

**PATIENT
INFORMATION LEAFLET**

Escitalopram NORMON 15 mg film - coated tablets

Escitalopram

Read this leaflet carefully before taking the medicine.

- Keep this leaflet, as you may need to read it again.
- If you have any question, consult your doctor or pharmacist.
- This medicine has been prescribed to you and it should not be given to other people, even if the symptoms are the same as yours, since it may harm them.
- If you think any of the side effects you suffer is severe or if you notice any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

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1. WHAT Escitalopram NORMON IS AND WHAT IT IS USED FOR

Escitalopram NORMON contains escitalopram and is indicated for the treatment of depression (major depressive episodes) and anxiety disorders (such as anguish disorder with or without agoraphobia, social anxiety disorder, generalised anxiety disorder and obsessive-compulsive disorder).

Escitalopram belongs to the group of antidepressants called selective serotonin reuptake inhibitors (SSRIs). These medications act on the brain serotonergic system, increasing serotonin levels. Serotonergic system disorders are considered to be a major factor in the development of depression and related diseases.

2. BEFORE TAKING Escitalopram NORMON

Do not take Escitalopram NORMON:

- If you are allergic (hypersensitive) to escitalopram or any of the other ingredients of Escitalopram NORMON (see Section 6 "Further information").
- If you are taking other medications from the group known as MAO inhibitors, including selegiline (used to treat Parkinson's disease), moclobemide (used to treat depression), and linezolid (an antibiotic).
- 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 take medicines for heart rhythm problems or that may affect the heart's rhythm (see section 2 "Using other medication").

Take special care with Escitalopram NORMON

Please tell your doctor if you suffer any other disorder or disease, as your doctor may need to consider it. Specifically, tell your doctor:

- If you suffer from epilepsy. Treatment with Escitalopram NORMON should be discontinued if you experience seizures or experience an increase in the frequency of seizures (see also Section 4 "Possible side effects").
- If you experience liver or renal insufficiency. Your doctor may need to adjust the dose.
- If you suffer from diabetes. Treatment with Escitalopram NORMON may affect the control of blood sugar levels. It may be necessary to adjust the dose of insulin and/or the oral hypoglycaemic agent.
- If your blood sodium levels are reduced.
- If you are susceptible to bleeding or bruising.
- If you are receiving electroconvulsive treatment.
- If you suffer from a coronary 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 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.

An increased risk of bone fractures have been observed in patients treated with this kind of medicine.

Please bear in mind:

Some patients with manic-depressive disease may enter a manic phase. This is characterised by an uncommon, fast change of ideas, disproportionate happiness and excessive physical activity. If you experience it, contact your doctor.

Symptoms such as restlessness or difficulty sitting down or standing up can also occur during the first weeks of treatment. Tell your doctor immediately if you experience these symptoms.

Suicidal thoughts and increased depression or anxiety disorder

If you are depressed and/or suffer an anxiety disorder, you may sometimes think about harming or killing yourself. These thoughts may increase when you take antidepressants for the first time, as it takes this medication a while to have an effect, generally around two weeks, though in some cases the timeframe might be greater. You would be more prone to this type of thoughts:

- If you have previously had thoughts of self-harm or suicide.
- If you are a young adult. The information from clinical trials has shown an increased risk of suicidal behaviours in adults under 25 years of age, with psychiatric diseases that were treated with an antidepressant.

If at any time you have thoughts of self-harm or suicide, contact your doctor or go to a hospital straight away.

It may be helpful for you to tell a relative or close friend that you are depressed or that you have an anxiety disorder and ask them to read this leaflet. You may ask them if they think if your depression or anxiety disorder have worsened or if they are worried about your changes in attitude.

Use in children and adolescents under 18 years of age

Escitalopram NORMON should not normally be used to treat children and adolescents under 18 years of age. Furthermore, it is important to know that in patients under 18 years of age there is a higher risk of side events, such as attempted suicide, suicidal thoughts and hostility (mainly aggression, confrontational behaviour and irritation) when they take this class of medication. However, your doctor may prescribe Escitalopram NORMON to patients under 18 years of age when your doctor decides that it is the most appropriate for the patient. If your doctor has prescribed Escitalopram NORMON to a patient under 18 years and you want to discuss this decision, please return to your doctor. You must tell your doctor if any of the above symptoms progress or you experience complications when patients under 18 years of age are taking Escitalopram NORMON. Furthermore, the long-term effects of escitalopram in terms of safety and effects relating to growth, maturity and cognitive and behavioural development of escitalopram in this age group have not been demonstrated yet.

