**If any of the following side effects occurs during your treatment, contact your doctor:**
Uncommon:
• Unusual bleeds, including gastrointestinal bleeds
Rare:
• If swelling of skin, tongue, lips, or face, or have difficulties breathing or swallowing (allergic reaction), inform your doctor or go to a hospital right away.
• If high fever, agitation, confusion, trembling and abrupt contractions of muscles emerge, these may be signs of a rare condition called serotonin syndrome. If you feel so, inform your doctor.

**If you experience any of the following symptoms you should contact your doctor or go to the hospital IMMEDIATELY:**
• Difficulties urinating
• Seizures (fits) (see also "USE ESIPRAM with caution in following conditions")
• Yellowing of the skin and the white in the eyes are signs of liver function impairment/hepatitis.
• Fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as Torsade de Pointes.

**In addition to the above the following side effects have been reported:**
Very common:
• Nausea
• Headache
Common:
• Blocked or runny nose (sinusitis)
• Decreased or increased appetite
• Anxiety, restlessness, abnormal dreams, difficulties falling asleep, feeling sleepy, dizziness, yawning, tremors, prickling of the skin
• Diarrhoea, constipation, vomiting, dry mouth
• Increased sweating
• Pain in muscle and joints (arthralgia and myalgia)
• Sexual disturbances (delayed ejaculation, problems with erection, decreased sexual drive and orgasm disorders in women)
• Fatigue, fever
• Increased weight
Uncommon:
Nettle rash (urticaria), rash, itching (pruritus)
• Grinding one's teeth, agitation, nervousness, panic attack, light-headedness, state of confusion
• Disturbed sleep, taste disturbance, fainting (syncope)
• Enlarged pupils (mydriasis), visual disturbance, ringing in the ears (tinnitus)
• Loss of hair
• Excessive menstrual bleeding
• Irregularity in menstrual period
• Decreased weight
• Fast heart beat
• Swelling of the arms or legs
• Nose bleeds
• Abnormal bleedings including gastro-intestinal bleedings
Rare:
• Aggression, depersonalisation (a different mood in which person alienates to his/her body completely or partially), hallucination
• Slow heart beat
Effects reported by some patients (frequency cannot be estimated from the available data):
• Thoughts of harming or killing yourself (see also "USE ESIPRAM with caution in following conditions")
• Decreased levels of sodium in the blood (the symptoms are feeling: sick and unwell with weak muscles; or confused)
• Dizziness when you stand up due to low blood pressure (orthostatic hypotension)
• Abnormal liver function test (increased amounts of liver enzymes in the blood)
• Movement disorders (involuntary movements of the muscles)
• Painful erections (priapism)
• Bleeding disorders including skin and mucous membrane bleedings (ecchymosis) and low
level of platelets in blood (thrombocytopenia)
• Sudden swelling of skin or mucosa (angioedemas)
• Increase in the amount of urine excreted (inappropriate ADH secretion)
• Flow of milk in women who are not nursing and in men
• Mania (seizure of abundance)
• An increased risk of bone fractures has been observed in patients taking this type of medicine
• Alteration of the heart rhythm (called "prolongation of QT interval", seen on ECG, measuring electrical activity of the heart).

In addition, a number of side effects are known to occur with drugs that work in a similar way to Escitalopram (the active ingredient of ESIPRAM ). These are:
• Motor restlessness (akathisia (not being able to stand still))
• Loss of appetite

Reporting of side effects
Talk with your doctor, pharmacist or nurse if you experience any side effect that is included or not included in this patient information leaflet. Also, report the side effects you have encountered, to Turkish Pharmacovigilance Center (TUFAM) via clicking "Drug Side Effect Report" icon on www.titck.gov.tr or via calling the side effect report line on 0800 314 00 08. By reporting experienced side effects, you will be contributing in obtaining more information regarding the safety of your drug.
*If you experience a side effect which is not mentioned in this patient information leaflet, inform your physician or pharmacist.*

**5. How to store ESIPRAM**
*Keep ESIPRAM out of reach and sight of children and in its packaging.*
Keep at room temperature below 25°C.
**Use in line with its expiry date.**
Do not use ESIPRAM after the expiry date on the package.
Do not use ESIPRAM if you notice any failure / defect in the product and / or packaging.
Do not throw away drugs that have expired or are not being used! Give them to the collection system determined by the Ministry of Environment and Urbanism.

