PACKAGE LEAFLET: Information for the patient

PRONIROL

Film-coated tablets – 0.5 mg or 1 mg

(Ropinirole hydrochloride)

Read this leaflet carefully before you start taking this medicine.

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

In this leaflet:

1. WHAT PRONIROL IS AND WHAT IT IS USED FOR

Pronirol contains the active substance ropinirole hydrochloride which belongs to a group of medicines called dopamine agonists. Dopamine is a natural substance occurring in the brain. Dopamine agonists (such as Pronirol) work in the same way as dopamine found in the body.
Pronirol is used:

- in Parkinson's disease under the following conditions:
  - first-line treatment as monotherapy to delay the need for initiation of levodopa therapy
  - as adjunctive treatment with levodopa during the course of the disease when the effect of levodopa therapy wears off or becomes inconsistent and when fluctuations in the

therapeutic effect occur ("end-of-dose" fluctuations or "on-off" effects).

- Pronirol is also indicated for the symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome.

Pronirol relieves discomfort and reduces the uncontrollable urge to move the limbs that disrupts night time sleep.

2. BEFORE YOU TAKE PRONIROL

Do not take Pronirol:

- if you are allergic (hypersensitive) to Pronirol or to any of the excipients of Pronirol;
- if you suffer from severe liver dysfunction;
- if you suffer from severe kidney dysfunction.

Talk to your doctor if you are not sure.

Take special care with Pronirol

Before you take Pronirol, it is important that you tell your doctor:

- if you are pregnant or think you may be pregnant;
- if you are breast-feeding;
- if your liver is not working properly;
- if you suffer from a severe cardiovascular (heart) complaint;
- if you have a serious mental health problem;
- if you or your family notice that you tend to act unusually and impulsively, or are tempted to commit certain activities that may harm you or others; these are called impulse control disorders and may include behaviours such as addictive gambling, excessive eating or spending, an abnormal increase in sexual desire or sexual thoughts or feelings; your doctor may need to adjust the dose or discontinue treatment;
- if you intend to give up or start smoking because your doctor may need to adjust your dose.

Tell your doctor if you experience symptoms such as depression, apathy, anxiety, fatigue, sweating or pain after stopping or reducing your ropinirole treatment (called dopamine agonist withdrawal syndrome or DAWS). If the problems persist more than a few weeks, your doctor

may need to adjust your treatment.

In these situations, your doctor should carefully monitor your treatment. Due to possible additive effects, please be particularly careful when taking Pronirol at the same time with sedative medications or alcohol.

Restless Legs Syndrome

If during treatment your symptoms become worse, start earlier in the day or after less time at rest, or affect other parts of your body such as your arms, your doctor may adjust the dose of Pronirol that you are taking.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Pronirol can affect the way in which some medicines work and vice versa. Such medicines include:

- ciprofloxacin (an antibiotic);
- enoxacin (an antibiotic);
- fluvoxamine (used to treat depression), antipsychotics (drugs used to treat psychiatric disorders), other medicines that block dopamine in the brain (e.g. sulpiride or metoclopramide);
- hormone replacement therapy (also called HRT);
- any other drug, which blocks dopamine in the brain;
- cimetidine, used in treatment of stomach ulcers;
- any other medicine for Parkinson.

If you are taking Pronirol simultaneously with vitamin K antagonists (used to reduce blood clotting) such as warfarin (coumadin), you should have some additional blood tests.

Taking Pronirol with food and drink

Taking Pronirol with a meal reduces your chances of feeling sick.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before taking any medicine.

Pronirol is not recommended during pregnancy.

Tell your doctor immediately:

- if you are pregnant;
- if you think that you might be pregnant;
- if you are planning to become pregnant. Your doctor will discuss with you what to do next.

Pronirol is not recommended if you are breastfeeding, as milk production may be affected. Tell your doctor immediately:

- if you are breastfeeding or
- if you are planning to start breastfeeding. Your doctor will advise you to discontinue this medicine.

Driving and using machines

This medicine does not usually affect people's normal activities. However, Pronirol can cause hallucinations, dizziness, extreme sleepiness (somnolence) and sudden sleep onset episodes. If you suffer from these effects, you must not drive or put yourself in a situation where sleepiness or falling asleep may put you at risk of serious injury or death (for example using machinery) until these episodes have been resolved.

Important information about some of the excipients of Pronirol

Contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

The film coating used in Pronirol 1 mg tablets contains an azo colouring agent, Allura red AC (E 129), which may cause allergic reactions.

3. HOW TO TAKE PRONIROL

Swallow the Pronirol tablet(s) whole with water, preferably with food. Taking Pronirol with food may decrease the occurrence of nausea (feeling sick), which is a possible side effect of Pronirol. Do not chew the tablets.

Restless Legs Syndrome

Take Pronirol once a day, every day at about the same time. Pronirol is usually taken just before bedtime, but it can be taken up to 3 hours before going to bed. The exact dose of Pronirol people take, can be different. Your doctor will decide on the dose you need to take each day and you should follow the doctor's instructions. When you begin taking Pronirol, the dose you take will be increased gradually.

The starting dose is 0.25 mg once daily. After two days your doctor will probably increase your dose to 0.5 mg once daily for the remainder of your first week of treatment. Then your doctor may increase your dose by 0.5 mg per week over three weeks to a dose of 2 mg per day. In some patients with insufficient improvement, the dose may be increased gradually up to a maximum of 4 mg daily.

After three months of treatment with Pronirol, your doctor may adjust your dose or discontinue your treatment depending on your symptoms and how you feel.

Do not forget to take your medication. Ask your doctor or pharmacist for advice if you have problems in remembering to take your tablets.

