# Package Leaflet: Information for the User

**[Nationally approved name] 5 mg film-coated tablets**
**[Nationally approved name] 10 mg film-coated tablets**
**[Nationally approved name] 20 mg film-coated tablets**

Active substance: Escitalopram (as oxalate)

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**



## 1. What [Nationally approved name] is and what it is used for

[Nationally approved name] contains escitalopram and is used to treat

- **depression** (major depressive episodes) and

- **anxiety disorders** (such as panic disorder with or without agoraphobia (e.g. fear of leaving the house, entering shops, being amongst crowds of people and in public places), social anxiety disorder, generalised anxiety disorder and obsessive-compulsive disorder).

Escitalopram 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.

It may take a couple of weeks before you start to feel better. Continue to take [Nationally approved name], 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 [Nationally approved name]

**Do not take [Nationally approved name]**

– 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 monoamine oxidase (MAO) inhibitors, like selegiline (used in the treatment of Parkinson's disease), moclobemide (for treatment of depression) and linezolid (for treatment of bacterial infections) (see section 2 "Taking other medicines").

– 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 medicines that may affect the heart's rhythm (see section 2 "Taking other medicines").

**Warnings and precautions**

Talk to your doctor before taking [Nationally approved name].
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** or have suffered seizures in the past. Treatment with [Nationally approved name] 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 function**. Your doctor may need to adjust your dosage.

– if you suffer from **impaired kidney function**. Your doctor may need to adjust your dosage.

– if you have **diabetes**. Treatment with [Nationally approved name] may alter glycaemic control (the level of sugar in the blood). Insulin and/or oral hypoglycaemic dosage may need to be adjusted.

– if you **tend to easily develop bleeding or bruising**, or if you are taking medicines which influence coagulation (blood clotting), such as acetylsalicylic acid (a painkiller), non-steroidal anti-inflammatory drugs (painkillers), certain medicines used to treat psychological disorders (atypical antipsychotics and phenothiazine), and most tricyclic antidepressants. The risk is also increased if, during treatment, you also take ticlopidine or dipyridamole (both of which are used to reduce the risk of thrombosis), or oral anticoagulants (medicines used to stop the blood clotting).

– if you are receiving **electroconvulsive treatment**.

– if you have **coronary heart disease**.

– if you have suffered **mania/hypomania** in the past (pathological highs). A manic phase is characterised by effusive and rapidly alternating thoughts, exaggerated cheerfulness and excessive physical activity. If you believe that you are in an acute manic phase, it is essential that you consult your doctor.

– if you have suffered **psychological disorders** from time to time (delusions, hallucinations, severe thought disturbances, abnormal mood swings or abnormal conduct).

– 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** (decreased level of sodium in the blood) 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 previously had eye problems, such as certain kinds of glaucoma (increased pressure in the eye).

**Please note**
As with other medicines used to treat depression or related diseases, the improvement is not achieved immediately. **After the start of [Nationally approved name] treatment it may take several weeks before you experience any improvement.** In the treatment of **panic disorder** it usually takes **2-4 weeks** before any improvement is seen. At the beginning of the treatment certain patients may experience **increased anxiety**, which will disappear during the continued treatment. Therefore, it is very important that you follow exactly your doctor's orders and do not stop the treatment or change the dose without consulting your doctor.

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.

**Thoughts of suicide and worsening of your depression or anxiety disorder**
If you are depressed or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. Such ideas 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 young 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.

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

Caution is advised if, at the same time as taking [Nationally approved name], you take other medicines which have a serotonergic effect (such as sumatriptan and other triptans, tramadol or tryptophan). **Serotonin syndrome** may occur in rare cases, and has been seen not only in combination with serotonergic agents but also very rarely in patients using selective serotonin re-uptake inhibitors (SSRIs). If you notice symptoms such as a high fever, muscle twitching, absent-mindedness, restlessness, jitteriness or chills, please tell your doctor without delay. If any of these symptoms occur, you should stop the treatment with [Nationally approved name] and the serotonergic medication immediately and notify a doctor who can initiate treatment straight away to deal with the symptoms.

The simultaneous use of [Nationally approved name] and products containing **St John's Wort** (*Hypericum perforatum*) should be avoided since there is a greater likelihood of side effects in such a case (see section 2 "Taking other medicines").

When **discontinuing treatment with [Nationally approved name]**, the dosage of [Nationally approved name] should be gradually reduced over a period of one to two weeks in order to avoid discontinuation symptoms (see section 3 "How to take [Nationally approved name]").

