**HIGHLIGHTS OF PRESCRIBING INFORMATION**

3 CONTRAINDICATIONS

These highlights do not include all the contraindications and precautions. See PRESCRIBING INFORMATION section for further information.

## Parkinson's Disease

### Normal Renal Function

- **Doses should be increased gradually from a starting dose of 0.375 mg/day given in three divided doses**
- **If needed**

### Renal Impairment

<table>
<thead>
<tr>
<th>Severe Impairment</th>
<th>Moderate Impairment</th>
<th>Mild Impairment</th>
<th>Dose Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.375 mg/day</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.5 mg/day</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.75 mg/day</td>
</tr>
</tbody>
</table>

5 Dosing in patients with Renal Impairment

- **Titration Step Duration**
- **Dose to be taken once daily, 2-3 hours before**
- **Afternoon**

6 Dosing for Restless Legs Syndrome

<table>
<thead>
<tr>
<th>Dose</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.25 mg</td>
<td>3 times a day</td>
</tr>
<tr>
<td>0.5 mg</td>
<td>3 times a day</td>
</tr>
<tr>
<td>0.75 mg</td>
<td>3 times a day</td>
</tr>
</tbody>
</table>

## Impediments of Fertility

- **Males**
- **Females**

7 Discontinuation of Treatment

- **If possible, avoid sudden discontinuation or rapid dose reduction in patients**

## Somnolence

### The incidence of somnolence with pramipexole at a dose of 1.5 mg/day was comparable to placebo.

### Incidence of somnolence was 6% compared to an incidence of 3% for placebo treated patients.

### Older than 65 years.

## Other Adverse Reactions

### Injection Site Reactions

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>3.1%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>2.3%</td>
</tr>
<tr>
<td>Somnolence</td>
<td>7.6%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>1.5%</td>
</tr>
<tr>
<td>Asthenia</td>
<td>1.0%</td>
</tr>
</tbody>
</table>

### Nervous System

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>2.3%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>1.0%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>0.7%</td>
</tr>
<tr>
<td>Asthenia</td>
<td>0.4%</td>
</tr>
</tbody>
</table>

### Skin & Appendages

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>0.7%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>0.4%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>0.3%</td>
</tr>
<tr>
<td>Asthenia</td>
<td>0.2%</td>
</tr>
</tbody>
</table>

### Urogenital System

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>0.7%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>0.4%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>0.3%</td>
</tr>
<tr>
<td>Asthenia</td>
<td>0.2%</td>
</tr>
</tbody>
</table>

### Peripheral Edema

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>0.7%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>0.4%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>0.3%</td>
</tr>
<tr>
<td>Asthenia</td>
<td>0.2%</td>
</tr>
</tbody>
</table>

### Respiratory System

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>0.7%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>0.4%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>0.3%</td>
</tr>
<tr>
<td>Asthenia</td>
<td>0.2%</td>
</tr>
</tbody>
</table>

### Cardiovascular System

<table>
<thead>
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<th>Reaction</th>
<th>Percentage</th>
</tr>
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<tbody>
<tr>
<td>Headache</td>
<td>0.7%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>0.4%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>0.3%</td>
</tr>
<tr>
<td>Asthenia</td>
<td>0.2%</td>
</tr>
</tbody>
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## Impulse Control/Compulsive Behaviors

- **Patients with a major psychotic disorder**

- **Pramipexole dihydrochloride tablets**

- **May be used as an alternative therapy for restless legs syndrome (RLS)**

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- **May be used as an alternative therapy for restless legs syndrome (RLS)**

### Augmentation

- **During therapy for RLS**

- **Augmentation refers to the earlier emergence or intensification of RLS symptoms**

- **After longer-term use of pramipexole**

### If pramipexole dihydrochloride tablets pass into your breast milk.

### You and your doctor should decide if you will take pramipexole dihydrochloride tablets or breastfeed.

- **Do not do both**

- **Tell your doctor about all the medicines you take**, including prescription and nonprescription medicines, vitamins, and herbal supplements.

### The combination of pramipexole dihydrochloride tablets and other medicines may affect each other and may cause side effects.

### Pramipexole dihydrochloride tablets may affect the way other medicines work, and other medicines may affect how pramipexole dihydrochloride tablets work.

