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 symptoms 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 Escitalax is and what it is used for

2. What you need to know before you take Escitalax

3. How to take Escitalax

4. Possible side effects

5. How to store Escitalax

6. Content of the pack and other information

1. What Escitalax is and what it is used for

Escitalax contains the active substance escitalopram. Escitalax 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.

Escitalax is used to treat depression (major depressive episodes) and anxiety disorders (such as panic disorder with or without apraphobia, 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 Escitalax, even if it takes some tiem 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 Escitalax

2. What you need to mone before you take Eschalax

If you are allergic to escitalopram or any of the other ingredients of this medicine (listed in section 6).

If you take other medicines which belongs to a group called MAO inhibitors, including selegiline (used in the treatment of Parkinson's disease), moclobemide (used in the treatment of depression) and linezoid (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 "other medicines and Escitalax").

Maming and Precautions
Tell your doctor or pharmacist before taking Escitalax. Please tell your doctor if you have any other condition or illness, as your doctor may need to take this into consideration. In particular,

- Trailing and to the condition or illness, as your doctor may need to take this into consideration. In particular, tell your doctor or pharmacist before taking Escitalax, Please ten your doctor.

 If you have epilepsy, Treatment with Escitalax should be stopped if seizures occur 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 Escitalax 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.

 If you are receiving electroconvolusive treatment.

 If you suffer or have suffered from heart problems or have recently had a heart attack.

 If you suffer or have suffered from heart problems or have recently had a heart attack.

 If you suffer on have suffered from heart problems or have recently had a heart attack.

 If you sufferen have suffered from heart, fainting, collapse or dizziness on standing up, which may indicate abnormal functioning of the heart rate.

 If you have not have previously had eye problems, such as certain kinds of glaucoma (increased pressure in the eye).

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 to in sitting or standing still can also occur during the first weeks of the treatment. Tell your doctor immediately if you experience these symptoms. Medicines like Escitalax (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping 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 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 antidepressal. 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.

oepression or anxiety is getting worse, or in they are worned about changes in your behaviour.

Des in children and adolescents

Eschalax 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 foredominately aggression, oppositional behaviour and angery when they take this class of medicines. Despite this, your doctor may prescribe Escitalax for patients under 18 because height edocides that this is in their best interest, (flyour doctor has prescribed Escitalax for a patient under 18 and you want to discuss this, 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 Escitalax. Also, the long term safely effects concerning growth, maturation and cognitive and behavioural development of Escitalax in this age group have not yet been demonstrated.

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

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 (IMAOIs"): containing phenelzine, iproniazid, socardoxazid, nalamide, and tranylopyromine as carbie ingredients. If you have taken any of these medicines you will need to wait 14 days before you saft taking Escalaa. After stopping Escatalax you must allow 7 days before taking any of tiese medicines.

"Reversible, selective NAO-A inhibitors", containing moclobemide (used to treat depression).

"Ireversible MAO-B inhibitors", containing selegiline (used to treat depression).

The antibiotic interzolid.

Lithium (used in the treatment of manic-depressive disorder) and tryptophan.

Imipramine and designamine (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 and omeprazole (used to treat stomach ulcers), fluconazole (used to treat fungal infections), fluvoamine (antidepressant) and ticopoline (used to reduce the risk of stroke). These mey cause increase the look of side effects.

Cimetidine and omeprazole (used to treat stomach ulcers), fluconazole (used to treat fungal infections), fluvoamine (antidepressant) and ticopoline (used to reduce the risk of stroke). These mey cause increase the look of seal effects.

S. John's Wort (*Pypercum perforatum): a herbal remedy used for depression.

S.I. John's Wort (*Pypercum perforatum): a herbal remedy used for depression, and relief or to thin the blood, so called anticoagularish, including seal and some paid and sontinum gescriata in order to verify they used or sealing and discontinuing Escriatax in order to verify they used or sealing escapilarish is still adequate.

Mefloquine (used to treat Malara), bupropon (used to treat depression) and tramadol (used to treat severe pain) due to a possible risk of a lowered threshold

Do not take Escitalax 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. phenotinizare derivatives, pimozide, haloperidol), ricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarial treatment particularly haldrantrine), certain antihistamines (e.g. asternizole, mizolastine). If you have any further questions about this you should speak to your doctor.