*This patient information leaflet is approved on 20/05/2015.*



**PATIENT INFORMATION LEAFLET**

**ESIPRAM 20 mg film coated tablet**
**For oral use.**

• ***Active substance:*** 20 mg Escitalopram (as Oxalate)
• ***Excipients:*** Microcrystalline cellulose (E460), crospovidone, croscarmellose sodium, colloidal silicon dioxide, sodium lauryl sulphate, povidone, magnesium stearate (E572), polyvinyl alcohol, polyethylene glycol (E1521), titanium dioxide (E171), talc (E553b).

**Read all of this LEAFLET carefully before you start using 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, please ask your doctor or pharmacist.*
• *This medicine has been prescribed for you personally and you should not pass it on to others.*
• *If you visit a doctor or a hospital during the usage of this drug, tell your doctor that you use this drug.*
• *Follow these instructions fully. Do not use a dose **higher** or **lower** than the dose recommended to you for the drug.*

**In this leaflet:**


**1. What ESIPRAM is and what it is used for**
• Each ESIPRAM 20 mg film coated tablet contains 20 mg Escitalopram. Tablets are white, oval, biconvex, scored on one side and film coated.
• ESIPRAM is marketed in packages of 28 tablets.
• ESIPRAM contains Escitalopram. This medicine is used to treat depression (major depressive episodes) and anxiety disorders (such as panic disorder with or without agoraphobia (phobia of open places)), social anxiety disorder, generalised anxiety disorder, and obsessive-compulsive disorder.
• Escitalopram belongs to a group of antidepressants called selective serotonin reuptake inhibitors (SSRIs). These medicines act on the serotonin-system in the brain by increasing the serotonin level. Disturbances in the serotonin-system are considered an important factor in the development of depression and related diseases.
It may take couple of weeks for you to feel better. Keep using ESIPRAM even it takes time to see healing in your condition.
If you do not feel better or you feel worse, you should talk this with a doctor.

**2. What you need to know before you use ESIPRAM**
**Do not use ESIPRAM in the following conditions**
• If you are allergic to Escitalopram or any of the other ingredients of ESIPRAM (see "Excipients").
• If you take other medicines which belong to a group called MAO (monoamine oxidase) inhibitors, including selegiline (used in the treatment of Parkinson's disease), moclobemide (used in the treatment of depression) and linezolid (an antibiotic).
• If you use pimozide (antipsychotic).
• If you are born with or have had an episode of abnormal heart rhythm (seen at ECG; an examination to evaluate how the heart is functioning).
• If you are taking medicines for heart rhythm problems or that may affect the heart's rhythm (Class IA and III antiarrhythmics, antipsychotics (e.g. phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarial medicines particularly halofantrine), certain antihistamines (e.g. astemizole, mizolastine) is contraindicated (tricyclic antidepressants (see "Taking with other medicines").

