

PATIENT INFORMATION LEAFLET

SECITA 20 mg film coated tablets

For oral use

- **Drug substance:** Each dose contains Escitalopram Oxalate equivalent to 20 mg of Escitalopram.
- **Excipients:** Microcrystalline Cellulose, Lactose Monohydrate, Colloidal Anhydrous Silica, Croscarmellose Sodium, Polyvinyl Pyrrolidone K30, Magnesium Stearate, Opadry White 04F28674 (HPMC 15cP, Talc, Titanium Dioxide, Macrogol (PEG 6000)).

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 to your doctor or pharmacist.*
- *This medicine has been prescribed for you only; do not share it with another person.*
- *During the usage of this drug, when you visit the doctor or the hospital, inform your doctor about this.*
- *Respect the instructions given to you about your drug. Do not use a dose above or below the dose prescribed for you.*

In this Leaflet:

1. ***What SECITA[®] is and what it is used for?***
2. ***What you need to know before you take SECITA[®]***
3. ***How to take SECITA[®]?***
4. ***Possible side effects***
5. ***How to store SECITA***

Sections are presented.

1. What SECITA[®] is and what it is used for?

- Each of SECITA[®] 20 mg tablets contains 20 mg of escitalopram. SECITA[®] is marketed in blister packs with 28, 56 and 84 film tablets. These are oval-shaped, white film coated tablets with scored on one side and embossed with “E20” on the other side tablets.
- SECITA[®] 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).
- Escitalopram belongs to a group of antidepressants called selective serotonin reuptake inhibitors (SSRIs). These medicines increase serotonin levels by affecting the serotonin-system in the brain. Disturbances in the serotonin-system are accepted an important factor in the development of depression and similar diseases.

2. What you need to know before you take SECITA®

DO NOT USE SECITA®

- If you have an allergic (hypersensitivity) to escitalopram or any of the other ingredients of SECITA® (see “Excipients”).
- If you take selegilin (used in the treatment of Parkinson’s disease), moclobemide (used in the treatment of depression) and linezolid (an antibiotic) which belong to a group called MAO inhibitors.
- If you take pimozide (an antipsychotic).
- If you are born with or have a history of 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 “Taking with other drugs”).

TAKE SPECIAL CARE WITH SECITA®

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 SECITA® should be discontinued if seizures occur for the first time, or if there is an increase in the seizure frequency (see section 4 “Possible side effects”).
- If you have a liver or kidney dysfunction, your doctor may need to adjust your dosage.
- If you have diabetes; treatment with SECITA® may alter glycemic control. Dosage of insulin and/or oral hypoglycemic medications may need to be adjusted.
- If you have a decreased level of sodium in the blood.
- If you have a tendency to develop bleedings or bruises.
- If you are receiving electroconvulsive (electroshock) 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 have salt depletion as a result of prolonged severe diarrhea 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 that may indicate abnormal functioning of the heart rate.
- Cautions is advised in patients at high risk of developing Torsades de Pointes (a kind of heart rhythm disorder), such as patients with congestive heart failure, recent myocardial infarction, slow heartbeat or tendency to hypokalemia (decreased potassium level in the blood) or hypomagnesaemia (decreased magnesium level in the blood) due to the concurrent illness or use of medications.

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, please contact your doctor.

Symptoms such as restlessness or difficulty in sitting or standing can 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 symptoms may be increased when first starting antidepressants. Because these medicines take a long time to be effective, usually about two weeks but sometimes longer.

This probability is more likely to occur in the following conditions:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information obtained from clinical trials has shown an increased risk of suicidal behavior 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 immediately.**

Antidepressant drugs may increase the potential of suicidal thoughts or suicidal behavior in patients less than 24 years old. Therefore, patients should be closely monitored by caregivers of patients during dosage increase/decrease or withdrawal period, especially at the initial of therapy and first months, due to the unexpected behavior changes such as restlessness, hyperactivity or suicide potential in patients.