Escitalax with food, drink and alcohol Escitalax can be taken with or without food (see section 3 "How to take Escitalax").

As with many medicines, combining Escitalax with alcohol is not advisable, although Escitalax is not expected to interact with alcohol.

Pregnancy, breast-deeding and fertility
ff 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. Do not take Escitalax if you are pregnant or breast-feeding, unless you and your doctor have discussed the risks and benefits involved.

If you take Escialax during the last 3 months of your pregnancy you should be aware that the following effects may be seen in your newborn baby: toolble with breathing, bluish skin, fits body temperature changes, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, vivid reflexes, tremor, litteriness, 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 midwife and/or doctor know you are on Esotlatax. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Esotlatax 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 Escitalax 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**You are advised not to drive a car or operate machinery until you know how Escitalax affects you.

3. How to take Escitalax Always take Escitalax exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults

Depression
The normally recommended dose of Escitalax 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 Escitalax 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 Escitalax 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 Escitalax 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 Escitalax 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 Escitalax is 5 mg taken as one daily dose. The dose may be increased by your doctor to 10 mg per day.

Use in children and adolescents
Escitalax should not normally be given to children and adolescents. For further information please see section 2 "Warnings and precautions".

You can take Escitalax 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.



Duration of treatment
It may take a couple of weeks before you start to feel better. Continue to take Escitalax 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 Escitalax 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.

least to months arrer you new near ogeni.

If you take more Escitalax than you should

If you take more than the prescribed dose of Escitalax, contact your doctor 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 discribes, theron, agaitation, comvalon, coma, nauses, womiting,
change in heart rhythm, decreased blood pressure and change in body fluidisalt balance. Take
the Escitalax bow/container with you when you go to the doctor or hospital.

If you forget to take Escitalax

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.

If you stop taking Escitalax
Do not stop taking Escitalax until your doctor tells you to do so. When you have completed your
course of treatment, it is generally advised that the dose of Escitalax is gradually reduced over
a number of weeks.

a flutine of views.

When you stop taking Escitalax, especially if it is abruptly, you may feel discontinuation symptoms. These are common when treatment with Escitalax is stopped. The risk is higher, when Escitalax has been used for a long time or in high doses or when the dose is reduced to 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 Escitalax, 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 (wivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling sick (nausea), sweating (including night sweats), feeling critiques and provided in the provided of some stated, feeling continuated or discrimitated, 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 medicine, ask your doctor or pharmacist.

Like all medicines, Escitalax 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 symptoms you should contact your doctor or go to the hospital straight away:

Uncommon (may affect up to 1 in 100 people):
- Unusual bleeds, including gastrointestinal bleeds

- Onusar Deeds, inclouding gasdionies and orecost
Rare (may affect up to 1 in 1000 people):
- Swelling of Skin, longue, lips, pharynx or face, hives or have difficulties breathing or swallowing (serious allergic reaction).
- High fever, agatiation, confusion, trembling and abrupt contractions of muscles these may be signs of a rare condition called serotonin syndrome.

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

- Difficulties urnating
- Seizures (fits), see also section 2 "Warnings and precautions"
- Vellowing 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
- Thoughts of harming or killing yourself, see also section 2 "warnings and precautions"
- Sudden swelling of skin or mucosa (angioedemas)

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

- readache
Common (may affect up to 1 in 10 people):
- Blocked or runny nose (sinustits)
- Decreased or increased appetite
- Anxiety, restlessness, abnormal dreams, difficulties falling asleep, feeling sleepy, dizziness, yawning, tremors, prickling of the skin
Diarrhoea, constituation, 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)
- Tatigue, (new - Increased weight
- Increased weight
- Increased weight

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

- Nettle rash (urticaria), rash, itching (pruritus)

- Grinding one's teeth, agriation, nervousness, panic attack, confusion
- Disturbed sleep, taste disturbance, fainting (syncope)
- Enlarged pupils (mydrasis), visual disturbance, ringing in the ears (tinnitus)
- Loss of hair

Enlarge person and the Constitution of the Con

Rare (may affect up to 1 in 1000 people):
- Aggression, depersonalisation, hallucination Aggression, depe

- Slow heart beat

Not known (frequency cannot be estimate 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 discorders (involuntary movements of the muscles)

- Painful erections (prajasim)

Signs of abnormal bleeding e.g. from skin and mucous membranes (ecchymosis)

- 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)

- Flow of milk in men and in women that are not nursing

- Mania

- An increased risk of hone fractures have been accounted.