Using other medication

- "Non-selective monoamine oxidase inhibitors (MAOIs)" which contain phenelzine, iproniazid, isocarboxazide, nialamide and tranylcypromine as active substances. If you have taken any of the above medication you must wait 14 days before you start taking Escitalopram NORMON. After you finish your course of Escitalopram NORMON medication you must not take any of these medicines for 7 days.
- "Reversible selective MAO-A inhibitors", containing moclobemide (used in the treatment of depression).

- “Irreversible MAO-B inhibitors”, containing selegiline (used to treat Parkinson’s disease). These increase the risk of side effects.
- The antibiotic linezolid.
- Lithium (used to treat maniac-depressive disorder) and tryptophan.
- Imipramine and desipramine (both used to treat depression).
- Sumatriptan and similar medication (used to treat migraines) and tramadol (used for severe pain). These drugs increase the risk of side effects.
- Cimetidine and omeprazole (used to treat stomach ulcers), fluvoxamine (antidepressant) and ticlopidine (used to reduce the risk of stroke). These may cause an increase in the blood concentration of Escitalopram NORMON.
- Saint John’s wort (*Hypericum perforatum*) –herbal medicine used for depression.
- Acetyl salicylic acid and non-steroidal anti-inflammatory drugs (medication for pain relief or in reducing the risk of thrombosis; these drugs are also known as anticoagulants).
- Warfarin, dipyridamole and phenprocoumon (medication used to reduce the risk of thrombosis, also known as anticoagulants). Your doctor will probably monitor blood clotting time at the start and at the end of treatment with Escitalopram NORMON, to verify that the dose of anticoagulant is still appropriate.
- Mefloquine (used to treat malaria), bupropion (used to treat depression) and tramadol (used to treat severe pain) due to the possible risk of reducing the seizure threshold.
- Neuroleptics (medication used to treat schizophrenia, psychosis) due to the possible risk of reducing the seizure threshold and antidepressants.
- Flecainide, propafenone and metoprolol (used in cardiovascular diseases), clomipramine and nortriptyline (antidepressants) and risperidone, thioridazine and haloperidol (antipsychotics). The dose of Escitalopram NORMON may need to be adjusted.
- Do not take Escitalopram NORMON 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 treatment particularly halofantrine), certain antihistamines (e.g. astemizole, mizolastine). If you have any further questions about this you should speak to your doctor.

Taking Escitalopram NORMON with food and drink

Escitalopram NORMON may be taken with or without food (see Section 3 “How to take Escitalopram NORMON”).

As with a lot of medication, the combination of Escitalopram NORMON and alcohol is not recommended, though Escitalopram NORMON is not likely to react with alcohol.

Pregnancy and breast-feeding

Tell your doctor if you are or may be pregnant. Do not take Escitalopram NORMON if you are pregnant unless you and your doctor have assessed the risks and benefits involved.

If you take Escitalopram NORMON during the last 3 months of pregnancy be aware that the newborn may show the following effects: breathlessness, bluish skin, fits, body temperature changes, problems eating, vomiting, low blood sugar levels, muscle rigidity or lethargy, intense reflexes, shaking, restlessness, irritability, lethargy, constant crying, drowsiness and difficulties in falling asleep. If your newborn baby has any of these symptoms, please contact your doctor immediately.

If Escitalopram NORMON is used during pregnancy, it should never be discontinued abruptly.

Make sure your midwife and/or doctor know you are on Escitalopram NORMON. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Escitalopram NORMON 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.

Do not take Escitalopram NORMON if you are breast-feeding unless you and your doctor have assessed the risks and benefits involved.

Citalopram, a medicine like escitalopram, has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

Ask your doctor or pharmacist for advice before taking any medication.

Driving and using machinery

You are recommended not to drive or handle machinery until it is known how Escitalopram NORMON may affect you.