**Use ESIPRAM with caution in following conditions**
Talk to your doctor or pharmacist before taking ESIPRAM . Please tell your doctor if you have any other condition or illness, as your doctor may need to take this into consideration.
In particular, tell your doctor:
• If you have epilepsy. Treatment with ESIPRAM should be stopped if seizures occur for the first time, or if there is an increase in the seizure frequency (see "Possible side effects").
• If you suffer from impaired liver or kidney function. Your doctor may need to adjust your dosage.
• If you have diabetes. Treatment with ESIPRAM may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted.
• If you have a decreased level of sodium in the blood.
• If you have a tendency to easily develop hemorrhage or bruises.
• If you are receiving electroconvulsive treatment.
• If you have coronary heart disease.
• If you suffer or have suffered from heart problems or have recently had a heart attack.
• If you have a low resting heart-rate and/or you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets).
• If you experience a fast or irregular heart beat, fainting, collapse or dizziness on standing up, which may indicate abnormal functioning of the heart rate.
• If there is a problem in your pupil such as widening (midriasis).
• Caution is recommended to be exercised in patients with high risk of developing Torsades de Pointes (a kind of cardiac arrhythmia), for example in patients with congestive heart failure, in patients with recent cardiac attack, in patient with slow heart rate, or in patients prone to hypokalemia (low level of potassium in blood) or to hypomagnesemia (low level of magnesium in blood) due to concomitant disease or drug usage.
**Please note**
Some patients with manic depressive illness may enter into a manic phase. This is characterized by unusual and rapidly changing ideas, inappropriate happiness and excessive physical activity. If you experience this, contact your doctor.
Symptoms such as restlessness or difficulty in sitting or standing still can also occur during the first weeks of the treatment. Tell your doctor immediately if you experience these symptoms.
Thoughts of suicide and worsening of your depression or anxiety disorder:
If you are depressed and/or have anxiety disorders 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.**

Antidepressant use, especially in children and adolescents aged up to 24 years, have potential to increase their suicidal ideation or behaviours. For this reason, you should closely be monitored by your family and

2202151-A

health care professionals especially at the beginning and for the first few months of treatment and during dosage increase/reduction or discontinuation period as you may display unexpected behavioural changes like irritability, hyperactivity or suicide probability may occur.

Children and adolescents
ESIPRAM should normally not be used for children and adolescents under 18 years. Also, you should know that patients under 18 have an increased risk of side effects such as suicide attempts, suicidal thoughts and hostility (predominately aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe ESIPRAM for patients under 18 because he/she decides that this is in their best interest. If your doctor has prescribed ESIPRAM for a patient under 18 and you want to discuss this, please consult to your doctor.
You should inform your doctor if any symptoms listed above develop or worsen when patients under 18 are taking ESIPRAM . Also, the long term safety effects concerning growth, maturation and cognitive and behavioural development of ESIPRAM in this age group is not yet definite.
Please consult your doctor if these warnings are valid for you, even for a period in the past.

**Use of ESIPRAM with food, beverages and alcohol**
ESIPRAM can be taken with or without food (see "How to use ESIPRAM ").
As with many medicines, combining ESIPRAM with alcohol is not advisable, although ESIPRAM is not expected to interact with alcohol.

**Pregnancy**
*Consult your doctor or pharmacist before using this medicine.*
Inform your doctor if you are pregnant or planning to become pregnant. Do not take ESIPRAM if you are pregnant, unless you and your doctor have discussed the risks and benefits.
If you take ESIPRAM during the last 3 months of your pregnancy you should be aware that the following effects may be seen in your newborn baby: trouble with breathing, bluish skin, fits, body temperature changes, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, excessive reflexes, tremor, jitteriness, irritability, lethargy, constant crying, sleepiness and sleeping difficulties. If your newborn baby has any of these symptoms, please contact your doctor immediately.
Make sure your doctor know you are using ESIPRAM . When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like ESIPRAM may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.
If used during pregnancy ESIPRAM should never be stopped abruptly.
*If you notice that you are pregnant in the course of treatment, consult your doctor or pharmacist immediately.*

**Breast Feeding**
*Consult your doctor or pharmacist before using this medicine.*
ESIPRAM is expected to pass into breast milk. Do not take ESIPRAM if you are breast-feeding, unless you and your doctor have discussed the risks and benefits involved and your doctor has found it appropriate for use.

**Fertility**
Animal data have shown that citalopram, which is like escitalopram, may affect sperm quality. Theoretically, this may effect the fertility but its impact on human fertility has not been observed yet.

**Driving and using machines**
You are advised not to drive a car or operate machinery until you know how ESIPRAM affects you.

