PACKAGE LEAFLET: INFORMATION FOR THE USER
Escitalpro 5 mg film-coated tablets
Escitalpro 10 mg film-coated tablets
Escitalpro 20 mg film-coated 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. 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

What is in this leaflet

1. WHAT ESCITALPRO IS AND WHAT IT IS USED FOR
Escitalpro belongs to a group of medicines called Selective .Serotonin Re-uptake Inhibitor (SSRI) antidepressants. 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.
Escitalpro can be given to treat the following conditions
- depression (major depressive episodes
- panic disorder which may or may not be associated with agoraphobia (fear of open spaces)
- Social anxiety disorder
- Generalised anxiety disorder
- Obsessive-compulsive disorder

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ESCITALPRO
Do not take Escitalpro:
- if you are allergic (hypersensitive) to escitalopram or any of the other ingredients of Escitalpro (see section 6 (“Further information”)
- if you take other medicines that 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 Escitalpro)

Warnings and precautions
Talk to your doctor or pharmacist before taking Escitalpro:
- if you suffer from impaired liver or kidney function. Your doctor may need to adjust your dosage
- if you are elderly
- if you have epilepsy or have a history of fits (seizures). Treatment with Escitalpro should be stopped if seizures occur for the first time, or if there is an increase of seizure frequency (see also section 4 “Possible side effects")
- if you are receiving electro-convulsive therapy (ECT)
- if you have a tendency to easily develop bleeding or bruises
- if you suffer from diabetes. Treatment with Escitalpro may alter glycaemic control (control of blood sugar levels). Your dosage of Insulin and/ or oral hypoglycaemic medicine may need to be adjusted
- if you have a decreased level of sodium in the blood
- 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 suffer from glaucoma (increased pressure in the eye)

Please note

Some patients with manic-depressive illness may enter into a manic phase. The symptoms of this may be unusual and rapidly changing ideas, feeling unusually happy for no reason and excessive physical activity. If you experience this, contact your doctor.

You may experience symptoms such as restlessness or difficulty in sitting or standing still 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.

Use in children and adolescents under 18 years of age

Escitalpro **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 (predominantly aggression, oppositional behaviour and ,anger) when they take this class of medicines. Despite this, your doctor may prescribe Escitalpro for patients under 18 because he/she decides that this is in their best interest. If your doctor has prescribed Escitalpro 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 get worse when patients under 18 are taking Escitalpro. Also, the long term safety effects of Escitalpro concerning growth, maturation and cognitive and behavioural development in this age group have not yet been demonstrated.

Other medicines and Escitalpro

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is especially important to tell your doctor if you are using some of the following medicines:

- '(non-selective monoamine oxidase inhibitors (MAOI's) containing phenelzine, iproniazid, isocarboxazid, nialamide and tranylcypromine as active ingredients (used to treat depression). If you have taken any of these medicines you will need to wait 14 days before you start taking Escitalpro. After stopping Escitalpro you must allow 7 days before taking any of these medicines.
- reversible, selective MAO-A inhibitors, containing (moclobemide (used to treat depression)
- linezolid (an antibiotic)
- irreversible MAO-B inhibitors, containing selegiline (used to treat Parkinson's disease). These increase the risk of side effects
- sumatriptan and similar medicines (used to treat migraine) and tramadol (used against severe pain).These increase the risk of side effects.
- cimetidine, omeprazole and lansoprazole (used to treat stomach ulcers), fluvoxamine (antidepressant) and ticlopidine (used to reduce the risk of stroke). These may cause increased blood levels of Escitalpro
- St. John's Wort (Hypericum perforatum) – herbal remedy used for depression
- lithium or tryptophan (used for depression) as these may increase the effect of Escitalpro
- acetylsalicylic acid (aspirin) (used for pain relief or to thin the blood) and non-steroidal anti-inflammatory drugs (NSAIDs) (medicines used for pain relief). These may increase bleeding-tendency.
- warfarin, dipyridamole, phenprocoumon or other anticoagulants (medicines used to thin the blood). Your doctor will probably check the coagulation time of your blood when starting and discontinuing Escitalpro to make sure that your dose of anti-coagulant is still adequate.
- mefloquin (used to treat malaria), bupropion (used when trying to stop smoking or to treat depression) and tramadol (used to treat severe pain) due to a possible risk of a lowered threshold for seizure (fits).
- neuroleptics (medicines to treat schizophrenia, psychosis) and antidepressants and other SSRI's due to a possible risk of a lowered threshold for seizures.
- flecainide, propafenone and metoprolol (used in cardio-vascular diseases) and imipramine, desipramine, clomipramine and nortriptyline (used to treat depression) and risperidone, thioridazine and haloperidol (antipsychotics). Your dosage of Escitalpro .may need to be adjusted
- medicines that induce low potassium levels in the blood (hypokalaemia) or low magnesium levels in the blood (hypomagnesaemia).

