

Package leaflet: Information for the user

Etalopro Melts 5 mg orodispersible tablets
Etalopro Melts 10 mg orodispersible tablets
Etalopro Melts 15 mg orodispersible tablets
Etalopro Melts 20 mg orodispersible tablets

Escitalopram

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

1. What Etalopro Melts is and what it is used for

Etalopro Melts contains the active substance escitalopram. Etalopro Melts 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.

Etalopro Melts 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 Etalopro Melts, 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 Etalopro Melts

Do not take Etalopro Melts:

- 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 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 take medicines for heart rhythm problems or that may affect the heart's rhythm (see section 2 "Other medicines and Etalopro Melts").

Warnings and precautions

Talk to your doctor or pharmacist before taking Etalopro Melts. 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 Etalopro Melts 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 Etalopro Melts 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 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 heartbeat, 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 sit or stand 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.**

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

Etalopro Melts 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 Etalopro Melts for patients under 18 because he/she decides that this is in their best interest. If your doctor has prescribed Etalopro Melts 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 Etalopro Melts. Also, the long term safety effects concerning growth, maturation and cognitive and behavioural development of Etalopro Melts in this age group have not yet been demonstrated.

Other medicines and Etalopro Melts

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 Etalopro Melts. After stopping Etalopro Melts 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), 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 thin the blood, so called anti-coagulant). Your doctor will probably check the coagulation time of your blood when starting and discontinuing Etalopro Melts in order to verify that your dose of anti-coagulant is still adequate;
- Mefloquin (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 (tricyclic antidepressants and SSRIs) due to a possible risk of a lowered threshold for seizures;
- Flecainide, propafenone and metoprolol (used in cardiovascular diseases), clomipramine and nortriptyline (antidepressants) and risperidone, thioridazine and haloperidol (antipsychotics). The dosage of Etalopro Melts 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 Etalopro Melts 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.

Etalopro Melts with food, drink and alcohol

Etalopro Melts should be taken without food (see section 3 "How to take Etalopro Melts").

As with many medicines, combining Etalopro Melts with alcohol is not advisable, although Etalopro Melts 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 Etalopro Melts if you are pregnant or breast-feeding, unless you and your doctor have discussed the risks and benefits involved.

If you take Etalopro Melts 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, vivid 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 midwife and/or doctor know you are on Etalopro Melts. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Etalopro Melts 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 Etalopro Melts should never be stopped abruptly.

It is expected that Etalopro Melts 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 Etalopro Melts affects you.

Etalopro Melts contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

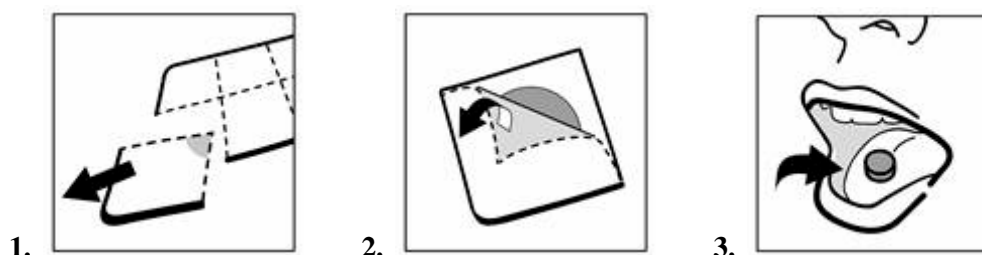
3. How to take Etalopro Melts

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

Etalopro Melts orodispersible tablets are taken every day as a single daily dose. You should take Etalopro Melts without food.

Etalopro Melts orodispersible tablets break easily, so you should handle the tablets carefully. Do not handle the tablets with wet hands as the tablets may break up.

1. Hold the blister strip at the edges and separate one blister cell from the rest of the strip by gently tearing along the perforations around it.
2. Carefully peel off the backing.
3. Place the tablet on your tongue. The tablet will rapidly disintegrate and can be swallowed without water.



<For MSs where 5 mg and 15 mg are not registered:>

Etalopro Melts is not suitable for all dosages described below. For these dosages, you should take other medicinal products available on the market. Ask your doctor or pharmacist.

Adults

Depression

The normally recommended dose of Etalopro Melts 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 Etalopro Melts 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 Etalopro Melts 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 Etalopro Melts 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 Etalopro Melts 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 Etalopro Melts 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

Etalopro Melts should not normally be given to children and adolescents. For further information please see section 2 “What you need to know before you take Etalopro Melts”.

Duration of treatment

It may take a couple of weeks before you start to feel better. Continue to take Etalopro Melts 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 Etalopro Melts 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 Etalopro Melts than you should

If you take more than the prescribed dose of Etalopro Melts, 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 dizziness, tremor, agitation, convulsion, coma, nausea, vomiting, change in heart rhythm, decreased blood pressure and change in body fluid/salt balance. Take the Etalopro Melts carton with you when you go to the doctor or hospital.