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

**Other medicines and [Nationally approved name]**

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

The following medicines may influence the effect of [Nationally approved name], or their effect may be influenced by [Nationally approved name]. Tell your doctor if you are taking any of the following medicines:

- "Non-selective monoamine oxidase inhibitors (MAOIs)", containing phenelzine, iproniazid, isoniacide, isocarboxazid, nialamide, and tranylcypromine as active ingredients, amongst others. These may not be taken in combination with [Nationally approved name]. Combined use can result in severe side effect, including serotonin syndrome (see section 2 "Do not take [Nationally approved name]" and section 4 "Possible side effects"). If you have taken any of these medicines you will need to wait 14 days before you start taking [Nationally approved name]. After stopping [Nationally approved name] you must allow 7 days before taking any of these medicines.

- "Reversible, selective MAO-A inhibitors", e.g. containing moclobemide (used to treat depression), may not or rather under accurate monitoring of the attending doctor be used in combination with [Nationally approved name]. These increase the risk of serotonin syndrome (see section 2 "Do not take [Nationally approved name]").

- "Irreversible MAO-B inhibitors", e.g. containing selegiline (used to treat Parkinson's disease), may not or rather under accurate monitoring of the attending doctor be used in combination with [Nationally approved name]. These increase the risk of serotonin syndrome (see section 2 "Do not take [Nationally approved name]").

- The antibiotic Linezolid, a reversible, non-selective MAO-A inhibitor, may not or rather under accurate monitoring of the attending doctor be used in combination with [Nationally approved name]. The risk of side effects like serotonin syndrome is increased (see section 2 "Do not take [Nationally approved name]").
- 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). These medicines may not be taken in combination with [Nationally approved name]. If you have any further questions about this you should speak to your doctor.

- Lithium (used in the treatment of manic-depressive disorder) and tryptophan (a food supplement which is converted into serotonin).

- Imipramine and desipramine (both used to treat depression).

- Sumatriptan and other triptans (used to treat migraine), and tramadol (used against severe pain). These increase the risk of side effects such as serotonin syndrome.

- Cimetidine, omeprazole, esomeprazole 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 [Nationally approved name] and necessitate a dose adjustment.

- St. John's Wort (*Hypericum perforatum*) - a herbal remedy used for depression - may increase the risk of side effects (see section 2 "Warnings and precautions").

- Medicines which influence coagulation, such as acetylsalicylic acid (a painkiller), non-steroidal anti-inflammatory drugs (painkillers), certain medicines used to treat psychological disorders (atypical antipsychotics and phenothiazine) and most tricyclic antidepressants. The risk of an increased bleeding tendency is also increased if, during treatment, you also take ticlopidine or dipyridamole (both of which are used to reduce the risk of thrombosis), or oral anticoagulants such as warfarin, dipyridamol and phenprocoumon (medicines used to stop the blood clotting). Your doctor will probably check the coagulation time of your blood when starting and discontinuing [Nationally approved name] 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 and/or psychosis, such as phenothiazine, thioxanthene and butyrophenone) and antidepressants (tricyclic antidepressants, selective serotonin re-uptake inhibitors) due to a possible risk of a lowered threshold for seizures.

- Flecainide, propafenone, and metoprolol (used in cardio-vascular diseases), desipramine, clomipramine, and nortriptyline (antidepressants) and risperidone, thioridazine, and haloperidol (antipsychotics). The dosage of [Nationally approved name] 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 disorders.
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**[Nationally approved name] with food, drink and alcohol**

[Nationally approved name] can be taken with or without food (see section 3 "How to take [Nationally approved name]").

As with many medicines, combining [Nationally approved name] with alcohol is not advisable.

**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 for advice before taking this medicine. Do not take [Nationally approved name] if you are pregnant or breast feeding unless you and your doctor have discussed the risks and benefits involved.

Pregnancy
If used during pregnancy [Nationally approved name] should never be stopped abruptly.
If you take [Nationally approved name] during the last 3 months of your pregnancy, please inform your doctor. You should be aware that the following effects (symptoms which are mostly seen within 24 hours of delivery) may be seen in your newborn baby: trouble with breathing, blue-ish 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 taking [Nationally approved name]. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like [Nationally approved name] 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.

Breast-feeding
It is possible that [Nationally approved name] is excreted into breast milk. There is a risk that the newborn baby may be affected. Do not take [Nationally approved name] when you are breast-feeding, unless you have discussed the risks and benefits with your doctor.

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

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**

You are advised not to drive a car or operate machinery until you know how [Nationally approved name] affects you.

## 3. How to take [Nationally approved name]

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

**The recommended dose is**

Adults
**Depression**
The normally recommended dose of [Nationally approved name] is 10 mg (2 film-coated tablets) taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg (4 film-coated tablets) per day.

