

PATIENT INFORMATION LEAFLET

ETKINIA® 1 mg Tablet

It is taken orally.

-Active substance: Each tablet contains 1.56 mg rasagiline mesylate equivalent to 1 mg rasagiline as active substance.

-Excipients: Pregelatinized starch, talc, mannitol (E421), corn starch, colloidal silicon dioxide and stearic acid.

Read this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet safe. You may need to read it again later.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally, do not give it to others.
- During the use of this medicine, when you go to the doctor or hospital, tell your doctor that you are taking this medicine.
- Follow these instructions exactly as written in this leaflet. Do not take **higher or lower doses** of this medicine than the recommended dose.

In this leaflet:

- 1. What is ETKINIA® and what is it used for?**
- 2. Things to consider before taking ETKINIA**
- 3. How to use ETKINIA®?**
- 4. What are the possible side effects?**
- 5. Storage of ETKINIA**

These are the headings.

1. What is ETKINIA® and what is it used for?

ETKINIA® 1 mg tablet contains 1.56 mg rasagiline mesylate equivalent to 1 mg rasagiline.

ETKINIA® 1 mg tablets are available in blister packs of 30 and 100 tablets in a cardboard box for patient use.

ETKINIA® tablets are white, round and flat. ETKINIA® is used in the treatment of Parkinson's disease.

In Parkinson's disease, there is a loss of dopamine-producing cells in the brain. Dopamine is a chemical in the brain that is involved in the control of movement. ETKINIA® helps to increase and maintain dopamine levels in the brain.

1. Things to consider before taking ETKINIA®

Do NOT use ETKINIA® in the following situations:

If you do,

- If you are allergic (hypersensitive) to the active substance rasagiline or any of the ingredients of ETKINIA®
- If you have severe liver problems

Do not take the following medicines while taking ETKINIA®:

- Monoamine oxidase inhibitors (MAOIs) used for the treatment of Parkinson's disease, depression or any other illness (including over-the-counter medicinal and natural products, e.g. St. John's Wort and its extract)
- Pethidine, a powerful painkiller

To start treatment with an MAOI or pethidine, you must be at least three days after stopping ETKINIA® treatment. You should wait 14 days.

Use ETKINIA® with Caution in the following situations:

- If you have any liver problems,
- If you notice changes in your skin that you have not seen before, which may be suspicious, you should talk to your doctor. Treatment with ETKINIA® may increase the risk of skin cancer.

Tell your doctor if you or your family/caregiver notice that you or your family/caregiver are engaging in unusual behaviors where you cannot resist your impulses, strong wishes or desires to act out in ways that may harm or damage yourself or others. These are called impulsive behavior disorders. In patients taking ETKINIA® or other medicines for the treatment of Parkinson's disease, behaviors such as compulsions, obsessive thoughts, addictive gambling, excessive spending of money, impulsive behaviors, and abnormal sex drive or an increase in sexually explicit thoughts or behaviors have been observed. Your doctor may need to adjust your dose or stop your treatment.

ETKINIA® may cause drowsiness, especially if you are also taking other dopaminergic medicines (used to treat Parkinson's disease), and may cause you to fall asleep suddenly during your daily activities. Please refer to the section on driving and using machines for more information.

Children

ETKINIA® is not recommended for use under the age of 18.

If these warnings apply to you, even at any time in the past, please consult your doctor.

Taking ETKINIA® with food and drink

ETKINIA® can be used with meals or alone.

Pregnancy

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

Since the effects of ETKINIA® on pregnancy and the unborn baby are not known, you should not take ETKINIA® if you are pregnant.

If you notice that you are pregnant during treatment, consult your doctor or pharmacist immediately.

Breastfeeding

Consult your doctor or pharmacist before using this medicine.

According to experimental data, ETKINIA® may adversely affect breastfeeding. Therefore, it should not be used during breastfeeding. It is not known whether it is excreted in breast milk.

Driving and using machines

As Parkinson's disease itself and treatment with ETKINIA® may affect your ability to drive and use machines, consult your doctor before doing so. ETKINIA® may cause drowsiness and dizziness and may cause sudden episodes of falling asleep.

This may be increased if you take ETKINIA® together with other medicines to treat the symptoms of your Parkinson's disease or other medicines or alcohol that cause drowsiness in you. Do not drive or operate machinery if you experience drowsiness and/or sudden attacks of falling asleep before or while taking ETKINIA®.

Important information about some excipients contained in ETKINIA®

It does not contain excipients that require warning.

Use with other medicines

Please tell your doctor or pharmacist if you are currently taking or have recently taken any prescribed or non-prescribed medicines.

Do not take the following medicines while taking ETKINIA®:

- Monoamine oxidase inhibitors (MAOIs) used for the treatment of Parkinson's disease, depression or any other illness (including over-the-counter medicinal and natural products, e.g. St. John's Wort and its extract)
- Pethidine, a powerful painkiller

To start treatment with an MAOI or pethidine, you must be at least three days after stopping ETKINIA® treatment.

You should wait 14 days.

Always consult your doctor before taking any of the following medicines together with ETKINIA®.

- Certain medications used to treat depression, known as antidepressants (selective serotonin reuptake inhibitors (SSRIs), selective serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic or tetracyclic antidepressants)
- Ciprofloxacin, an antibiotic used against infections
- Cough suppressant dextromethorphan
- Sympathomimetics such as eye drops, nasal or oral medicines to relieve nasal congestion (nasal and oral decongestants) and cold medicines containing ephedrine or pseudoephedrine.

