Package leaflet: Information for the user

Edronax® 4 mg tablets

reboxetine

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

- 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Edronax is and what it is used for
2. What you need to know before you take Edronax
3. How to take Edronax
4. Possible side effects
5. How to store Edronax
6. Contents of the pack and other information

1. What Edronax is and what it is used for

The active substance in Edronax is reboxetine which is part of a group of medicines called antidepressants. Edronax is used in acute treatment of depressive illness / major depression as well as for maintaining the improvement of your symptoms when you have initially responded to treatment with reboxetine.

2. What you need to know before you take Edronax

Do not take Edronax

- if you are allergic to reboxetine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Edronax, if you:

- suffer from convulsions or epilepsy. Treatment with reboxetine should be stopped if seizures occur.
- have any signs of urinary problems, enlarged prostate or a history of heart problems.
- are taking medicines to lower your blood pressure.
- have liver or kidney problems. Your doctor may need to adjust your dosage.
- are taking a medicine called a 'monoamine oxidase inhibitor' (MAOI) used for depression, or have taken an MAOI in the last 2 weeks. Your doctor may need to stop the MAOI at least 2 weeks before starting Edronax.
- ever had episodes of mania (overactive behaviour or thoughts).
- have eye problems, such as certain kinds of glaucoma (increased pressure in the eye).

<u>Serotonin syndrome</u>

Serotonin syndrome is a potentially life-threatening condition which may occur when taking Edronax alone, or in combination with other medicines (see section 2 "Other medicines and Edronax"). Signs and symptoms of serotonin syndrome may include a combination of the following: confusion, restlessness, hallucinations, coma, fast heart beat, increased body temperature, fast changes in blood pressure, sweating, flushing, tremor,

overactive reflexes, nausea, vomiting, and diarrhoea. **Contact a doctor or go to your nearest emergency department immediately if you think serotonin syndrome is happening to you.**

Thoughts of suicide and worsening of your depression
If you are depressed you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.
You may be more likely to think like this:
- if you have previously had thoughts about killing or harming yourself.
- if you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.
If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**
You may find it helpful to tell a relative or close friend that you are depressed, and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

Children and adolescents

Edronax should not usually be used in children and adolescents less than 18 years old. Patients under 18 have an increased risk of undesirable effects, such as suicide attempt, suicidal thoughts and hostility (mainly aggressiveness, oppositional behaviour and anger) when they are treated with this class of medicines. Nevertheless, it is possible that your doctor decides to prescribe Edronax to a patient under 18 if it is in the patient's interest. If your doctor has prescribed Edronax to a patient less than 18 years old and you want to discuss this, please contact him/her.

Furthermore, if any of the symptoms listed above appear or worsen when a patient under 18 is taking Edronax, you should inform your doctor.

Also, the long-term safety of Edronax in regard to growth, maturation and cognitive and behavioural development in this age group has not yet been demonstrated.

Other medicines and Edronax

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Edronax may affect or be affected by other medicines. These include:

- Certain antifungals, e.g. ketoconazole
- Certain antibiotics, e.g. erythromycin, rifampicin
- Medicines called ergot derivatives used to treat migraine or Parkinson's disease
- Any potassium-losing diuretics (medicines for eliminating water), e.g. thiazides
- Medicines used to treat epilepsy e.g. phenobarbital, carbamazepine and phenytoin
- Herbal medicines containing St. John's Wort *(Hypericum perforatum)*
- Medicines that taken together with Edronax could increase the risk of developing serotonin syndrome (see section 2 "Warnings and precautions"):
    - Certain antidepressants called MAO inhibitors, tricyclics, tetracyclics, nefazodone, SSRIs (such as fluvoxamine), other serotonin-norepinephrine reuptake inhibitors [SNRIs], or lithium
    - Medicines called triptans used to treat migraine
    - Other MAO inhibitors such as linezolid (an antibiotic) and methylene blue (used to treat high levels of methaemoglobin in the blood)
    - Medicines containing opioids (such as buprenorphine) used to treat severe pain and/or opioid addiction
    - Medicines to treat anxiety such as buspirone
    - Products containing tryptophan (used for problems such as sleep or depression)

Your doctor will tell you whether you can take Edronax with 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, herbal medicines, as well as vitamins and minerals.

Edronax with food and drink
Edronax can be taken with or without food.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

There are no adequate experiences from the use of Edronax in pregnant women. Do not take Edronax if you are pregnant, unless your doctor considers it absolutely necessary, following a careful clinical risk/benefit consideration. Tell your doctor immediately if you are pregnant or are planning to become pregnant.

Breast-feeding

Edronax passes into the breast milk in small amounts. There is a risk of a potential effect on the baby. Therefore, you should discuss the matter with your doctor and he/she will decide whether you should stop breast-feeding or stop the therapy with Edronax.

