

PATIENT INFORMATION LEAFLET

SECITA® 10 mg Film Coated Tablets

For oral use

Active substance: Each film-coated tablet contains 12,77 mg of escitalopram oxalate.

Excipients: Microcrystalline cellulose, lactose monohydrate (bovine source), colloidal anhydrous silica, croscarmellose sodium, polyvinylpyrrolidone K30, magnesium stearate, Opadry White 04F28674 (HPMC 2910/hypromellose 15 cP, talc, titanium dioxide, macrogol/PEG 6000).

Before starting to use this medicine, carefully read this PATIENT INFORMATION LEAFLET, 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 symptoms are the same as yours.*
- *Please tell your doctor that you are taking this medicine if you seek medical assistance during the use of this medicine.*
- *Follow these instructions carefully. Do not take **higher or lower** doses than recommended*

What is in this leaflet:

1. *What SECITA® is and what it is used for?*
2. *What you need to know before you use SECITA®?*
3. *How to use SECITA®?*
4. *What are possible side effects?*
5. *How to store SECITA®?*

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

- SECITA® 10 mg film-coated tablets are white, oval-shaped tablets containing 10 mg of escitalopram. They have a score line on one side and "E10" imprinted on the other.
- SECITA® is available in packs of 28, 56, and 84 tablets.
- SECITA® contains escitalopram, which is used to treat depression (major depressive disorders), panic disorder with or without agoraphobia (fear of open spaces), social anxiety disorder, generalized anxiety disorder, and obsessive-compulsive disorder.
- Escitalopram belongs to a class of antidepressants called selective serotonin reuptake inhibitors (SSRIs). These drugs affect the serotonin system in the brain, increasing serotonin levels. Dysregulation of the serotonin system is recognized as a significant factor in the development of depression and related disorders.
- SECITA® contains lactose monohydrate sourced from bovine (cow) milk.
- It may take a few weeks to start feeling better. Even if improvement in your condition takes some time, continue using SECITA®.
- If you do not feel better or feel worse, talk to a doctor.

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

DO NOT USE SECITA® if you have the following conditions:

- If you are allergic to escitalopram or any of the other ingredients in SECITA® (see "Excipients"),
- If you are taking MAO (monoamine oxidase) inhibitors such as selegiline (used in the treatment of Parkinson's disease), moclobemide (used in the treatment of depression), or linezolid (an antibiotic),
- If you are taking pimozide (an antipsychotic),
- If you have a history of congenital or acquired abnormal heart rhythm (seen on EKG; an examination that evaluates how the heart works),
- If you are taking medication for heart rhythm problems or medications that could affect your heart rhythm (Class IA and III antiarrhythmics, antipsychotics (e.g., phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g., sparfloxacin, moxifloxacin, intravenous erythromycin, pentamidine, especially anti-malarial drugs like halofantrine), some allergy medications (astemizole, hydroxyzine, mizolastine) (see "Concomitant use with other medications").

SECITA® should be used WITH CAUTION in following conditions:

Before taking SECITA®, please consult your doctor or pharmacist. Inform your doctor if you have any other conditions or illnesses that need consideration, especially:

- If you have epilepsy (seizures), or if you experience your first seizure or increased frequency of seizures during the use of SECITA® (see "What are the possible side effects?"), SECITA® should be discontinued.
- If you have impaired liver or kidney function, your doctor may need to adjust the dosage.
- If you have diabetes, SECITA® treatment may affect blood sugar control. Adjustment of insulin and/or oral blood sugar-lowering medication doses may be necessary.
- If you have low blood sodium levels.
- If you have a tendency to develop bleeding or bruising, or if you are pregnant (see "Pregnancy").
- If you are receiving electroconvulsive therapy (electroshock therapy).
- If you have coronary heart disease.
- If you have recently had a heart attack, or if you have current or past heart problems.
- If your heart rate is low at rest, or if you have experienced prolonged severe diarrhea and vomiting (illness), or if you have lost salt due to diuretic (urinary medication) use.
- If you experience abnormalities in heart rate function such as fast or irregular heartbeat while standing, fainting, falls, or dizziness.
- If you have eye problems such as certain types of glaucoma (increased eye pressure), or if you have had eye problems in the past.

