

## Package leaflet: Information for the user

### Escitalopram Normon 10 mg film-coated tablets.

Escitalopram oxalate

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

### 1. What Escitalopram Normon is and what it is used for

Escitalopram Normon contains the active substance escitalopram. Escitalopram Normon 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.

Escitalopram Normon contains escitalopram and is used to treat depression (major depressive episodes) and anxiety disorders (such as panic disorder with or without agoraphobia, social anxiety disorder, generalised anxiety disorder and obsessive-compulsive disorder).

It may take a couple of weeks before you start to feel better. Continue to take Escitalopram Normon, even if it takes some time before you feel any improvement in your condition.

You must talk to a doctor if you do not feel better or if you feel worse.

### 2. What you need to know before you take Escitalopram Normon

#### Do not take Escitalopram Normon

- If you are allergic (hypersensitive) to escitalopram or any of the other ingredients of Escitalopram Normon (listed in section 6)
- If you take other medicines which belong to a group called MAO inhibitors, including selegiline (used in the treatment of Parkinson's disease), moclobemide (used in the treatment of 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 are taking medicines for heart rhythm problems or that may affect the heart's rhythm (see section 2 "Other medicines and Escitalopram Normon").

## Warnings and precautions

### Talk to your doctor or pharmacist before taking Escitalopram Normon

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 Escitalopram Normon should be stopped if seizures occur for the first time or if there is an increase in the seizure frequency (see also section 4 “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 Escitalopram Normon 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 bleedings or bruises or if you are pregnant (see “Pregnancy, breast-feeding and fertility”).
- 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.
- If you experience a fast or irregular heartbeat, fainting, collapse or dizziness on standing up, which may indicate abnormal functioning of the heart rate.
- If you have angle-closure glaucoma or history of glaucoma (increased pressure in the eye).

### Please note:

Some patients with manic-depressive illness may enter into a manic phase. This is characterised 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 to sit or stand still can also occur during the first weeks of the treatment. Tell your doctor immediately if you experience these symptoms.

Medicines such as Escitalopram Normon (also called SSRIs/SNRI's) may cause sexual dysfunction symptoms (see section 4). In some cases, these symptoms persist after suspending treatment.

### 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**.

**You may find it helpful to tell a relative or close friend** that you are depressed or have an anxiety disorder and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

### Children and adolescents

Escitalopram Normon should normally not be used for the treatment of 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 Escitalopram Normon for patients under 18 because he/she decides that this is in their best interest. If your doctor has prescribed

Escitalopram Normon for a patient under 18 and you want to discuss this decision, please go back to your doctor. You should inform your doctor if any symptoms listed above develop or worsen when patients under 18 are taking Escitalopram Normon. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Escitalopram Normon in this age group have not yet been demonstrated.

### **Other medicines and Escitalopram Normon**

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

#### **Tell your doctor if you are taking any of the following medicines:**

- “Non-selective monoamine oxidase inhibitors (MAOIs)”, containing phenelzine, iproniazid, isocarboxazid, nialamide and tranylcypromine as active ingredients. If you have taken any of these medicines, you will need to wait 14 days before you start taking Escitalopram Normon. After stopping Escitalopram Normon, you must allow 7 days before taking any of these medicines.
- “Reversible, selective MAO-A inhibitors”, containing moclobemide (used to treat 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 in the treatment of manic-depressive disorder) and tryptophan.
- 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), fluconazole (used to treat fungal infections), 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 and non-steroidal anti-inflammatory drugs (medicines used for pain relief or to thin the blood, so called anti-coagulant). These may increase bleeding tendency.
- Warfarin, dipyridamole, and phenprocoumon (medicines used to reduce the risk of thrombosis, also called anticoagulants). Your doctor will probably check the coagulation time of your blood when starting and discontinuing Escitalopram Normon in order to verify that your dose of anticoagulant is still adequate.
- Mefloquine (used to treat malaria), bupropion (used to treat depression) and tramadol (used to treat severe pain) due to a possible risk of a lowered threshold for seizures.
- Neuroleptics (medicines to treat schizophrenia, psychosis) and antidepressants (tricyclics, SSRIs) due to a possible risk of a lowered threshold for seizures and antidepressants.
- Flecainide, propafenone, and metoprolol (used in cardiovascular diseases), clomipramine and nortriptyline (antidepressants) and risperidone, thioridazine and haloperidol (antipsychotics). The dosage of Escitalopram Normon may need to be adjusted.
- Medicines that decrease blood levels of potassium or magnesium as these conditions increase the risk of life-threatening heart rhythm disorder.