**Important information about some of the excipients of ESIPRAM**
It does not contain any excipient that requires warning.

**Using with other medicines**
Tell your doctor or pharmacist if you are using or have recently used or have the possibility to use any other medicine.

Inform your doctor if you use any of the drugs below:
• "Non-selective monoamine oxidase inhibitors (MAOIs)", containing phenelzine, iproniazid, isocarboxazid, nialamide, and tranylcypromine. If you have taken any of these medicines you will need to wait 14 days before you start taking ESIPRAM . After stopping ESIPRAM you must allow 7 days before taking any of these medicines.
• "Reversible, selective MAO-A inhibitors", containing moclobemide (used to treat depression) increase the risk of side effects.
• "Irreversible MAO-B inhibitors", containing selegiline (used to treat Parkinson's disease). These increase the risk of side effects.
• The antibiotic linezolid.
• Lithium (used in the treatment of manic-depressive disorder) ve tryptophan (it is an amino acid and is used as nutritional support).
• Imipramine and desipramine (both used to treat depression).
• Sumatriptan and similar medicines (used to treat migraine) and tramadol (used against severe pain). These increase the risk of side effects.
• Cimetidine, lansoprazole and omeprazole (used to treat stomach ulcers), fluvoxamine (antidepressant) and ticlopidine (used to reduce the risk of stroke). These may cause increased blood levels of escitalopram.
• St. John's wort (*hypericum perforatum*) - a herbal remedy used for depression
• Acetylsalicylic acid (aspirin) and non-steroidal anti-inflammatory drugs (medicines used for pain relief or to thin the blood, so called antiaggregant). These may increase bleeding-tendency
• Warfarin, dipyridamole, and phenprocoumon (medicines used to thin the blood, so called anti-coagulant). Your doctor will probably check the coagulation time of your blood when starting and discontinuing ESIPRAM in order to verify that your dose of anti-coagulant is still adequate.
• Mefloquine (used to treat Malaria), bupropion (used to treat depression) and tramadol (used to treat severe pain) due to a risk of a lowered threshold for seizures
• Neuroleptics (medicines to treat schizophrenia, psychosis) and antidepressants (tricyclic antidepressants and SSRIs) due to a risk of a lowered threshold for seizures
• When administered together with flecainide, propafenone, and metoprolol (used in cardiovascular diseases) clomipramine, and nortriptyline (antidepressants) and risperidone, thioridazine, and haloperidol (antipsychotics), the dosage of ESIPRAM may need to be adjusted.

• Do not take ESIPRAM if you take medicines for heart rhythm problems or medicines that may affect the heart's rhythm, such as Class IA and III antiarrhythmics, antipsychotics (e.g. phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarial medicines particularly halofantrine), certain antihistamines (e.g. astemizole, mizolastine).
• Medicines lowering the potassium and magnesium values in the blood, increase the risk of life threatening heart rhythm disorder.
*Please tell your doctor or pharmacist if you are using or have recently used any prescribed or non-prescribed medicine.*



**3. How to use ESIPRAM**
• **Instructions for proper use and dosing/administration frequency:**
Always use ESIPRAM exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
Adults
*Depression*
The normally recommended dose of ESIPRAM is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

*Panic disorder*
The starting dose of ESIPRAM is 5 mg as one daily dose for the first week before increasing the dose to 10 mg per day. The dose may be further increased by your doctor to a maximum of 20 mg per day.
*Social anxiety disorder*
The normally recommended dose of ESIPRAM is 10 mg taken as one daily dose. Your doctor can either decrease your dose to 5 mg per day or increase the dose to a maximum of 20 mg per day, depending on how you respond to the medicine.

*Generalised anxiety disorder*
The normally recommended dose of ESIPRAM is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.
*Obsessive-compulsive disorder*
The normally recommended dose of ESIPRAM is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

• **Route and method of administration:**
You can take ESIPRAM with or without food. Swallow the tablet with some water. Do not chew them, as the taste is bitter.
If necessary, you can divide the tablets by firstly placing the tablet on a flat surface with the score facing upwards. The tablets may then be broken by pressing down on each end of the tablet, using both forefingers as shown in the drawing.