It is recommended to exercise caution in patients at high risk of developing Torsades de pointes (a type of heart rhythm disorder), such as those with congestive heart failure, recent heart attack, slow heart rate, or susceptibility to hypokalemia (low blood potassium levels) or hypomagnesemia (low blood magnesium levels) due to concurrent illness or medication use.

Please pay attention to the following important information:

For some patients with bipolar disorder (manic-depressive illness), there is a risk of entering a manic phase. This condition is characterized by strange and rapidly changing thoughts, inappropriate happiness, and excessive physical activity. If you experience such symptoms, contact your doctor immediately.

During the first weeks of treatment, you may experience symptoms such as restlessness, constant desire for movement, or inability to stay still. If you notice these symptoms, inform your doctor right away.

Medications like SECITA® (SSRIs/SNRIs) can cause symptoms of sexual dysfunction (see Section 4). In some cases, these symptoms have persisted even after discontinuing treatment.

Worsening of depression and anxiety disorders, including thoughts of suicide: If you are experiencing depression and/or anxiety, you may sometimes have thoughts of harming yourself or committing suicide. These symptoms may increase when you first start taking antidepressants because it often takes about 2 weeks or longer for these medications to take effect.

The risk of these thoughts is higher in the following situations:

- If you have had thoughts of suicide or self-harm before.
- If you are a young adult. Information from clinical studies has shown an increased risk of suicidal behavior in adults under the age of 25 with psychiatric disorders treated with antidepressants.

If you have ever had thoughts of harming yourself or committing suicide at any time, contact your doctor immediately or go to the hospital.

It may be helpful to inform a family member or close friend that you are experiencing depression or anxiety and ask them to read these instructions. You can ask them if they think your depression or anxiety is getting worse or if they are concerned about any changes in your behavior.

Antidepressant medications may increase the risk of suicidal thoughts or behaviors in children and young adults up to 24 years old. Therefore, especially during the initiation of treatment and in the first months, it is crucial for you to be closely monitored by your family or those treating you for unexpected changes in behavior such as restlessness, excessive activity, or the possibility of suicide when the medication dose is adjusted, increased, decreased, or discontinued.

SECITA® is used in adults aged 18 and older for depression (major depressive disorders), panic disorder with or without agoraphobia (fear of open spaces), social anxiety disorder, generalized anxiety disorder, and obsessive-compulsive disorder (obsessions-compulsions). SECITA® should not be used in children and adolescents (under 18 years old).

The effectiveness of SECITA® in elderly patients with social anxiety disorder has not been studied.

Children and adolescents

SECITA® should not normally be used in children and adolescents under 18 years of age. Additionally, it should be noted that in patients under 18 years of age, there is a higher risk of side effects such as attempted suicide, suicidal tendencies, and hostility (often aggression, oppositional behavior, and anger) when using medications of this kind. Nevertheless, your doctor may start

SECITA® in a patient under 18 years of age if they consider it the most appropriate option. If your doctor has prescribed SECITA® to a patient under 18 years of age and you wish to discuss this further, please consult your doctor. If you are under 18 years of age and any of the above symptoms appear or worsen while using SECITA®, you should inform your doctor. Furthermore, the long-term safety effects of SECITA® on growth, maturation, cognitive, and behavioral development in this age group are not yet fully known. If these warnings apply to you, even if it is in a past period, please consult your doctor.

Effects of food and drinks on SECITA®

You can take SECITA® with or without food (see "How to use SECITA®?"). There is no expected interaction between SECITA® and alcohol. However, like many medications, it is not recommended to take SECITA® with alcohol.