## Especially tell your doctor if you take:

- **Medicines called monoamine oxidase inhibitors (MAOIs)**

- **Other medicines that affect the pain-killing action of pramipexole**

- **Pramipexole dihydrochloride tablets**

- **May increase the effects of some other medicines**

### Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

## How should I take Pramipexole dihydrochloride tablets?

- **Your doctor will tell you how much pramipexole dihydrochloride tablets to take and when**

- **If you take more than the amount prescribed by your doctor, you may feel very dizzy or you may have a low blood pressure**

### If you do not take pramipexole dihydrochloride tablets as prescribed:

- **Call your doctor if you do not feel better**

### Before taking Pramipexole dihydrochloride tablets:

- **Tell your doctor if you have**

### Before starting any new medicine:

- **Tell your doctor if you have**

### Before driving or using machinery:

- **Tell your doctor if you have**

### Before you get any medical tests:

- **Tell your doctor if you have**

### Side Effects

- **See Warnings and Precautions (5.9)**

### Uncommon, rare, or isolated reports of serious side effects have included:

### Anaphylaxis

- **Deaths have occurred in patients with a history of anaphylaxis**

### Fatigue

- **Deaths have occurred in patients with a history of fatigue**

### Allergic Reactions

- **Deaths have occurred in patients with a history of allergic reactions**

### Pain

- **Deaths have occurred in patients with a history of pain**

### Deaths

- **Deaths have occurred in patients with a history of deaths**

### Skin Reactions

- **Deaths have occurred in patients with a history of skin reactions**

### Stiffness

- **Deaths have occurred in patients with a history of stiffness**

### Unusual Tiredness

- **Deaths have occurred in patients with a history of unusual tiredness**

### Unsteadiness

- **Deaths have occurred in patients with a history of unsteadiness**

### Waking

- **Deaths have occurred in patients with a history of waking**
Pramipexole dihydrochloride tablets may cause you to fall asleep while you are doing daily activities such as driving, talking with other people, or writing.

- Some people taking the medicine in pramipexole dihydrochloride tablets have had accidents because they fell asleep while driving.
- Do not drive, use machinery, or do anything that needs alertness until you are sure you will not fall asleep.
- Avoid driving and using machines that need alertness during bedtime if you take pramipexole while you sleep.
- Talk to your doctor if you feel drowsy.

Do not give pramipexole dihydrochloride tablets to other people, even if they have the same symptoms you have. It is not known if pramipexole dihydrochloride tablets are safe or effective in children.

Talk to your doctor if you have any side effect that bothers you.

What are the ingredients in Pramipexole dihydrochloride tablets?

The chemical name of pramipexole dihydrochloride is -(2-amino-4,5,6,7-tetrahydro-6-oxo-2-pyrimidinyl)ethyl (3-hydroxy-2-carboxy-4-oxo-2,3-dihydro-1H-3-benzazepine-1-carboxylic acid). Pramipexole dihydrochloride tablets, for oral administration, contain 0.125 mg, 0.25 mg, and 0.5 mg pramipexole dihydrochloride per tablet.

The following inactive ingredients are present in pramipexole dihydrochloride tablets:

- Lactose
- Magnesium stearate
- Pharmaceutical D&C Red No. 30 Lake
- Pharmaceutical D&C Yellow No. 10 Lake
- Silica
- Talc

Pramipexole dihydrochloride tablets are white to off white colored circular tablets, debossed as ‘P1’ on one side and plain on the other.

How should I store Pramipexole dihydrochloride tablets?

- Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).
- Keep pramipexole dihydrochloride tablets out of the light.
- Keep pramipexole dihydrochloride tablets and all medications out of the reach of children.

General Information about the safe and effective use of Pramipexole dihydrochloride tablets:

Medications can be harmful if used by anyone other than the patient for whom they are prescribed. A patient information leaflet is not a substitute for medical advice. Do not use pramipexole dihydrochloride tablets for a condition for which it was not prescribed. Do not give pramipexole dihydrochloride tablets to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about pramipexole dihydrochloride tablets. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about pramipexole dihydrochloride tablets that is written for healthcare professionals.

For more information, go to www.stridespharma.com or call Strides Pharma Inc. at 1-877-344-9825 or go to www.stridesshasun.com or FDA at 1-800-FDA-1088 in the U.S.

What are the ingredients in Pramipexole dihydrochloride tablets?

Active Ingredients: Pramipexole dihydrochloride monohydrate

Inactive Ingredients: expander, corn starch, cellulose, silicon dioxide, magnesium stearate, titanium dioxide, and iron oxide.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Manufactured by:
Strides Shasun Limited
Bengaluru - 560076, India.

Distributed by:
Strides Pharma Inc.
East Brunswick, NJ 08816.

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