Use in children and adolescents below 18 years of age

SECITA[®] should normally not be used for children and adolescents below 18 years. In addition, it should be known that patients under 18 have an increased risk of side effects such as suicide attempts, suicidal thoughts and hostility (predominately aggression, oppositional behavior and anger) when taking this kind of medicines. Nevertheless, your doctor may prescribe SECITA[®] for patients under 18, taking into account that this is the best treatment. If your doctor has prescribed SECITA[®] to a patient below 18 years and you want to discuss this, please tell your doctor. If you are below 18 years; you should inform your doctor if any symptoms listed above develop or worsen while you are taking SECITA[®]. Furthermore, the long term safety effects relating with growth, maturation and cognitive and behavioral development of escitalopram in this age group have not yet been demonstrated.

If these warnings at any time in history even apply to you, please consult your doctor.

Using SECITA[®] with food and drink

You can take SECITA[®] with or without food (see section 3 “How to take SECITA[®]”). SECITA[®] is not expected to interact with alcohol. However, as with many medicines, it is not recommended to take SECITA[®] with alcohol.

Pregnancy

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

Inform your doctor if you are pregnant or planning to become pregnant. If you are pregnant, do not take SECITA[®] prior to discuss the related risks and benefits with your doctor.

If you use SECITA[®] during the last 3 months of your pregnancy; you should know that the following effects may be seen in your newborn baby: breathing difficulties, bluish skin, seizures, body temperature changes, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, extremely vivid reflexes, tremor, restlessness, nervousness, lethargy, constant

crying, sleepiness and sleeping difficulties. If any of these symptoms are seen in your newborn baby, please contact your doctor immediately.

Tell your doctor if you are taking SECITA[®], absolutely. Using the medicines like SECITA[®] during pregnancy, particularly in the last 3 months of pregnancy, may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn. This makes the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens in your baby, contact your doctor immediately.

If you are using SECITA[®] during pregnancy, it should never be stopped abruptly.

If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast Feeding

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

If you are breast-feeding, do not take SECITA[®] prior to discuss the related risks and benefits with your doctor.

Driving and using machine

It is not advised to drive a car or operate machinery until you know how SECITA[®] affects you.

Important information regarding some excipients in SECITA[®]

SECITA[®] contains lactose. If you have been told by your doctor that you cannot tolerate some sugar, talk to your doctor before taking this product.

Taking with other drugs

Please inform your doctor if you are taking one of the following medicines.

- “Non-selective monoamine oxidase inhibitors (MAOIs)” (containing phenelzine, iproniazid, isocarboxazid, nialamide and tranylcypromine a drug substance). If you have taken any of these medicines you should need to wait 14 days before starting to take SECITA[®]. Following discontinuation of SECITA[®], you must wait for 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.
- Linezolid, an antibiotic.
- Lithium (used in the treatment of manic-depressive disorder) and tryptophan (an aminoacid and used as nutritional support).
- Imipramine and desipramine (both used to treat depression).
- Sumatriptan and similar medicines (used to treat migraine) and tramadol (used to treat severe pain). These increase the risk of side effects.
- Cimetidine and omeprazole (used to treat stomach ulcers), fluvoxamine (antidepressant) and ticlopidine (used to reduce the risk of stroke). These may increase the blood levels of SECITA[®].

- St. John's Wort (*Hypericum perforatum*) – a herbal preparation used for depression.
- Acetylsalicylic acid and non-steroidal anti-inflammatory drugs (medicines used for pain relief or to thin the blood, called anti-aggregant). These may increase bleeding-tendency.
- Warfarin, dipyridamole, and phenprocoumon (medicines used to thin the blood, called anti-coagulant). Your doctor may check the coagulation time of your blood when starting and discontinuing SECITA[®] in order to verify that your dose of anti-coagulant is still appropriate.
- Mefloquine (used to treat malaria), bupropion (used to treat depression) and tramadol (used to treat severe pain) due to risk of a lowered threshold for seizures.
- Neuroleptics (medicines to treat schizophrenia, psychosis) and antidepressants due to risk of a lowered threshold for seizures.
- Dosage adjustment with SECITA[®] may be required when co-administered with flecainide, propafenone, and metoprolol (used in cardiovascular diseases), clomipramine, and nortriptyline (antidepressants) and risperidone, thioridazine, and haloperidol (antipsychotics).
- Do not use SECITA[®] if you take medicines for the heart rhythm problems or medicines that affect 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 are taking or have recently taken any other medicines including medicines obtained with or without a prescription, please tell your doctor or pharmacist.