• **Various age groups:**
**Children and adolescents:**
ESIPRAM should not normally be given to children and adolescents below 18 years of age). For further information please see section 2 "What you need to know before you take ESIPRAM ".
**Elderly patients (above 65 years of age):**
The recommended starting dose of ESIPRAM is 5 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 10 mg per day.

**Special usage conditions**
**Kidney and liver failure**
No dose adjustment is required for the patients with mild to moderate kidney failure.
For the patients with mild to moderate liver function disorder, recommended initial dose is 5 mg for first two weeks of treatment. This dose may be increased to maximum 10 mg by your doctor.
Special attention should be paid in patients with severe kidney or liver failure.

**Duration of treatment:**
It may take a couple of weeks before you start to feel better. Continue to use ESIPRAM even if it takes some time before you feel any improvement in your condition.

Do not change the dose of your medicine without talking to your doctor first.

Continue to take ESIPRAM for as long as your doctor recommends. If you stop your treatment too soon, your symptoms may return. It is recommended that treatment should be continued for at least 6 months after you feel well again.
*If you have any impression as the ESIPRAM 's effect is too strong or too weak, consult your physician or pharmacist.*

**If you use more ESIPRAM than you should:**
*If you take more than the prescribed dose of ESIPRAM , contact a doctor or a pharmacist or nearest hospital emergency department immediately*.
Do this even if there are no signs of discomfort.
Some of the signs of an overdose could be dizziness, tremor, agitation, convulsion, coma, nausea, vomiting, change in heart rhythm (slower or faster than normal), decreased blood pressure and change in body fluid/salt balance.
Take the ESIPRAM box/container with you when you go to the doctor or hospital.

**If you forget to use ESIPRAM :**
*Do not take a double dose to make up for forgotten doses*. If you do forget to take a dose, and you remember before you go to bed, take it straight away. Carry on as usual the next day. If you only remember during the night, or the next day, leave out the missed dose and carry on as usual.
**Possible effects of discontinuation of ESIPRAM treatment:**
Do not stop taking ESIPRAM until your doctor tells you to do so.
When you have completed your course of treatment, it is generally advised that the dose of ESIPRAM is gradually reduced over a number of weeks to be discontinued.
When you stop taking ESIPRAM abruptly, you may feel discontinuation symptoms. These are common when treatment with ESIPRAM is stopped abruptly. The risk is higher, when ESIPRAM has been used for a long time or in high doses or when the dose is reduced too quickly. Most people find that the symptoms are mild and go away on their own within two weeks. However, in some patients they may be severe in intensity or they may be prolonged (2-3 months or more). If you get severe discontinuation symptoms when you stop taking ESIPRAM , please contact your doctor. He or she may ask you to start taking your tablets again and discontinue in a longer time interval by reducing the dose gradually.
Discontinuation symptoms include: Feeling dizzy (unsteady or off-balance), feelings like pins and needles, burning sensations and (less commonly) electric shock sensations, including in the head, sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling sick (nausea), sweating (including night sweats), feeling restless or agitated, tremor (shakiness), feeling confused, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations).
If you have any further questions on the use of this product, ask your doctor or pharmacist. .

**4. Possible side effects**
Like all medicines, ESIPRAM can cause side effects in people sensitive to ingredients contained.
The side effects usually disappear after a few weeks of treatment. Please be aware that many of the effects may also be symptoms of your illness and therefore will improve when you start to get better.
Side effects are listed as shown in the following categories:
Very common: Affects more than 1 in 10 people using the drug.
Common: Affects 1 to 10 users in 100 people.
Uncommon: Affects 1 to 10 users in 1000 people.
Rare: Affects 1 to 10 users in 10000 people.
Unknown: Frequency cannot be estimated from the available data.

2202151-A