Mania An increased risk of bone fractures has been observed in patients taking this type of medicines. Alternation 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 Escitalax).

The Addition restlessness (akathisia)
- Loss of appetite

Reporting of side effects
If you get any side effects, talk to your doctor, This includes any possible side effects not listed in this leaflet, You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine. 5. How to store Escitalax

Do not store above 30°C.
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 label or 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. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information What Escitalax contain

i**ns** De is escitalopram. Each tablet contains 10 mg of escitalopram (as escitalopram oxalate).

The other ingredients are:
- Tablet core: colloidal anhydrous silica, lactose monohydrate, povidone, microcrystalline cellulose, croscarmellose sodium, talc and magnesium stearate.
- Coating: hypromellose, titanium dioxide and Macrogol 400.

What Escitalax looks like and contents of the pack
The tablets are cylindrical, white, biconvex, scored and engraved with code ES1.
Escitalax is supplied in packs containing 28 tablets (7's blister x 4).

Marketing Authorisation Holder and Manufacturer Laboratorios Cinfa, S.A. Olaz-Chipi, 10. Polígono Industrial Areta 31620 Huarte-Pamplona (Navarra), Spain

This leaflet was last revised in 06/2019.

To Report any side effect(s):

The National Pharmacovigilance & Drug Safety Centre (NPC)
- Fax +966-11-205-762
- Call NPC at +966-11-205-822, tsts: 2317-2356-2353-2354-2334-2340.
- Toll free phone: 8002490000
- E-mail: npc.drug@sista.gov.sa
- Website: www.sida.gov.sa/npc

This is a Medicament

Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
The doctor and the pharmacist are the experts in medicines, their benefits and risks. Do not by yourself interrupt the period of treatment prescribe for you. Do not repeat the same prescription without consulting your doctor. Keep all medicaments out of reach of children.

Council of Arab Health Ministers Union of Arab Pharmacists







What is in this leaflet:

1. What Escitalax is and what it is used for

2. What you need to know before you take Escitalax

3. How to take Escitalax

4. Possible side effects

5. How to stree Escitalax

6. Content of the pack and other information

1. What Escitalax is and what it is used for

Escitalax contains the active substance escitalopram. Escitalax 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.

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

It may take a couple of weeks before you start to feel better. Continue to take Escitalax, even if it takes some tiem 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 Escita

- Do not take Escitalax If you are allergic to escitalopram or any of the other ingredients of this medicine (listed in you are ection 6).
- section 6).

 If you take other medicines which belongs 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 take medicines for heart rhythm groblems or that may affect the heart's rhythm (see section 2 "other medicines and Escitalax").

Warning and Precautions
Tell your doctor or pharmacist before taking Escitalax. 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 or pharmacist before taking Escitalax, Please tell your doctor if you have any other condition or liheases, as your doctor may need to take this into consideration. In particular, tell your doctor:

- If you have gitlepsy. Treatment with Escitalax should be stopped if seizures occur or if there is an increase in the seizure frequency (see also section 4 "Possible side effects").
- If you suffer from impained liver or kidney function. Your doctor may need to adjust your dosage.
- If you have diabetes. Treatment with Escitalax 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 decreased level of sodium in the blood.
- If you have a decreased level of sodium in the blood.
- If you have a tendency to easily develop bleedings or bruises.
- If you have comany heard disease.
- If you have a low resting heart-rate and/or you know that you may have salt depletion as a result of prolonged severe disrinces and vomiting (Bengis sick) or usage of diuretics (water fables).
- If you experience a fast or irregular heart hoat, fainting, collapse or dizziness on standing up, which may indicate abnormal functioning of the heart rate.
- If you have or have previously had eye problems, such as certain kinds of glaucoma (increased pressure in the eye).

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 to in sitting or standing still can also occur during the first weeks of the treatment. Tell your doctor immediately if you experience these symptoms. Medicines like Escitalax (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping 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.