3. HOW TO TAKE Escitalopram NORMON

Always take Escitalopram NORMON exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

Adults

Depression

The recommended standard dose of Escitalopram NORMON is 10 mg taken as single daily dose. Your doctor may increase it to up to 20 mg a day.

Anguish disorder

The starting dose of Escitalopram NORMON is 5 mg and is taken as a single daily dose during the first week after which it is increased to 10 mg a day. Your doctor may then increase it to up to 20 mg a day.

Social anxiety disorder

The recommended standard dose of Escitalopram NORMON is 10 mg taken as single daily dose. Your doctor may reduce your dose to 5 mg a day or increase the dose up to 20 mg a day, based on your response to this medication.

Generalised anxiety disorder

The recommended standard dose of Escitalopram NORMON 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 recommended standard dose of Escitalopram NORMON is 10 mg taken as single daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

Elderly (over the age of 65)

The recommended standard dose of Escitalopram NORMON is 5 mg taken as single daily dose. The dose may be increased by your doctor to 10 mg per day.

Children and adolescents (under 18 years of age)

Escitalopram NORMON should not be normally administered to children or adolescents. For further information please see section 2 "Before taking Escitalopram NORMON".

You may take Escitalopram NORMON with or without food. Swallow the tablets with water. Do not chew them, as they are bitter.

If necessary, you may break up the tablets placing the tablet over a smooth surface with the score facing up. The tablets may be broken pressing downwards in each edge of the tablet, with the two index fingers.

Treatment duration

It may take two weeks before you start to feel better. Continue taking Escitalopram NORMON even if you start to feel better before the expected time.

Do not change the medication dose before talking to your doctor.

If you take more Escitalopram NORMON than you should

If you take more doses of Escitalopram NORMON than that prescribed, contact your doctor immediately or go to the emergency room of the closest hospital. Do it even if you do not notice any discomfort or signs of intoxication. Some of the signs of overdosing may be also dizziness, shaking, agitation, seizures, coma, nausea, vomiting, changes in heart rate, blood pressure reduction and changes in body water-salt balance. Take the container of Escitalopram NORMON if you go to the doctor or hospital.

If you forget to take Escitalopram NORMON

Do not take a double dose to make up for a dose missed. If you forget to take a dose and remember it before going to bed, take it straight away. The next day continue as usual. If you remember it at night or the next day, skip the missed dose and continue as usual.

If you stop taking Escitalopram NORMON

Do not stop treatment with Escitalopram NORMON until your doctor tells you to do so. When you finish your treatment course, it is generally recommended that the dose of Escitalopram NORMON is reduced gradually for several weeks.

When you stop taking Escitalopram NORMON, particularly if it is abruptly, you may experience withdrawal symptoms. These are common when treatment with Escitalopram NORMON is discontinued. The risk is higher when Escitalopram NORMON has been used for a long time, at high doses or when the dose is reduced too fast. Most people find that these symptoms are mild and disappear spontaneously in two weeks. However, in some patients they may be severe or prolonged (2-3 months or longer). If you experience severe withdrawal symptoms when you stop taking Escitalopram NORMON, please contact your doctor. He or she may ask you to take your tablets again and to discontinue them more slowly.

The withdrawal symptoms include: dizziness (unstable or without equilibrium), tingling, burning and (less frequently) electrical shock, even to the head, sleep disruption (very intense dreams, nightmares, inability to sleep), restlessness, headache, light-headedness (nausea), sweating (including nocturnal sweating), a feeling of restlessness, shaking (instability), feeling of confusion or disorientation, feelings of excitement or irritation, diarrhoea (soft stools), visual impairment, fast pulse and palpitations.

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

4. POSSIBLE SIDE EFFECTS

Adverse events usually disappear after a few weeks of treatment. Please be aware that many of the effects may be symptoms of your disease and therefore will improve when you start to feel better.

Visit your doctor if you think you have any of the following adverse events during the treatment:

Uncommon (at least 1 person in 1,000 and less than 1 in 100):

- Unusual bleeding, including gastrointestinal bleeding.