Driving and using machines
Caution is recommended when driving or using machines.
You should not drive or operate machinery until you know you are not affected (i.e. feel drowsy) by Edronax, and that it is safe to do so.

3. How to take Edronax

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose in adults is 8 mg a day (one 4 mg tablet twice a day). Based on how you respond to the medicine, after 3 to 4 weeks your doctor may tell you to take up to 10 mg per day if necessary. The maximum daily dose should not exceed 12 mg.

- In patients with poor kidney or liver function, the starting dose is 4 mg per day. This may be increased depending on the individual response.

- The use of Edronax 4 mg tablets cannot be recommended for elderly patients.

- Edronax should not be used in children and adolescents under 18 years.

The tablets should be taken in two divided doses, one dose in the morning and one in the evening. You should swallow your tablet with a glass of water. The tablet can be divided into equal doses. Do not chew the tablet.

To help you remember to take Edronax, you may find it easier to take your tablets at the same time every day.

Like other drugs Edronax will not relieve your symptoms immediately. You should start to feel better within a few weeks.

It is important that you continue to take your tablets, even though you feel better, until your doctor advises you to stop. Please be patient, if you stop taking your tablets too early, your symptoms might come back.

If you take more Edronax than you should

You should never take more tablets than your doctor recommends. If you take too many tablets, contact your doctor or local hospital immediately. If you take more Edronax than you should, you may experience symptoms of overdose including low blood pressure, anxiety and hypertension.

If you forget to take Edronax

If you forget to take Edronax, take your next dose at the normal time. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Edronax
You should not stop your medicine without talking to your doctor, as your symptoms may come back.

There have been a few reports of withdrawal symptoms including headache, dizziness, nervousness and nausea (feeling sick), when patients stopped treatment with Edronax.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. With Edronax most side effects are mild and usually go away after the first few weeks of treatment.

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

Very common: may affect more than 1 in 10 people
- Difficulties to sleep (insomnia)
- Dizziness
- Dry mouth
- Constipation
- Nausea (feeling sick)
- Sweating

Common: may affect up to 1 in 10 people
- Headache
- Lack or loss of appetite
- Agitation, anxiety
- Paraesthesia (pins and needles), inability to sit or stand still, altered taste sensation
- Lack of visual focus
- Increased heart rate, palpitation (heart pounding)
- Widened blood vessels, fall in blood pressure when standing up, increased blood pressure
- Vomiting
- Rash
- Sensation of incomplete emptying or slowed emptying of the bladder, urinary infection, painful urination, inability to completely empty the bladder
- Erectile dysfunction (impotence), ejaculatory pain or ejaculatory delay
- Chills

Uncommon: may affect up to 1 in 100 people
- Dilated pupils

- Spinning sensation

Rare: may affect up to 1 in 1,000 people
- Glaucoma (a condition resulting in increased pressure in the eye)

Not known: frequency cannot be estimated from the available data
- Serotonin syndrome (see section 2 "Warnings and precautions")
- Hyponatremia (very low levels of sodium in the blood)
- Aggressive behaviour, hallucination
- Suicidal ideation, Suicidal behaviour
  Cases of suicidal ideation and suicidal behaviours have been reported during reboxetine therapy or early after treatment discontinuation (see section 2 "Warnings and precautions")
- Cold extremities, Raynaud's phenomenon (poor blood circulation to the extremities usually in the toes and fingers but could also affect nose and ears, the skin turns pale and becomes cold and numb)
- Allergic skin inflammation
- Testicular pain
- Irritability
- Increased pressure in the eye

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Edronax

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

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store Edronax above 25°C.
Bottle: Keep the container tightly closed in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Edronax contains

The active substance is reboxetine. Each tablet contains 4 mg of reboxetine.

The other ingredients are cellulose microcrystalline, calcium hydrogen phosphate dihydrate, crospovidone, silica colloidal hydrated and magnesium stearate.

What Edronax looks like and contents of the pack

Edronax are white, round, convex tablets with a breakline. A 'P' is marked on the left side of the breakline and a 'U' is marked on the right side. The side opposite the breakline is marked "7671". The tablet can be divided into equal doses.

Edronax is available in 10, 20, 50, 60, 100, 120, and 180 tablets in blisters packs, and multipacks of 3x60, 5x60 and 10x60 tablets in blisters, or 20 and 60 tablets in high-density polyethylene (HDPE) bottle with a cylinder containing silica gel desiccant, closed with a polypropylene child-resistant, squeeze-and-turn closure cap. Each bottle contains a silica gel desiccant that must be kept in the bottle to help protect your tablets. The silica gel desiccant is contained in a separate cylinder and should not be swallowed.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK.

Manufacturer:
Pfizer Italia S.r.l. – 63100
Localita Marino Del Tronto
Ascoli Piceno,
Italy

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria, Belgium, Denmark, Ireland, Italy, Luxembourg, Portugal, Sweden and United Kingdom (Northern Ireland): Edronax
Spain: Norebox

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