Use in children and adolescents

Use in children and adolescents
Escialas 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, suicida
know that patients under 18 have an increased risk of side effects such as suicide attempts, suicida
thoughts and hostility (predominately aggression, oppositional behaviour and anger) when they take
this class of medicines. Despite this, your doctor may prescribe Escitalax for patients under 18
because heishe decides that this is in their best interest, if your doctor has prescribed Escitalax for a patient under 18 and you want to discuss this, please glo back to your doctor, You should inform your doctor if any symptoms listed above develop or worsen when patients under 18 are taking Escitalax,
Also, the long term safety effects concerning growth, maturation and cognitive and behavioural
development of Escitalax in this age group have not yet been demonstrated.

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

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

 "Non-selective monoamine oxidase inhibitors (MAOIsi"), 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 sart taking Escitalax. After stopping Escitalax ou must allew 7 days before taking any of these medicines you will need to wait 14 days before you sart taking Escitalax. After stopping Escitalax ou must allew 7 days before taking any of these medicines you will need to wait 14 days before you sart taking Escitalax. After stopping Escitalax ou must allew 7 days before taking any of these medicines (used to treat depression).

 "Inversible MAO-8 inhibitors", containing selegiline (used to treat depression).

 "Inversible MAO-8 inhibitors", containing selegiline (used to treat depression).

 "Internation of the depression of the selection of th

To not take Escitalax 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. phenothizane dervatives, pimozide, haloperdoll, ricyclic 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.

Escitalax with food, drink and alcohol Escitalax can be taken with or without food (see section 3 "How to take Escitalax").

As with many medicines, combining Escitalax with alcohol is not advisable, although Escitalax is not expected 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 taking this medicine. Do not take Escitalax if

If you take Escitalax during the last 3 months of your pregnancy you should be aware that the following effects may be seen in your newborn baby: thouble with breathing, blush skin, fits, body temperature changes, feeding difficulties, wornting, low blood sugar, stiff or floopy muscles, wind reflexes, trenor, filterness, initability, lethargy, constant crying, sleepiness and sleeping difficulties. If your newborn baby has any of these symptoms, passe confact your doctor immediately and the summary of the symptoms, passe confact your doctor immediately and the symptoms, passe confact your doctor immediately and the symptoms, passe confact your doctor immediately and the symptoms of the symptoms

Make sure your midwife and/or doctor know you are on Escitalax. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Escitalax 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 Escitalax 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**You are advised not to drive a car or operate machinery until you know how Escitalax affects you.

3. How to take Escitalax

Always take Escitalax exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The normally recommended dose of Escitalax 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 Escitalax 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 Escitalax 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 Escitalax 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 Escitalax 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 Escitalax is 5 mg taken as one daily dose. The dose may be increased by your doctor to 10 mg per day.

Use in children and adolescents
Escitalax should not normally be given to children and adolescents. For further information please see section 2 "Warnings and precautions".

You can take Escitalax 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.



Duration of treatment
It may take a couple of weeks before you start to feel better. Continue to take Escitalax 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 Escitalax 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 soon, your symptoms may return. It is r least 6 months after you feel well again. least 6 months arrer you reen wern agenn. If you take more Escitalax than you should If you take more Escitalax than you should If you take more than the prescribed dose of Escitalax, contact your doctor 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 dizzness, temora, agaitation, comvision, coma, neases, womiting, change in heart rhythm, decreased blood pressure and change in body fluid/salt balance. Take the Escitalax bow/container with you when you go to the doctor or hospital.

If you forget to take Escitalax

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.

If you stop taking Escitalax
Do not stop taking Escitalax until your doctor tells you to do so. When you have completed your
course of freatment, it is generally advised that the dose of Escitalax is gradually reduced over
a number of weeks.

When you stop taking Escitalax, especially if it is abruptly, you may feel discontinuation symptoms. These are common when treatment with Escitalax is stopped. The risk is higher, when Escitalax 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 most) or more). If you get severe discontinuation symptoms when you stop taking Escitalax, 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 (wid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling sick (nausea), sweating (including night sweats), feeling restless or agitated, termor (shakiness), feeling confused or discrientated, feeling emotional or initable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (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. Escitalax 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 symptoms you should contact your doctor or go to the hospital straight away:

Uncommon (may affect up to 1 in 100 people): - Unusual bleeds, including gastrointestinal bleeds

- Orusian breess, including gastuminestimal breess
Rare (may affect up to 1 in 1000 people):
- Swelling of skin, tongue, lips, pharynx or face, hives or have difficulties breathing or swallowing (serious allergic reaction).
- High Tever, agitation, confusion, trembling and abrupt contractions of muscles these may be signs of a rare condition called serotonin syndrome.

signs or a rare conotion called serotonin syndrome.