Do not take Escitalpro if you take medicines for heart rhythm problems or medicines that may affect the heart's rhythm, such as Class IA and III antiarrhythmics, antipsychotics (e.g. phenothiazine derivatives, pimozide,

haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarial treatment particularly halofantrine), certain antihistamines (e.g. astemizole mizolastine). If you have any further questions about this you should speak to your doctor.

Escitalpro with food, drink and alcohol

Escitalpro can be taken with or without food (see section 3 “How to take Escitalpro")

You **should avoid** alcohol while you are taking this medicine.

Pregnancy, breastfeeding 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.

Pregnancy

Tell your doctor if you are pregnant or planning to get pregnant. **Do not** take Escitalpro if you are pregnant unless you and your doctor have discussed the risks and benefits involved. You **should not** discontinue treatment with Escitalpro abruptly.

Make sure your midwife and/or doctor know you are on Escitalpro. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Escitalpro ,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. Other symptoms that may occur when Escitalpro is used in the late stages of pregnancy might include not being able to sleep or feed properly, being too hot or cold, being sick, crying a lot, vomiting, low blood sugar, stiff or floppy muscles, irritability, lethargy, tremors, jitters or fits. If your baby has any of these symptoms when it is born, talk to your doctor immediately who will be able to advise you.

Breast-feeding

Tell your doctor if you are breast-feeding. Escitalpro is likely to pass into breast milk. Do not breast-feed if you are taking Escitalpro. Your doctor will decide whether you /should continue/discontinue breast-feeding or continue discontinue the therapy with Escitalpro.

Fertility

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 use machines until you know how Escitalpro affects you.

Escitalpro contains lactose

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

3. HOW TO TAKE ESCITALPRO

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Remember that you may need to take Escitalpro tablets for 2 or more weeks before you begin to feel better.

Adults

Depression –

The recommended dose is 10 mg of Escitalpro a day. Your doctor may increase this dose to a maximum of 20 mg a day. It may take 2 to 4 weeks before you start to feel better. Treatment should last for at least 6 months after you feel better.

Panic disorder - The recommended starting dose is 5 mg of Escitalpro a day. After the first week, this dose may be increased by your doctor to 10 mg a day, and if necessary up to a maximum dose of 20 mg a day. The maximum effect is reached after 3 months.

Social anxiety disorder - The recommended dose is 10 mg of Escitalpro a day. It may take 2 - 4 weeks before you start to feel better. After this your dose may be lowered to 5 mg per day or increased to 20 mg per day, depending on how well the treatment is working. Normally a treatment course of 12 weeks is recommended.

Generalised anxiety disorder - The recommended dose is 10 mg of Escitalpro a day. Your doctor may increase this dose to a maximum of 20 mg a day. Your doctor should review your dose regularly.

Obsessive-compulsive disorder - The recommended dose is 10 mg of Escitalpro a day. Your doctor may increase this dose to a maximum of 20 mg a day. Your doctor should review your dose regularly.

Elderly patients (above 65 years of age)

Your doctor will give you a lower dose to that stated above, as elderly patients may be more sensitive to the effects of Escitalpro. The recommended starting dose of Escitalpro 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 (below 18 years of age)

Escitalpro should not normally be given to children and adolescents under the age of 18. For further information please see section 2 “What you need to know before you take Escitalpro".

If you have liver or severe kidney problems, your doctor will give you a lower dose than stated above.

You can take Escitalpro with or without food. Swallow the tablet with some water. Do not chew them, as the taste is bitter.

Keep on taking your tablets for as long as your doctor recommends, even after you start to feel better. This should be for at least three to six months after you recover to stop your symptoms coming back.

The 10 mg, 15 mg and 20 mg tablet can be divided into equal doses.

If you take more Escitalpro than you should

Contact your doctor or nearest hospital casualty department immediately. Do this even if there are no signs of discomfort. Some of the signs of overdose could be dizziness, shaking, agitation, convulsion, coma, feeling and being sick, change in heart rhythm (slower or faster heartbeat), decreased blood pressure and change in body fluid/salt balance. Take the container and any remaining tablets with you when you go to the doctor or hospital.

If you forget to take Escitalpro

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 Escitalpro

Do not stop taking Escitalpro until your doctor tells you to do so. When you have completed your course of treatment, it is generally advised that the dose of Escitalpro is gradually reduced over a number of weeks.
When you stop taking Escitalpro, especially if it is abruptly you may feel discontinuation symptoms. These are common when treatment with Escitalpro is stopped. The risk is higher, when Escitalpro 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 Escitalpro, 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 and 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.

See your doctor if you get any of the following side effects during treatment:

Unusual bleeds, including gastrointestinal bleeds
If you experience swelling of skin, tongue, lips, or face, or have difficulties breathing or swallowing (allergic reaction), contact your doctor or go to a hospital straight away.
If you have a high fever, agitation, confusion, trembling and abrupt contractions of muscles these may be signs of a rare condition called serotonin syndrome. If you feel like this contact your doctor.
If you experience the following side effects you should contact your doctor or go to the hospital straight away:

- difficulties urinating
- 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 Torsades de Pointes.

