children and adolescents

Children and adolescents

Ropinirole Film-coated Tablets are not recommended for use in children and adolescents.

taking other medicines and Ropinirole Film-coated Tablets

Tell your doctor if:

- you are taking medicines to treat high blood pressure, or for heart problems
- you give up or start smoking while taking Ropinirole;
- you are taking medicines to treat high blood pressure, or for heart problems.

Tell your doctor if you:

- you are taking medicines to treat high blood pressure, or for heart problems
- you give up or start smoking while taking Ropinirole;
- you are taking medicines to treat high blood pressure, or for heart problems.

Driving and using machines

This medicine does not usually affect people’s normal activities.

Before you drive or use machinery:

You have told your doctor that you have an intolerance to some sugars,

If you are pregnant or breast-feeding, think you may be pregnant or are

Tell your doctor if:

- you are taking Ropinirole Film-coated Tablets and the doctor is going
to prescribe you any other medicine.

After more than three months of treatment with Ropinirole Film-coated Tablets, your doctor may adjust your dose, and the doctor is going to prescribe you any other medicine.

Ropinirole Film-coated Tablets with food, drink and alcohol

Always swallow the tablets whole with water and preferably with food.

Do not chew them.

Taking Ropinirole Film-coated Tablets with food may reduce the likelihood of you feeling or being sick.

The effect of Ropinirole Film-coated Tablets may be increased or decreased by other medicines, and vice versa. These medicines include:

- antipsychotics and other drugs that block dopamine in the brain
- antidepressants and other drugs that block dopamine in the brain
- anti-epileptic drugs
- mood stabilizers
- certain other medicines

Tell your doctor if:

- you are taking medicines to treat high blood pressure, or for heart problems
- you give up or start smoking while taking Ropinirole Film-coated Tablets.

Ropinirole Film-coated Tablets with other medicines

If you are unsure, it is essential to talk to your doctor.

- you have a history of any unusual urges and/or behaviours (such as excessive gambling or excessive sexual behaviour)
- if you have serious liver disease.

Do not:

- take more than your doctor has recommended.
- take more than the label tells you.
- take Ropinirole Film-coated Tablets with any other medicine.

Ropinirole Film-coated Tablets are used to treat the symptoms of moderate to severe idiopathic Restless Legs Syndrome.

Ropinirole Film-coated Tablets may cause some of the symptoms of,
4. Possible side effects

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

The more common side effects of Ropinirole Film-coated Tablets sometimes occur when patients first start their therapy and/or when the dose is increased. These effects are generally mild and may become less after you have taken the medicine for a short time.

Restless Legs Syndrome

The side effects reported in people taking ropinirole for Restless Legs Syndrome are listed below:

-  Strong impulse to gamble excessively despite serious personal or family consequences.
-  Uncontrollable excessive shopping or spending.
-  Urge to have sex which is not needed to satisfy your sexual desire.
-  Excessive daytime drowsiness.
-  Loss of appetite.
-  Nausea, vomiting, calories feeling tired.

Common Side Effects (they occur in between one and ten per 100 patients who receive treatment):

- Confusion, hallucinations, dizziness, (a spinning sensation)
- Stomach ache, fatigue (mental or physical tiredness).”

Uncommon Side Effects (they occur in between one and ten per 100 patients who receive treatment):

- Confusion, hallucinations, (faint blood pressure which may make you feel dizzy or faint especially when standing up from a sitting or lying position)

Very rare: They occur in less than one per one thousand patients who receive treatment.

- Dizziness (mainly due to low blood pressure), extreme sleepiness or sudden sleep onset episodes (suddenly falling asleep without any apparent warning)

Unknown frequency: Cannot be estimated from the data.

(a) Dyskinesia (involuntary, convulsive movements of the limbs or face)

(b) Voice changes (including hoarseness).

(c) Breast enlargement.

(d) Hair loss.

(e) Infection (inflammation)

(f) Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, such as severe laryngeal oedema.

(g) Fainting or sudden loss of consciousness (suddenly falling asleep without any apparent reason).

You may experience the following side effects:

- Inability to resist the urge to drive or to perform an action that could be harmful to you or others, which may include:
  - Strong impulse to gamble excessively despite serious personal or family consequences.
  - More or increased sexual interest and behavior of significant concern to you or to others, for example, an increased sexual drive.
  - An uncontrolled excessive eating or spending.
  - Oldest eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger).

Tell your doctor if you experience any of these behaviors; they will discuss ways of managing or reducing the symptoms.

During treatment with Ropinirole Film-coated Tablets you may experience unusual symptoms of hunger (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.

 Reporting of side effects

If you or any of your family experience any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. You can also report side effects directly via the Medically Scheme at www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ropinirole Film-coated Tablets

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Store in the original package in order to protect from light.

HDPE containers only: keep the container tightly closed in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the carton and blister foil.

The expiry date refers to the last day of that month.

Do not throw any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use.

These measures will help protect the environment.

6. Contents of the pack and other information

What Ropinirole Film-coated Tablets contain

The active substance is ropinirole (as ropinirole hydrochloride).

The other ingredients are:

- Tablet Core
  - Lactose monohydrate
  - Microcrystalline cellulose
  - Hydroxypropyl starch
  - Magnesium stearate
  - Film Coating

- Uncoated films tablets are white, round, biconvex and 7 mm in diameter.

- They are marked R 25 on one side.

- The 0.5 mg film-coated tablets any yellow, round and 7 mm in diameter.

- They are marked R 5 on one side.

- The 2 mg film-coated tablets are green, round and 7 mm in diameter.

- They are marked R 2 on one side.

- The 4 mg film-coated tablets are pink, round and 7 mm in diameter.

- They are marked R 1 on one side.

Pack size

Ropinirole Film-coated tablets are available in blister packs of 12, 28 or 96 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Actavis Group PTC Ltd.

Rheinparkweg 75-79

220 Vålerenga/for

Iceland

Manufacturer:

Actavis Ltd

816 Buckingham Industrial Estate

Zejtun190x380 PIL Malta

This leaflet was last revised in August 2015

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Report the following side effects to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. You can also report side effects directly via the Medically Scheme at www.mhra.gov.uk/yellowcard.

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