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-malarian treatment particularly halofantrine), certain antihistamines (astemizole, mizolastine). If you have any further questions about this you should speak to your doctor.

### **Escitalopram Normon with food, drink and alcohol**

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

As with many medicines, combining Escitalopram Normon with alcohol is not advisable, although Escitalopram Normon has been shown not to interact with alcohol.

### **Pregnancy, breast-feeding and fertility**

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 using this medicine.

Do not take Escitalopram Normon if you are pregnant or breast-feeding unless you and your doctor have discussed the risks and benefits involved.

If you take Escitalopram Normon near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking Escitalopram Normon so they can advise you.

If you take Escitalopram Normon during the last 3 months of your pregnancy, you should be aware that the following effects may be seen in your new-born baby: trouble with breathing, bluish skin, fits, body temperature changes, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, lethargy, constant crying, sleepiness and sleeping difficulties. If your new-born baby has any of these symptoms, please contact your doctor immediately.

Make sure your midwife and/or doctor knows you are on Escitalopram Normon. During pregnancy, particularly in the last 3 months, medicines like Escitalopram Normon may increase the risk of a serious condition in new-borns, called persistent pulmonary hypertension of the new-born (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, contact your midwife and/or doctor immediately.

If Escitalopram Normon is used during pregnancy, it should never be stopped abruptly.

It is expected that escitalopram will be excreted into breast milk.

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.

### **Driving and using machines**

Do not drive or operate machinery until you know how Escitalopram Normon affects you.

## **3. How to take Escitalopram Normon**

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

### **Adults**

#### *Depression*

The normally recommended 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.

#### *Panic disorder*

The starting dose of Escitalopram Normon is 5 mg as a single 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 Escitalopram Normon 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 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 normally recommended 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.

### **Elderly patients (above 65 years of age)**

The recommended starting dose of Escitalopram Normon is 5 mg taken as one 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 normally be given to children and adolescents. For further information please see section 2 “Warnings and precautions”.

How to take the tablets.

You can take Escitalopram Normon with or without food. Swallow the tablets with 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.

### **Duration of treatment**

It may take a couple of weeks before you start to feel better. Continue to take Escitalopram Normon 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 Escitalopram Normon 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 take more Escitalopram Normon than you should**

If you take more than the prescribed dose of Escitalopram Normon, contact your doctor immediately or go to the nearest hospital emergency department or call the Servicio de Información Toxicológica (Toxicology Information Service): +34 915.620.420. Do this even if there are no signs of discomfort or intoxication. Some of the signs of an overdose could be dizziness, tremor, agitation, convulsion, coma, nausea, vomiting, change in heart rhythm, decreased blood pressure and change in body fluid/salt balance. Take the Escitalopram Normon package with you when 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 forgotten dose. If you forget to take a dose, and you remember about it before going to bed, take it straight away. Carry on as usual the next day. If you remember during the night or the next day, leave the missed dose out and carry on as usual.

### **If you stop taking Escitalopram Normon**

Do not stop taking Escitalopram Normon unless your doctor tells you to. When you have completed your course of treatment, it is generally advised that the dose of Escitalopram Normon is gradually reduced over a number of weeks.

When you stop taking Escitalopram Normon, especially if it is abruptly, you may feel discontinuation symptoms. These are common when treatment with Escitalopram Normon is stopped. The risk is higher

when Escitalopram Normon 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 Escitalopram Normon, please contact your doctor. He or she may ask you to start taking your tablets again and come off them more slowly.

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 or disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, pounding heartbeat or palpitations.

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.

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.

**If you experience any of the following side effects, you should contact your doctor or go to hospital immediately:**

**Uncommon** (may affect up to 1 in 100 people):

- Unusual bleeds, including gastrointestinal bleeds.