**Panic disorder**
The starting dose of [Nationally approved name] is 5 mg (1 film-coated tablet) as one daily dose for the first week before increasing the dose to 10 mg (2 film-coated tablets) per day. The dose may be further increased by your doctor to a maximum of 20 mg (4 film-coated tablets) per day.

**Social anxiety disorder**
The normally recommended dose of [Nationally approved name] is 10 mg (2 film-coated tablets) taken as one daily dose. Your doctor can either decrease your dose to 5 mg (1 film-coated tablet) per day or increase the dose to a maximum of 20 mg (4 film-coated tablets) per day, depending on how you respond to the medicine.

**Generalised anxiety disorder**
The normally recommended dose of [Nationally approved name] is 10 mg (2 film-coated tablets) taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg (4 film-coated tablets) per day.

**Obsessive-compulsive disorder**
The normally recommended dose of [Nationally approved name] is 10 mg (2 film-coated tablets) taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg (4 film-coated tablets) per day.

Elderly patients (above 65 years of age)
The recommended starting dose of [Nationally approved name] is 5 mg (1 film-coated tablet) taken as one daily dose. The dose may be increased by your doctor to 10 mg (2 film-coated tablets) per day.

Use in children and adolescents
[Nationally approved name] should not normally be given to children and adolescents. For further information please see section 2 “Before you take [Nationally approved name] – Children and adolescents”.

Patients with special risk factors
The starting dose for patients with mild to moderate liver dysfunction should not exceed 5 mg daily (1 film-coated tablet) during the first 14 days. Thereafter, your doctor may increase the daily dose, depending on the patient's response, to 10 mg daily (2 film-coated tablets). Caution is necessary, and precise dose adjustment required, in patients with severe liver dysfunction.

No dose adjustment is necessary in the event of mild to moderate kidney dysfunction. Caution should be exercised in patients with severe kidney dysfunction (creatinine clearance < 30 ml/min).

Treatment should be commenced at a dose of 5 mg daily (1 film-coated tablet) for the first two weeks in patients known to have reduced metabolic CYP2C19 activity (a specific liver enzyme). Depending on the individual response, the daily dose can then be increased to 10 mg (2 film-coated tablets).

**Method of administration**

- You can take [Nationally approved name] with or without food.
- Swallow the film-coated tablets with some water.
- Do not chew them, as the taste is bitter.

**Duration of treatment**

It may take a couple of weeks before you start to feel better.

- Continue to take [Nationally approved name] even if it takes some time before you feel any improvement in your condition. The maximum effect in the treatment of panic disorder is achieved after about 3 months.

- Do not change the dose of your medicine without talking to your doctor first.

- The total duration of treatment can vary greatly from patient to patient, and will be determined by your doctor. Continue with treatment 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.

Talk with your doctor or pharmacist if you think that the effect of [Nationally approved name] is too strong or too weak.

**If you take more [Nationally approved name] than you should**

If you take more than the prescribed dose of [Nationally approved name], or if another person has taken your medicine by mistake, **contact your doctor or nearest hospital emergency department immediately. Do this even if there are no signs of discomfort.** Take the [Nationally approved name] box/container and remaining film-coated tablets with you when you go to the doctor or hospital.

**Some of the signs of an overdose** may be drowsiness, dizziness, tremor, agitation, convulsion, coma, , nausea, vomiting, change in heart rhythm, decreased blood pressure and change in body fluid/salt balance.

**If you forget to take [Nationally approved name]**

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 taking [Nationally approved name] as usual.

**If you stop taking** [Nationally approved name]

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

When you stop taking [Nationally approved name], especially if it is abruptly, you may experience discontinuation symptoms. These are common when treatment with [Nationally approved name] is stopped. The risk is higher, when [Nationally approved name] 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 [Nationally approved name], 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 (also including in the head), sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling sick (nausea and/or vomiting), 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 (affects 1 to 10 patients in 1000):
- Unusual bleeds, including gastrointestinal bleeds

Rare (affects 1 to 10 patients in 10000):
- If you experience swelling of skin, tongue, lips, or face, or have difficulties breathing or swallowing (allergic anaphylactic 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.