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

- Difficulties unroating

- Seizures (fits), see also section 2 "Warnings and precautions"

- 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

- Thoughts of harming or killing yourself, see also section 2 "warnings and precautions"

- Sudden swelling of skin or mucosa (angioedemas)

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

- Headache

Common (may affect up to 1 in 10 people):
- Blocked or runny nose (sinusitis)
- Decreased or increased appetite
- Anxiety, restlessness, shormal dreams, difficulties falling asleep, feeling sleepy, dizziness, vanning, tremors, prickling of the skin
- Diarrhose, constipation, womiting, dry mouth
- Increased sweating
- Pain in muscle and joints (arthralgia and myalgia)
- Sexual disturbances (delayed ejeculation, problems with erection, decreased sexual drive and women may experience difficulties achieving orgasm)
- Fatigue, I even

Fatigue, fever Increased weight

- Increases weight
- Increases weight
- Nettle rash (urticaria), rash, itching (pruntus)
- Nettle rash (urticaria), rash, itching (pruntus)
- Grinding one's teeth, agitation, nervousness, panic attack, confusion
- Disturbed sepen, taste disturbance, rainting (syncope)
- Enlarged pupils (mydrasis), visual disturbance, ringing in the ears (tinnitus)
- Loss of hair
- Excessive menstrual bleeding
- Irregular menstrual period
- Decreased weight
- Fast heart beat
- Swelling of the arms or legs
- Nosebleeds

Rare (may affect up to 1 in 1000 people):
- Aggression, depersonalisation, hallucination
- Slow heart beat

Not known (frequency cannot be estimate 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 (organism)

Movement disorders (involuntary movements of the muscles)
Painful erections (prippism)
Signs of abnormal bleeding e.g. from skin and mucous membranes (ecchymosis)
Increased secretion of a hormône called ADH, causing the body to retain water and dilute the
blood, reducing the amount of sodium (inappropriate ADH secretion)
Flow of milk in men and in women that are not nursing
Mania
An increased risk of hone fractures has been observed in nations taking this type of medicines

Wania An increased risk of bone fractures has been observed in patients taking this type of medicines. Alternation 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 Escitalax).

These are:

- Motor restlessness (akathisia)
- Loss of appetite

Reporting of side effects
If you get any side effects, talk to your doctor, This includes any possible side effects not listed in
this leaflet. You can also report side effects directly (see details below). By reporting side effects,
you can help provide more information on the safety of this medicine.

Do not store above 30°C. 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 label or 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. Ask your pharmacist how to throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information What Escitalax contains
The active substance is escitalopram. Each tablet contains 20 mg of escitalopram (as escitalopram oxalate).

The other ingredients are:

- Tablet core: colloidal anhydrous silica, lactose monohydrate, povidone, microcrystalline celluluse, croscarmellose sodium, talc and magnesium stearate.

- Coating: hyprometose, titanium dioxide and Macrogol 400. What Escitalax looks like and contents of the pack
The tablets are cylindrical, white, biconvex, scored and engraved with code ES3.
Escitalax is supplied in packs containing 28 tablets (7's blister x 4).

Marketing Authorisation Holder and Manufacturer Laboratorios Cinfa, S.A. Olaz-Chipi, 1.O. Poligono Industrial Areta 31620 Huarte-Pamplona (Navarra), Spain

This leaflet was last revised in 06/2019.

To Report any side effect(s):

The National Pharmacovigilance & Drug Safety Centre (NPC)
- Fax: +966-11-205-7662
- Call NPC at +966-11-205-8222, tsts: 2317-2356-2353-2354-2334-2340.
- Toll free phone: 800,2490,000
- E-mail: npc.drug@stda.gov.sa
- Website: www.stda.gov.sa/npc

This is a Medicament

Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

pharmacist who sold the medicament.

The doctor and the pharmacist are the experts in medicines, their benefits and risks.

Do not by yourself interrupt the period of treatment prescribed for you.

Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of reach of children.



Council of Arab Health Ministers Union of Arab Pharmacists