3. How to take SECITA[®]?

- **Instruction for appropriate use and dose/application frequency:**

Always take SECITA[®] exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults

Depression

The recommended dose of SECITA[®] is 10 mg as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg in a day.

Panic disorder

The initial dose of SECITA[®] is 5 mg as one daily dose for the first week before increasing the dose to 10 mg in a day. The dose may be increased by your doctor to a maximum of 20 mg per day.

Social anxiety disorder

The recommended dose of SECITA[®] is 10 mg taken as one daily dose. Depending your responding to the medicine; your doctor can either decrease your dose to 5 mg per day or increase the dose to a maximum of 20 mg per day.

Generalised anxiety disorder

The recommended dose of SECITA[®] 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 recommended dose of SECITA[®] is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

Route and method of application:

You can take SECITA[®] with or without food. Swallow the tablets with a glass of water.

Do not chew, its taste is bitter.

If necessary, tablets can be divided into two equals by placing the tablet on a flat surface with the score facing upwards. The tablet can be divided into two pieces by pressing down on each end of the tablet using forefingers as shown in the drawing.



Different age groups:

Children and adolescents (below 18 years of age):

SECITA[®] should not be used in children and adolescents. For further information, please see section 2 “What you need to know before you take SECITA[®]”.

Elderly patients (above 65 years of age):

The recommended initial dose of SECITA[®] is 5 mg taken as one daily dose. The dose may be increased by your doctor to 10 mg per day.

Duration of treatment:

It may take a couple of weeks before you start to feel better yourself. Continue to use SECITA[®] 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.

Continue to take SECITA[®] for as long as your doctor recommends. If you stop your treatment earlier, symptoms of the illness may be repeated. It is recommended that treatment should be continued for at least 6 months after you feel well again.

If you think that the effect of SECITA[®] is very strong or very poor, please tell your doctor or pharmacist.

If you use more SECITA[®] than you should:

If you have used more than necessary to use from SECITA[®], please tell your doctor or pharmacist or contact nearest hospital emergency department immediately.

Do this even if there are no signs of discomfort.

Some of the symptoms of an overdose are as follows: Dizziness, tremor, agitation, convulsion, coma, nausea, vomiting, tachycardia or bradycardia, decreased blood pressure and change in body fluid/salt balance.

Take the SECITA[®] container with you when you go to the doctor or hospital.

If you forget to take SECITA®

Do not take double doses to compensate for forgotten dose.

If you forget to take a dose and you remember prior to go to bed, take it immediately. Continue as usual the next day. If you remember during the night or the next day, pass the missed dose and continue on as usual.

Before stopping SECITA® treatment

Do not stop taking SECITA® until your doctor recommends you to stop this medicine. If you have completed the treatment period, generally it is advised that the dose of SECITA® is gradually reduced in a few weeks.

If you stop taking SECITA® abruptly, you may feel discontinuation symptoms. These symptoms are commonly seen when SECITA® treatment is stopped abruptly. This risk is higher, when SECITA® has been used for a long time or in higher doses or when the dose is reduced immediately. The symptoms are mild in most of people and resolve on their own within two weeks. However, in some patients they may be more severe or more prolonged (2-3 months or more). If you get severe discontinuation symptoms when you stop taking SECITA®, please contact your doctor. Your doctor may advise you to start taking your tablets again and come off them more slowly.

Discontinuation symptoms are as follows: Dizziness (dizziness or imbalance), feelings like pins and needles, burning sensations and electric shock sensations including in the head (less commonly), sleeping disturbances (vivid dreams, nightmares, inability to sleep), anxiety, headaches, nausea, sweating (including night sweats), restlessness or agitation, tremor, confusion, emotion or irritability, diarrhea (loose stools), visual disturbances, fluttering or palpitations.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, side effects may occur in people who are hypersensitive to the ingredients of SECITA®.