If you forget to take Etalopro Melts

Do not take a double dose to make up for a forgotten dose. 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 Etalopro Melts

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

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

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

- Swelling of skin, tongue, lips, or face, or have difficulties breathing or swallowing (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 heart beat, fainting which could be symptoms of a life-threatening condition known as Torsade de Pointes
- Thoughts of harming yourself or killing yourself, see also section “Warnings and precautions”

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, 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 women may experience difficulties achieving orgasm)
- Fatigue, fever
- Increased weight

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

- Nettle rash (urticaria), rash, itching (pruritus)
- Grinding one’s teeth, agitation, nervousness, panic attack, confusion
- Disturbed sleep, taste disturbance, fainting (syncope)
- Enlarged pupils (mydriasis), 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 1,000 people):

- Aggression, depersonalisation, hallucination
- Slow heart beat

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)
- Signs of increased bleeding e.g. from skin and mucous (ecchymosis)

- Sudden swelling of skin or mucosa (angioedemas)
- Increase in the amount of urine excreted (inappropriate ADH secretion)
- Flow of milk in men and in women that are not nursing
- Mania
- An increased risk of bone fractures has been observed in patients taking this type of medicines.
- Alteration of the heart rhythm (called “prolongation of QT interval”, seen on ECG, 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 Etalopro Melts). These are:

- Motor restlessness (akathisia)
- Loss of appetite

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Etalopro Melts

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 carton and blister foil after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions; store in the original package in order to protect from light and moisture.

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

6. Contents of the pack and other information

What Etalopro Melts contains

- The active substance is escitalopram.
Etalopro Melts 5 mg: Each orodispersible tablet contains 5 mg escitalopram equivalent to 6.3875 mg escitalopram oxalate.
Etalopro Melts 10 mg: Each orodispersible tablet contains 10 mg escitalopram equivalent to 12.775 mg escitalopram oxalate.
Etalopro Melts 15 mg: Each orodispersible tablet contains 15 mg escitalopram equivalent to 19.1625 mg escitalopram oxalate.
Etalopro Melts 20 mg: Each orodispersible tablet contains 20 mg escitalopram equivalent to 25.55mg escitalopram oxalate.
- The other ingredients are: cellulose, microcrystalline, lactose monohydrate, croscarmellose sodium, polacrillin potassium, acesulfame potassium, neohesperidine-dihydrochalcone, magnesium stearate, peppermint flavor [containing Maltodextrin (maize), Modified starch E1450 (waxy maize) and Peppermint oil (mentha arvensis)], hydrochloric acid, concentrated (for pH adjustment).

What Etalopro Melts looks like and contents of the pack

Etalopro Melts 5 mg: white to off-white round, flat tablets with beveled edges, a diameter of 7 mm and engraved with “5” on one side.

Etalopro Melts 10 mg: white to off-white round, flat tablets with beveled edges, a diameter of 9 mm and engraved with “10” on one side.

Etalopro Melts 15 mg: white to off-white round, flat tablets with beveled edges, a diameter of 11 mm and engraved with “15” on one side.

Etalopro Melts 20 mg: white to off-white round, flat tablets with beveled edges, a diameter of 12 mm and engraved with “20” on one side.

Etalopro Melts orodispersible tablets are available in cartons containing
5 mg: 10, 28, 30, 50, 90 orodispersible tablets

10 mg: 10, 28, 30, 50, 90, 100 orodispersible tablets

15 mg: 28, 30, 50, 90 orodispersible tablets

20 mg: 10, 28, 30, 50, 90 orodispersible tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

Genepharm S.A., 18th km Marathonos Ave, Pallini Attiki, 15351, Greece

Pharmadox Healthcare Ltd, KW20A Kordin Industrial Park, Paola, PLA 3000, Malta

STADA Arzneimittel AG, Stadastrasse 2–18, 61118 Bad Vilbel, Germany

STADA Arzneimittel GmbH, Muthgasse 36, 1190 Wien, Austria

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Centrafarm Services B.V., Nieuwe Donk 9, 4879 AC Etten-Leur, The Netherlands

Rontis Hellas S.A., Medical and Pharmaceutical Products, Industrial Area of Larissa, P.O. Box 3012, GR41004 Larissa, Greece

This medicinal product is authorised in the Member States of the EEA under the following names:

PT: Escitalopram STADA

AT: Escitalopram STADA 5 mg, 10 mg, 20 mg schmelztabletten

IE: Etalopro Melts 5 mg, 10 mg, 15 mg, 20 mg orodispersible tablets

NL: Escitalopram CF 5 mg, 10 mg, 15 mg, 20 mg, orodispergeerbare tabletten

SI: Escitalopram STADA 10 mg, 20 mg orodisperzibilne tablete

This leaflet was last revised in April 2014.