Concomitant use of ETKINIA® with antidepressants containing fluoxetine or fluvoxamine should be avoided.

You should wait at least five weeks after stopping fluoxetine treatment before starting treatment with ETKINIA®.

To start treatment with fluoxetine or fluvoxamine, you must wait at least 14 days after stopping ETKINIA®.

If you smoke or intend to stop smoking, please tell your doctor or pharmacist. Smoking may reduce the amount of ETKINIA® in the blood.

3.How to use ETKINIA®?

- Instructions for appropriate use and dose/frequency of administration:

Always take ETKINIA® as directed by your doctor. If you are not sure, you should check with your doctor or pharmacist.

ETKINIA® is taken one tablet (1 mg) once daily.

- Route and method of administration:

It is taken by mouth. It can be taken with food or alone. Take the tablets with enough liquid (for example, a glass of water).

- Different age groups:

Use in children:

The use of ETKINIA® in children and adolescents is not recommended.

Use in the elderly:

No dose adjustment is required in elderly patients.

- Special conditions of use:

Renal impairment:

No dose adjustment is required in patients with renal impairment.

Hepatic impairment:

ETKINIA® should be used with caution in patients with mild hepatic impairment. Use should be discontinued in patients who progress from mild hepatic impairment to moderate hepatic impairment. It should never be used in patients with severe hepatic impairment.

If you have the impression that the effect of ETKINIA® is too strong or too weak, talk to your doctor or pharmacist.

If you have used more ETKINIA® than you should:

If you have taken more ETKINIA® than you should, talk to a doctor or pharmacist.

Take the box of ETKINIA® with you to show your doctor or pharmacist.

Symptoms of mild euphoria (feeling overly happy), severe high blood pressure and serotonin syndrome (symptoms such as confusion, restlessness, increased body temperature, sweating, loss of muscle coordination, muscle twitching) have been reported if you take more ETKINIA® than you should.

If you forget to take ETKINIA

Do not take a double dose to make up for forgotten doses.

Take the next dose when it is due.

If you stop taking ETKINIA

Do not stop taking ETKINIA® without talking to your doctor first. Ask your doctor or pharmacist if you have any further questions about the use of this medicine.

4. What are the possible side effects?

Like all medicines, side effects may occur in people who are sensitive to the ingredients in ETKINIA®, although not in everyone.

If any of the following happens, stop taking ETKINIA® and tell your doctor IMMEDIATELY or contact your nearest hospital emergency department:

- Allergic reaction (rash, itching, swelling in the mouth, face, throat, swelling of the mouth, face, throat, difficulty breathing) (common)
- If you develop unusual behaviors such as compulsive cravings, obsessive thoughts, addictive gambling, excessive shopping and spending, impulsive behaviors, and abnormal sex drive or sexual thoughts (impulse control disorder) (unknown)
- You see or hear things that are not real (hallucinations) (common)
- Any combination of hallucinations, increased body temperature, restlessness, tremors and sweating (serotonin syndrome) (unknown)
- If you notice any suspicious skin changes because they increase the risk of skin cancer (melanoma) (common)

These are all very serious side effects.

If you have any of these, you may need urgent medical attention or hospitalization.

The following side effects were reported in placebo-controlled clinical trials: Side effects are described as shown in the categories below:

Very common: Occurred in at least 1 in 10 patients.

Common: Less than 1 in 10 patients, but more than 1 in 100 patients.

Uncommon: Less than one in 100 patients, but more than one in 1,000 patients.

Rare: Less than one in 1,000 but more than one in 10,000 patients.

Very rare: Less than one in 10,000 patients.
Unknown: (cannot be estimated based on available data)

Very common

- Abnormal movements (dyskinesia)
- Headache

Common

- Abdominal pain
- Falling
- Allergic reaction
- Fire
- Influenza (influenza)
- Feeling generally unwell (malaise)
- Neck pain
- Chest pain (angina pectoris)
- Low blood pressure on standing up (orthostatic hypotension) with lightheadedness and dizziness
- Decreased appetite
- Constipation
- Dry mouth
- Nausea and vomiting
- Gas
- Abnormal blood test results (leukopenia)
- Joint pain (arthralgia)
- Back pain
- Musculoskeletal pain
- Inflammation in the joints (arthritis)
- Numbness and muscle weakness in the hand (carpal tunnel syndrome)
- Weight loss
- Abnormal dreams
- Obsessive thoughts
- Difficulty in muscle coordination (balance disorder)
- Depression
- Headache
- Dizziness (vertigo)
- Insomnia/inability to sleep
- Prolonged muscle contraction (dystonia)
- Rhinitis (cold)
- Skin irritation (dermatitis)
- Rash
- Blood in the eyes (conjunctivitis)
- Sudden urinary urgency

Uncommon

- Stroke (cerebrovascular accident)
- Heart attack (myocardial infarction)
- Skin rash (vesiculobullous rash)

Unknown

- High blood pressure
- Excessive sleepiness

- Sudden onset of sleep
- Impulsive behavior

If you experience any side effects not listed in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

Talk to your doctor, pharmacist or nurse if you experience any side effects listed or not listed in this leaflet. Also reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

5. Storage of ETKINIA®

Keep ETKINIA® out of the sight and reach of children and in its original packaging.

Store in the original package at room temperature below 25°C.

Do not throw away expired or unused medicines! Give it to the collection system designated by the Ministry of Environment and Urbanization.

Use in accordance with the expiration date.

Do not use ETKINIA® after the expiry date on the package.

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