Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Edronax®
Tablets

Each tablet contains: reboxetine (as methanesulphonate) 4 mg

Inactive ingredients and allergens in the medicine: See section 6 'Further information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

What do I have to know about the medicine?

Antidepressants and anti-anxiety medicines increase the risk of suicidal behaviour and thoughts in children, adolescents and young adults aged up to 25 years.
When starting treatment with the medicine, patients of all ages and their relatives should monitor behavioural changes such as worsening of depression, suicidal thoughts, aggression etc.
If such changes occur, contact the doctor immediately (see section 2).

1. WHAT IS THIS MEDICINE INTENDED FOR?

The medicine is intended for treatment of depression.

Therapeutic group:
The active ingredient belongs to the group of selective norepinephrine reuptake inhibitors (NRI) used for treatment of depression.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).

Special warnings regarding use of the medicine
Before treatment with Edronax, tell your doctor if:

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

Serotonin syndrome

Serotonin syndrome is a potentially life-threatening condition which may occur when taking Edronax alone, or in combination with other medicines (see section 2 'Drug interactions'). Signs and symptoms of serotonin syndrome may include a combination of the following: confusion, restlessness, hallucinations, coma, fast heartbeat, 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 that you experience serotonin syndrome.**

Thoughts of suicide and worsening of depression:
If you are depressed, you can sometimes have thoughts of harming or killing yourself. These thoughts 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 experience such thoughts:
- 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
This medicine is not intended for children and adolescents under the age of 18 years. Patients under the age of 18 years have an increased risk of side effects, such as suicide attempts, suicidal thoughts and hostility (mainly aggressiveness, aggressive behaviour and anger) when they are treated with this class of medicines. Nevertheless, the doctor may decide to prescribe the medicine to a patient under the age of 18 years if it is in the patient's interest. If the doctor has prescribed Edronax to a patient under the age of 18 years and you want to discuss this - please contact your doctor again for consultation. Furthermore, if any of the symptoms listed above appear or worsen when a patient under the age of 18 years is taking Edronax, you should inform the 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.

Drug interactions
If you are taking, or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.
Edronax may affect or be affected by other medicines. These include:
- Certain antifungals, e.g. ketoconazole
- Certain antibiotics, e.g. erythromycin, rifampicin
- Medicines which are ergot derivatives used to treat migraine or Parkinson’s disease
- Any potassium-losing diuretics (medicines causing fluid loss), e.g. thiazides
- Medicines used to treat epilepsy e.g. phenobarbital, carbamazepine and phenytoin
- Herbal medicines containing Hypericum perforatum (St. John's wort)
- Medicines that taken together with Edronax could increase the risk of developing serotonin syndrome (see section 2 'Special warnings regarding use of the medicine'):
    - Certain antidepressants called MAO inhibitors (MAOI), 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 (MAOI) 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.

Using this medicine and food
The medicine can be taken with or without food.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or plan to become pregnant, consult your doctor before taking this medicine.
Pregnancy
There is no sufficient information about the use of Edronax in pregnant women. Do not take Edronax if you are pregnant, unless your doctor considers it necessary following a risk/benefit consideration. Tell your doctor immediately if you are pregnant or plan to become pregnant.
Breastfeeding
Edronax passes into the breast milk in small amounts. There may be a risk of a potential effect on the baby. Therefore, you should consult your doctor and he/she will decide whether you should stop breastfeeding or stop the therapy with Edronax.

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

3. HOW TO USE THIS MEDICINE?
Always use this medicine according to your doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.
The dosage and treatment regimen will be determined by your doctor only.

- The recommended dosage in adults is 8 mg (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 dosage should not exceed 12 mg.
- In patients with poor kidney or liver function, the starting dosage is 4 mg per day. The dosage may be increased depending on the individual response.
- The use of Edronax tablets cannot be recommended for elderly patients.

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

To help you remember to take Edronax, you may find it easier to take the tablets at the same time every day.
Do not exceed the recommended dose.
Adhere to the treatment as recommended by your doctor.

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 the tablets, even though you feel better, until your doctor advises you to stop. Please be patient, if you stop taking the tablets too early, your symptoms might come back.

If you have taken a higher dosage of Edronax or if a child has accidentally swallowed some medicine

Do not take more tablets than your doctor recommends. If you have taken too many tablets, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. 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 usual time. Do not take a double dose to make up for the forgotten tablet.

If you stop taking Edronax

Do not stop taking the medicine without consulting your doctor, as your symptoms may come back.

There have been a few reports of withdrawal symptoms including headaches, dizziness, nervousness and nausea when patients stopped treatment with Edronax.

Do not take medicines in the dark! Check the label and dose <u>each time</u> you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Edronax may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them. With Edronax, most side effects are mild and usually resolve after the first few weeks of treatment.

Very common side effects (affect more than 1 in 10 users):

- Insomnia
- Dizziness
- Dry mouth
- Constipation
- Nausea
- Sweating

Common side effects (affect 1-10 in 100 users):

- Headaches
- Lack or loss of appetite
- Agitation, anxiety
- Paraesthesia, inability to stand still, impaired taste sensation
- Impaired visual focus
- Increased heart rate, palpitations
- Widened blood vessels, fall in blood pressure when standing up, increased blood pressure
- Vomiting
- Rash
- Sensation of incomplete emptying or slowed emptying of the urinary bladder, urinary tract infection, painful urination, inability to completely empty the urinary bladder
- Impotence, ejaculatory pain or ejaculatory delay
- Chills

Uncommon side effects (affect 1-10 in 1000 users):

- Dilated pupils
- Spinning sensation

Rare side effects (affect 1-10 in 10,000 users):
- Glaucoma (increased pressure in the eye)

Side effects of unknown frequency (the frequency of these effects has not yet been established):
- Serotonin syndrome (see section 2 'Special warnings regarding use of the medicine')
- Hyponatremia (very low levels of sodium in the blood)
- Aggressive behaviour, hallucinations
- Suicidal ideation, suicidal behaviour
  Cases of suicidal ideation and suicidal behaviours have been reported during Edronax therapy or early after treatment discontinuation (see section 2 'Special warnings regarding use of the medicine')
- 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

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?
- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store the medicine at a temperature below 25˚C

6. FURTHER INFORMATION
In addition to the active ingredient, this medicine also contains:
cellulose microcrystalline, dibasic calcium phosphate dihydrate, crospovidone, silicon dioxide, magnesium stearate.

What the medicine looks like and contents of the pack:
A white round tablet, with a score line on one side, with 'P' imprinted on its left side and 'U' imprinted on its right side, and with '7671' imprinted on the other side of the tablet.
The packs contain 20 or 60 tablets.

Not all pack sizes may be marketed.

Registration holder and address: Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Registration number of the medicine in the Ministry of Health National Drug Registry:
113-94-29592-00

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