The side effects usually disappear after a few weeks of treatment. Please consider that many of the effects may also be symptoms of your illness and therefore will improve when you start to get better.

The side effects are listed as shown in the following categories:

Very common:	may be affected in more than one patient from 10
Common:	may be affected in 1-10 patients from 100
Uncommon:	may be affected in 1-10 patients from 1000
Rare:	may be affected in 1-10 patients from 10000
Unknown:	cannot be estimated from the available data

Contact your doctor if any of the following side effects occur:**Uncommon:**

- Unusual bleedings including gastrointestinal bleedings

Rare:

- If you feel swelling of skin, tongue, lips or face, or have difficulties breathing or swallowing (allergic reaction), contact your doctor or go to hospital immediately.
- If high fever, agitation, confusion, tremor and abrupt contractions of muscles occur, these may be signs of a rare condition called serotonin syndrome. If you feel some of these, inform your doctor.

If you experience any of the following symptoms you should contact your doctor or go to the hospital immediately:

- Urinary difficulties
- Seizures (see also “Take special care with SECITA[®]”)
- Yellowing of the skin and the white in the eyes are the symptoms of liver function impairment/hepatitis.
- Fast, irregular heartbeat, fainting: these could be the symptoms of a life-threatening condition called as Torsade de Pointes.

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

- Nausea

Common:

- Blocked or runny nose (sinusitis)
- Decreased or increased appetite
- Anxiety, restlessness, abnormal dreams, sleeping difficulties, feeling sleepy, dizziness, yawning, tremors, tingling of the skin
- Diarrhea, constipation, vomiting, dry mouth
- Increased sweating
- Pain in muscle and joints (arthralgia and myalgia)
- Sexual disturbances (delayed ejaculation, erection problems, decreased sexual drive and orgasm difficulties in women)
- Fatigue, fever
- Increased weight

Uncommon:

- Urticaria, rash, itching (pruritus)
- Teeth grinding, agitation, nervousness, panic attack, confusion
- Sleep disturbances, taste disturbances, fainting (syncope)
- Enlarged pupils (mydriasis), visual disturbance, ringing in the ears (tinnitus)
- Loss of hair
- Menstrual bleeding
- Decreased weight
- Fast heart beat
- Swelling of the arms and legs
- Nose bleedings

Rare:

- Aggression, depersonalisation, hallucination
- Slow heart beat

Effects reported by some patients (frequency cannot be estimated from the available data):

- Thoughts of harming or killing yourself (see also “Take special care with SECITA[®]”)
- Decreased levels of sodium in the blood (the symptoms: nausea, feel sick and weak muscles or confusion)
- Dizziness when you stand up due to low blood pressure (orthostatic hypotension)
- Abnormal liver function test (increased liver enzymes in the blood)
- Movement disorders (involuntary movements of the muscles)
- Painful erections (priapism)
- Bleeding disturbances including skin and mucous membranes bleedings (ecchymosis) and decreased platelet level (thrombocytopenia)
- Sudden swelling of skin or mucosa (angioedema)
- Increase in the amount of urine (inappropriate ADH secretion)
- Flow of milk in women that are not nursing
- Mania
- 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”, electrical activity of the heart monitored on ECG).

In addition, a number of side effects are known to occur with drugs acting in a similar way to escitalopram (the active ingredient of SECITA[®]). These are:

- Motor restlessness (akathisia)
- Anorexia (loss of appetite)

Reporting of side effects

Talk to your doctor, pharmacist or nurse if you experience any side effects listed or not listed in this leaflet. Also reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

5. How to store SECITA[®]

Keep out of SECITA[®] sight and reach of children in its original packaging.
Store below 25 °C.

Use within shelf life.

Do not use SECITA[®] after the expiry date which is stated on the package/outer box.

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*This leaflet has been approved <{DD month YYYY}>.
[To be completed nationally]*