Keep taking your tablets, even if at first you do not notice any obvious improvement. It can take a few weeks before any effect of the medicine is felt. If you have the impression that the effect of Pronirol is too strong or too weak, talk to your doctor or pharmacist. Do not exceed the tablet dose recommended by your doctor.

Parkinson's disease

To start with in early Parkinson's disease, Pronirol dosage should be 0.25 mg t.i.d for one week and then increased by 0.25 mg per week up to 3 mg a day, thereafter by 0.5 mg per week. The common therapeutic dose range is 3-24 mg/day. The optimal response is achieved usually within the range of 3 – 9 mg daily; higher doses may be required if used with levodopa. The daily dosage should not exceed 24 mg.

Patients with mild to moderate kidney dysfunction

If you belong to this group, your dose will not need adjusting.

Elderly patients

Any increase in your number of tablets should be gradual and adjusted to your individual response to treatment. Follow your doctor's instructions exactly.

Children and adolescents

Pronirol is not recommended for children and adolescents under 18 years of age.

If you take more Pronirol than you should

Someone who has taken an overdose may experience:

- fainting;
- feeling drowsy;
- feeling/being sick;
- hallucinations, heartburn;
- stomach pain;
- dizziness (or spinning sensation);
- swelling of the legs.

If you take more Pronirol than you should, or if someone else has taken your medicine, tell a doctor or pharmacist immediately. Show them your pack of tablets.

If you forget to take Pronirol

If you find you have forgotten to take your dose of Pronirol, do not take an extra dose to make up for forgotten individual doses.

When you do remember to take Pronirol, take your next dose of Pronirol at the usual time.

Consult your doctor if you have forgotten to take Pronirol for more than several days. He/she will tell you how to start taking your tablets again.

If you stop taking Pronirol

Do not stop taking Pronirol unless your doctor tells you to. If treatment is stopped suddenly, it can cause neuroleptic malignant syndrome which may represent a major health risk. Symptoms include: akinesia (loss of muscle movement), muscle stiffness, fever, unstable blood pressure, tachycardia (increased heart rate), confusion, decreased level of consciousness (e.g. coma).
In case of stopping the treatment, the dose should always be reduced gradually. Your doctor will advise you.
If you feel worse at the end of treatment with Pronirol, please see your doctor.
If you have any further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS OF PRONIROL

Like all medicines, Pronirol can cause side effects, although not everybody gets them.
Tell your doctor if you notice any side effects and they worry you. The more common side effects of Pronirol can happen:

- when patients first start their therapy and/or
- when the dose is increased.

The side effects are generally mild and may become less after you have taken the medicine for a short time. The following frequencies are used in evaluating side effects:

Very common:	more than 1 in 10 patients treated
Common:	less than 1 in 10, but more than 1 in 100 patients treated
Uncommon:	less than 1 in 100, but more than 1 in 1,000 patients treated
Rare:	less than 1 in 1,000, but more than 1 in 10,000 patients treated
Very rare:	less than 1 in 10,000 patients treated, or unknown

Possible side effects:

<u>Very common:</u>

- feeling drowsy;
- fainting (syncope);
- feeling or being sick.

Common:

- experiencing hallucinations (seeing things that aren't really there);
- dizziness (or spinning sensation);
- fatigue (mental or physical tiredness);
- nervousness;
- leg swelling;
- heartburn;
- stomach pain;

Uncommon:

- a drop in blood pressure that may make you feel dizzy or faint especially when standing up from a sitting or lying position;
- excessive daytime somnolence (excessive drowsiness) and very rarely sudden sleep onset episodes where patients fall asleep suddenly without apparently feeling sleepy;
- other psychotic reactions in addition to hallucinations such as delirium, delusion and irrational suspiciousness (paranoia).

Very rare:

- altered liver function (abnormal blood tests).

There are some reports of patients treated with medicinal products of this group of substance (dopamine agonists) who showed pathological compulsive gambling or compulsive and excessive sexual drive. These adverse effects were reversible when doses were reduced or treatment was stopped.

People who are taking Pronirol with levodopa may develop other side effects over time:

- uncontrolled jerky movements are a very common side effect;
- feeling confused is a common side effect.

Tell your doctor immediately if you notice any severe changes in your behaviour or senses of perception. During treatment with Pronirol you may experience unusual worsening of Restless

Legs Syndrome symptoms (e.g. symptoms become worse, start earlier in the day or after less time at rest, or affect other parts of your body such as your arms). If this occurs, you should see your doctor.

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

5. HOW TO STORE PRONIROL

Keep out of the reach and sight of children!
Do not use Pronirol after the expiry date which is stated on the blister and outer carton.
Do not store above 25°C.
In order to protect from moisture store in the original package.

6. OTHER INFORMATION

What Pronirol 0.5 mg film-coated tablets contain

The active substance is ropinirole hydrochloride.
One film-coated tablet contains 0.57 mg ropinirole hydrochloride (corresponding to 0.50 mg ropinirole).
The excipients are:
Tablet core: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate.
Film coating: polyvinyl alcohol, titanium dioxide, macrogol, talc, yellow iron oxide, red iron oxide, black iron oxide.

What Pronirol 1 mg film-coated tablets contain

The active substance is ropinirole hydrochloride.
One film-coated tablet contains 1.14 mg ropinirole hydrochloride (corresponding to 1.0 mg ropinirole).
The excipients are:
Tablet core: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate.

Film coating: polyvinyl alcohol, titanium dioxide, macrogol, talc, indigo carmine, Allura red AC (colouring agent), black iron oxide.

Contents of the pack:

Pronirol 0.5 mg film-coated tablets

Carton box with 30 tablets.

Pronirol 1 mg film-coated tablets

Carton box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

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St. "Skënder Vila",
Tirana, Albania.
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