**Rare** (may affect up to 1 in 1,000 people):

- Swelling of the skin, tongue, lips pharynx or face, urticaria or have difficulties breathing or swallowing (serious allergic reaction).
- High fever, agitation, confusion, trembling and abrupt contractions of muscles these may be signs of a rare condition called serotonin syndrome.

**Not known** (frequency cannot be estimated from the available data):

- Difficulties urinating.
- Seizures (fits), see also section “Warnings and precautions”.
- Yellowing of the skin and the white in the eyes are signs of liver function impairment/hepatitis.
- Fast, irregular heartbeat or fainting, which could be symptoms of a life-threatening condition known as Torsade de Pointes.
- Thoughts of harming yourself or thoughts of killing yourself, see also section “Warnings and precautions”.
- Sudden swelling of skin or mucosa (angioedema).
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see “Pregnancy, breast-feeding and fertility” in section 2 for more information.

In addition to above, the following side effects have been reported:

**Very common** (may affect more than 1 in 10 people):

- Feeling sick (nausea).
- Headache.

**Common** (may affect up to 1 in 10 people):

- Blocked or runny nose (sinusitis).
- Decreased or increased appetite.

- Anxiety, restlessness, abnormal dreams, difficulties falling asleep, feeling sleepy, dizziness, yawning, tremors, itchy 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 women may experience difficulties achieving orgasm).
- Fatigue, fever.
- Weight gain.

**Uncommon** (may affect up to 1 in 100 people):

- Urticaria, skin rash, itching (pruritus).
- Grinding one's teeth, agitation, nervousness, panic attack, confusion state.
- Disturbed sleep, taste disturbance, fainting (syncope).
- Enlarged pupils (mydriasis), visual disturbance, ringing in the ears (tinnitus).
- Loss of hair.
- Excessive menstrual bleeding.
- Menstrual irregularity.
- Weight loss.
- Fast heartbeat.
- Swelling of the arms or legs.
- Nose bleeds.

**Rare** (may affect up to 1 in 1000 people):

- Aggression, depersonalisation, hallucination.
- Slow heartbeat

**Not known** (frequency cannot be estimated from the available data):

- 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).
- Increased secretion of a hormone called ADH, causing the body to retain water and dilute the blood, reducing the amount of sodium (inappropriate ADH secretion).
- Signs of bleeding disorders including skin and mucous bleeding (ecchymosis).
- Flow of milk in men and women that are not breast-feeding.
- Mania.
- An increased risk of bone fractures has been observed in patients treated with this type of medication.
- Alteration of the heart rhythm (called "prolongation of QT interval", seen on ECG).

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 Escitalopram Normon). These are

- Motor restlessness (akathisia).
- Loss of appetite.

**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. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Escitalopram Normon

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

Store below 30°C.

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

Do not throw away any medicines via wastewater or household waste. Dispose of containers and medicines you no longer need at the SIGRE Point  at your pharmacy. If you are not sure, ask your pharmacist how to throw away medicines and packages you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What Escitalopram Normon contains

The active substance is escitalopram.

Each table of Escitalopram Normon contains 10 mg of escitalopram (as oxalate).

The other ingredients are:

Core: microcrystalline cellulose, colloidal silica, sodium croscarmellose and magnesium stearate.

Coating: hypromellose, macrogol 6000, titanium dioxide (E-171) and talc.

### What Escitalopram Normon looks like and contents of the pack

Escitalopram Normon 10 mg comes in film-coated tablets.

Escitalopram Normon 10 mg film-coated tablets are white or off-white, round, biconvex, scored and marked tablets supplied in packages containing 28 and 56 tablets.

### Marketing Authorisation Holder and Manufacturer

LABORATORIOS NORMON, S.A.

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Spain

### OTHER PRESENTATIONS

Escitalopram Normon 15 mg film-coated tablets.

Escitalopram Normon 20 mg film-coated tablets.

**This leaflet was last reviewed in: January 2021**

Detailed information on this medicine is available on the Spanish Agency for Medicines and Healthcare Products (AEMPS) website: <http://www.aemps.gob.es/>.