcohol can add to the drowsiness caused by this medication. Tell your doctor if you regularly drink alcoholic drinks. tell your doctor if you use tobacco products. Call your doctor if you start or stop smoking during your treatment with ropinirole. Smoking may decrease the effectiveness of this medication.

you should know that some people who took medications such as ropinirole developed gambling problems or other intense urges or behaviors that were compulsive or unusual for them, such as increased sexual urges or behaviors. There is not enough information to tell whether the people developed these problems because they took the medication or for other reasons. Call your doctor if you have an urge to gamble that is difficult to control, you have intense urges, or you are unable to control your behavior. Tell your family members about this risk so that they can call the doctor even if you do not realize that your gambling or any other intense urges or unusual behaviors have become a problem.



you should know that ropinirole may cause dizziness, lightheadedness, nausea, or sweating when you get up too quickly from a sitting or lying position. This is more common when you first start taking ropinirole or with an increase in the dose of ropinirole. To avoid this problem, get out of the chair or bed slowly, resting your feet on the floor for a few minutes before standing up.

## DRUG DESCRIPTION

Ropinirole hydrochloride is an orally administered non-ergoline dopamine agonist. It is the hydrochloride salt of 4-[2-(dipropylamino)ethyl]-1,3-dihydro-2H-indol-2-one monohydrochloride and has an empirical formula of  $C_{16}H_{24}N_2O \cdot HCl$ . The molecular weight is 296.84 (260.38 as the free base). Ropinirole hydrochloride is a white to yellow solid with a melting range of 243° to 250°C and a solubility of 133 mg/mL in water. Ropinirole tablet with beveled edges contains ropinirole hydrochloride equivalent to ropinirole, 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg, or 5 mg. Inactive ingredients consist of: croscarmellose sodium, hydrous lactose, magnesium stearate, microcrystalline cellulose, and one or more of the following: carmine, FD&C Blue No. 2 aluminum lake, FD&C Yellow No. 6 aluminum lake, hypromellose, iron oxides, polyethylene glycol, polysorbate 80, titanium dioxide. Ropinirole is used alone or with other medications to treat the symptoms of Parkinson's disease (PD; a disorder of the nervous system that causes difficulties with movement, muscle control, and balance), including shaking of parts of the body, stiffness, slowed movements, and problems with balance. Ropinirole is also used to treat Restless Legs Syndrome a condition that causes discomfort in the legs and a strong urge to move the legs, especially at night and when sitting or lying



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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:  
91 022 30601000.

This leaflet was prepared by  
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MPSTJ278

Last revised: 29 August 2009