Rare (at least 1 person in 10,000 and less than 1 in 1,000):

- If you notice swelling of the skin, tongue, lips or face, or have breathing or swallowing difficulties (allergic reaction), contact your doctor or go to the hospital immediately.
- If you experience high fever, agitation, confusion, shaking and sudden muscle contraction, these may be signs of an uncommon situation called serotonergic syndrome. If you experience it, contact your doctor.

If you experience the following adverse events, you must contact your doctor or go to the hospital immediately:

- Urinary problems.
- Seizures (fits), see also the section "Take special care with Escitalopram NORMON".
- Yellowish skin and eye whitening, are signs of liver dysfunction/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 adverse events have been reported:

Very common (at least 1 person in 10):

- Feeling dizzy (nausea).
- **Common** (at least 1 person in 100 and less than 1 in 10):
- Nose stuffiness or mucosity (sinusitis).
- Increased or reduced appetite.
- Anxiety, agitation, abnormal dreaming, difficulties in falling asleep, drowsiness, dizziness, yawning, shaking, skin itching.
- Diarrhoea, constipation, vomiting, dry mouth.
- Increased sweating.
- Muscle and joint pain (arthralgia and myalgia).
- Sexual disorders (delayed ejaculation, erection problems, reduced sexual behaviour and women may experience difficulties in reaching orgasm).
- Fatigue, fever.
- Weight gain.

Uncommon (at least 1 person in 1,000 and less than 1 in 100):

- Urticaria, skin rash, itching (pruritus).
- Teeth grinding, agitation, nervousness, panic attacks, state of confusion.
- Sleep disruption, problems tasting, fainting (syncope).
- Pupil dilation (midriasis), visual disturbances, tingling in the ears (tinnitus).
- Hair loss.
- Vaginal bleeding.
- Weight loss.
- Fast heart rate.
- Swelling of the arms and legs.
- Nose bleeding.

Rare (at least 1 person in 10,000 and less than 1 in 1,000):

- Aggression, depersonalisation, hallucinations.
- Low heart rate.

Some patients have reported (unknown frequency):

- Thoughts of self-harm or suicide, also see the section "Take special care with Escitalopram NORMON".
- Reduction in blood sodium levels (symptoms of feeling dizzy and uncomfortable, with muscle weakness or confusion).
- Light-headedness when standing up due to low blood pressure (orthostatic hypotension).
- Impaired liver function tests (increased liver enzymes in blood).
- Movement disorders (involuntary muscle movements).
- Painful erections (priapism).
- Clotting disorders, including skin and mucosal bleeding (ecchymosis) and low blood platelet levels (thrombocytopenia).
- Sudden swelling of the skin or mucosae (angioedema).
- Increased urinary output (inadequate ADH secretion).
- Milk flow in non-nursing women.
- Mania.
- Motor restlessness (akathisia).
- Anorexia.
- Alteration of the heart rhythm (called "prolongation of QT interval", seen on ECG, measuring electrical activity of the heart)

If any side effect becomes serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE Escitalopram NORMON

Store below 25°C and protect from humidity.

Keep out of the reach and sight of children.

Do not use Escitalopram NORMON after the expiry date printed on the package. Expiry date refers to the last day of the indicated month.

Medicinal products should not be poured down the drain or thrown into the rubbish. Ask your pharmacist how to dispose of medicinal products you do not need. This will help to protect the environment.

6. FURTHER INFORMATION

Composition of Escitalopram NORMON

The active substance is escitalopram.

Each tablet contains 15 mg of escitalopram (as oxalate).

The others of the components (excipients) are: microcrystalline cellulose, colloidal silica, sodium croscarmellose, hypromellose, magnesium stearate, titanium dioxide (E-171), macrogol 6000 and talc.

Product appearance and contents of the package

Escitalopram NORMON 15 mg is presented in the form of film-coated tablets. Escitalopram NORMON 15 mg are white or almost white, round, biconvex, scored and marked tablets. Each package contains 28 or 56 film -coated tablets.

Marketing authorisation holder and manufacturer

LABORATORIOS NORMON, S.A.

Ronda de Valdecarrizo, 6 28760 Tres Cantos Madrid (SPAIN)

OTHER PRESENTATIONS

Escitalopram NORMON 10 mg film-coated tablets

Escitalopram NORMON 20 mg film-coated tablets

This patient information leaflet has been reviewed in May 2017