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

Very common may affect more than 1 in 10 people

- headache
- feeling sick (nausea)

Common may affect up to 1 in 10 people

- lack of appetite
- increased appetite
- weight increase
- feeling anxious or restless
- difficulty falling asleep
- feeling sleepy
- abnormal dreams
- tingling or numbness of the hands and feet
- shaking
- feeling dizzy
- yawning
- inflamed swollen sinuses causing pain, high temperature, tenderness (known as sinusitis)
- diarrhoea
- constipation
- vomiting
- dry mouth
- increased sweating

- fever
- muscle or joint pain
- feeling unusually tired
- sexual problems (delayed ejaculation, problems with erection, decreased sexual drive and women may experience difficulties achieving orgasm).

Uncommon may affect up to 1 in 100 people
- decreased weight
- feeling confused
- agitated
- nervous
- grinding teeth while asleep
- panic attack
- taste disturbance
- change in your sleep pattern
- fainting
- enlarged pupils (mydriasis), visual disturbance
- ringing in the ears (tinnitus)
- fast heart beat
- nose bleed
- bleeding from the gut including the rectum seen as blood in the stools
- hair loss
- nettle rash or hives
- rash
- itchy skin
- heavy periods or bleeding between periods
- excessive fluid in the body

Rare may affect up to 1 in 1,000 people
- feeling aggressive or detached from yourself
- hallucinations
- slow heart beat

Some patients have reported (frequency cannot be estimated from the available data)
- thrombocytopenia (reduction in blood platelets which increases risk of bleeding and bruising)
- increased levels of a hormone (ADH) leading to fluid or water retention
- a lower than normal level of sodium in the blood making you feel weak and confused with aching
- mania (feeling elated or over-excited, which causes unusual behaviour)
- thoughts of harming yourself or thoughts of killing yourself, see also section 2 “Warnings and precautions"
- abnormal muscle movements
- convulsions
- dizziness when you stand up due to low blood pressure (orthostatic hypotension)
- changes to the results of liver enzyme tests
- persistent painful erection of the penis
- abnormal production of milk from the breasts in men
- an increased risk of bone fractures has been observed in patients taking this type of medicine
- alteration of “the heart rhythm (called “prolongation of QT interval seen on ECG, electrical activity of the heart)

In addition, **other** side effects are known to occur with drugs that work in a similar way as Escitalpro.
These are:
- restlessness or difficulty sitting still (psychomotor restlessness/akathisia)
- anorexia

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

Store below 25 °C.
Store in the original package.
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 Escitalpro contains

The active substance is escitalopram. One tablet contains 5 mg, 10 mg or 20 mg of escitalopram (as oxalate).
The other ingredients are;
Tablet core: microcrystalline cellulose, colloidal anhydrous silica, talc, croscarmellose sodium and magnesium stearate.
The coating contains lactose monohydrate, macrogol 4000, titanium dioxide (E171) and hypromellose

What Escitalpro looks like and contents of the pack

Escitalpro is a film-coated tablet.
The 5mg film-coated tablets are white, round and marked 'EC 5' on one side and ‘G’ on the other side.
The 10mg film-coated tablets are white, oblong, scored and marked with 'EC/10' on one side and 'G' on the other. The tablet can be divided into equal halves.
The 20mg film-coated tablets are white, oblong, scored .and marked with 'EC/20' on one side and 'G' on the other. The tablet can be divided into equal halves.
Escitalpro is available in packs of 28 film-coated tablets.

Product procured from within the EU by the Parallel Product Authorisation Holder:
WPR Healthcare Limited, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.
Product repackaged and distributed by:
PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

Parallel Product Authorisation Numbers:

Escitalpro 5mg	PPA 565/55/1
Escitalpro 10mg	PPA 565/55/2
Escitalpro 20mg	PPA 565/55/3

Manufacturer: Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

This leaflet was prepared by PCO Manufacturing: May 2015

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

Austria:	Escitalopram Arcana 5mg Filmtabletten, Escitalopram Arcana 10mg Filmtabletten, Escitalopram Arcana 15mg Filmtabletten. Escitalopram Arcana 20mg Filmtabletten.
Czech Republic:	Escitalopram Mylan
Denmark:	Escitalopram Mylan
Finland:	Escitalopram Mylan
Greece:	ESCITALOPRAM/GENERICS
Hungary:	Escigen
Ireland:	Escitalpro 5mg Film-coated Tablets Escitalpro 10mg Film-coated Tablets Escitalpro 15mg Film-coated Tablets Escitalpro 20 mg Film-coated Tablets
Norway:	Escitalopram Mylan
Poland:	PramoGen
Portugal:	Escitalopram Mylan
Slovakia:	Escitalopram Generics 10mg
Slovenia:	Escitalopram Mylan 5mg filmsko obložene tablete, Escitalopram Mylan 10mg filmsko ,obložene tablete
Spain:	Escitalopram Mylan 5mg comprimidos recubiertos con pelicula, Escitalopram Mylan 10mg comprimidos recubiertos con pelicula, Escitalopram Mylan 15mg ,comprimidos recubiertos con pelicula Escitalopram Mylan 20mg comprimidos recubiertos con pelicula