Not known (frequency cannot be estimated from the available data:
- 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*
- Thoughts of harming or killing yourself, see also section 2 "Warnings and precautions"

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

Very common (affects more than 1 user in 10):
- Feeling sick (nausea)
- Headache

Common (affects 1 to 10 users in 100):
- 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, numbness/obdormition of the arms/legs, disturbed cryesthesia/sensation of heat (paresthesia)
- Diarrhoea, constipation, vomiting, dry mouth
- Increase sweating
- Pain in muscle and joints (arthralgia and myalgia)
- Sexual disturbances (delayed ejaculation, problems with erection, decreased sexual drive of men and women, women may experience difficulties achieving orgasm)
- Fatigue, fever
- Increased weight

Uncommon (affects 1 to 10 users in 1000):

- Nettle rush (urticaria), rash, itching (pruritus)
- Grinding one's teeth, agitation, nervousness, panic attack, confusion state
- Disturbed sleep, taste disturbance, fainting (syncope)
- Enlarged pupils (mydriasis), visual disturbance, ringing in the ears (tinnitus)
- Loss of hair
- Vaginal bleeding, unusual profuse or prolonged menstruation
- Decreased weight
- Fast heart beat
- Swelling of the arms and legs
- Nosebleeds

Rare (affects 1 to 10 users in 10000):
- Aggression, depersonalisation, hallucination
- Slow heart beat

Some patients have reported (frequency can not 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)
- Bleeding disorders including skin and mucous bleeding (ecchymosis) and low level of blood platelets (thrombocytopenia)
- Sudden swelling of skin or mucosa (angiooedemas)
- Increase in the amount of urine excreted (inappropriate ADH secretion)
- Flow of milk in women that are not nursing
- Mania (euphoric mood)
- Cardiac arrhythmias
- Alteration of the heart rhythm (called *prolongation of QT-interval*, that can be seen on ECG, a method for determination the electrical activity of the heart)
- Motor restlessness (akathisia)[1]
- Eating disorders, Anorexia[1]

[1] These side effects have been observed at a certain group of medicines, the selective serotonin re-uptake inhibitors). [Nationally approved name] belongs to this group of medicines.

An increased risk of bone fractures has been observed in patients taking these types of medicines (serotonin re-uptake inhibitors or tricyclic antidepressants).

**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 [*the national reporting system listed in Appendix V*]. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store [Nationally approved name]

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date, which is stated on the blister and 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 medicines you no longer use. These measures will help to protect the environment.

## 6. Contents of the pack and other information

**What [Nationally approved name] 5 mg, 10 mg, 20 mg contains:**
The active substance is Escitalopram.
Each [Nationally approved name] film-coated tablet contains 5 mg, 10 mg, or 20 mg escitalopram (as oxalate).

The other ingredients are:
*Tablet core:*
Microcrystalline cellulose (E 460), croscarmellose sodium (E 468), silica, colloidal anhydrous, magnesium stearate (E 470b).
*Tablet film coating:*
hypromellose (E 464), titanium dioxide (E 171) and macrogol 400.

**What [Nationally approved name] film-coated tablets look like and contents of the pack**

[Nationally approved name] 5 mg film-coated tablets:
White to off-white, round, biconvex film-coated tablets.

[Nationally approved name] 10 mg film-coated tablets:
White to off-white, oval shaped (approx. 8.1 x 5.6 mm), film-coated tablets with break line on one side.

[Nationally approved name] 20 mg film-coated tablets:
White to off-white, oval shaped (approx. 11.6 x 7.1 mm), film-coated tablets with break line on one side.

The 10 mg and 20 mg film-coated tablets can be divided into equal doses.

[Nationally approved name] is presented as 5 mg, 10 mg and 20 mg film-coated tablets in blister packs of 7, 10, 14, 15, 20, 28, 30, 50, 56, 60, 98 and 100 film-coated tablets.

Not all pack sizes may be marketed.

**Marketing authorisation holder and manufacturer**

*Marketing authorisation holder*
[To be completed nationally]
*Manufacturer*
Genericon Pharma Gesellschaft m.b.H.
Hafnerstrasse 211
A-8054 Graz
AUSTRIA
E-Mail: genericon@genericon.at

**This medicinal product is authorised in the Member States of the EEA under the following names:**
<{Name of the Member State}> <{Name of the medicinal product}>
<{Name of the Member State}> <{Name of the medicinal product}>

**This leaflet was last revised in**

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**The following information is intended for healthcare professionals only:**

*Symptoms of overdose*
Symptoms reported following an overdose of escitalopram were mainly related to the central nervous system (ranging from vertigo, tremor and agitation to rare cases of serotonin syndrome, convulsions and coma), the gastrointestinal system (nausea/vomiting) and the cardiovascular system (hypotension, tachycardia, QT prolongation and arrhythmias), as well as the electrolyte balance (hypokalaemia, hyponatraemia).

*Treatment for overdose*
There is no specific antidote. Establish and maintain the airways, ensure adequate oxygenation and respiratory function. Gastric lavage and the use of activated charcoal should be considered. Gastric lavage should be carried out as soon as possible after oral ingestion. It is advisable to monitor the cardiac and vital signs as well as to undertake general symptomatic supportive measures.