Pregnancy

Before using this medication, consult your doctor or pharmacist.

If you are pregnant or planning to become pregnant, inform your doctor. Do not use SECITA® without discussing its risks and benefits with your doctor if you are pregnant.

If you have used SECITA® during the last 3 months of pregnancy, you should be aware of potential effects on your newborn baby, which may include difficulty breathing, bluish skin, seizures, changes in body temperature, feeding difficulties, vomiting, low blood sugar, stiff or limp muscles, excessive reflexes, trembling, involuntary movements, irritability, lethargy, persistent crying, sleepiness, and sleep disturbances. If your baby shows any of these symptoms, contact your doctor immediately.

Be sure to inform your doctor that you are using SECITA®. Medications like SECITA® used during pregnancy, especially in the last 3 months, may increase the risk of a serious condition called persistent pulmonary hypertension of the newborn in your baby, which causes the baby to breathe more frequently and appear bluish. These symptoms typically begin within the first 24 hours after birth. If your baby experiences this condition, contact your doctor immediately.

If you take SECITA® towards the end of your pregnancy, especially if you have a history of bleeding disorders, there may be an increased risk of heavy vaginal bleeding shortly after giving birth. Your doctor or midwife should be informed that you are using SECITA® so they can provide appropriate advice.

If you are using SECITA® during pregnancy, the medication should never be stopped suddenly. If you realize you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breastfeeding:

Before using the medicine, consult your doctor or pharmacist.

It is expected that SECITA® will pass into breast milk. If you are breastfeeding, it is not recommended to use SECITA®, but you may use it if your doctor discusses the risks and benefits with you and deems it appropriate.

Fertility:

Studies in animals have shown that sitalopram, a medicine like escitalopram, can reduce sperm quality. Theoretically, this could affect fertility, but its effect on human fertility has not yet been observed.

Ability to drive and use machinery

It is not recommended to operate vehicles or machinery until you understand how SECITA® affects you.

Important information on some of the excipients of SECITA®

SECITA® contains lactose monohydrate of bovine origin. If your doctor has previously told you that you have an intolerance to some sugars, it is important to contact your doctor before taking this medicinal product.

Concurrent use with other medicines

If you are taking any other medicines, or have taken any recently or might take any in the near future, please inform your doctor or pharmacist.

Notify your doctor if you are using any of the following medications:

- Any medication belonging to the group called "Non-selective monoamine oxidase inhibitors (MAOI)" (including phenelzine, iproniazid, isocarboxazid, nialamide, and tranylcypromine). If you have used any of these medications, you should wait 14 days before starting SECITA®. After stopping SECITA®, you should wait 7 days before taking these medications.
- "Reversible selective MAO-A inhibitors" containing moclobemide (used in depression treatment). They increase the risk of side effects.
- "Irreversible MAO-B inhibitors" containing selegiline (used in Parkinson's disease treatment). These medications increase the risk of side effects.
- Antibiotic linezolid.
- Lithium (used in manic-depressive disorder treatment) and tryptophan (an amino acid used as a dietary supplement).
- Imipramine and desipramine (both used in depression treatment).
- Sumatriptan and similar medications (used in migraine treatment) and tramadol and similar medications (opioids used in severe pain). These medications increase the risk of side effects.
- Cimetidine, lansoprazole, and omeprazole (used in gastric ulcer treatment), fluconazole (used to treat fungal infections), fluvoxamine (an antidepressant), and ticlopidine (used to reduce stroke risk). These can increase the levels of escitalopram in the blood.
- St. John's Wort (*Hypericum perforatum*) – a herbal product used in depression.
- Acetylsalicylic acid and non-steroidal anti-inflammatory drugs (used as pain relievers or as antiplatelet agents). These medications can increase the risk of bleeding.
- Warfarin, dipyridamole, and fenprocoumon (anticoagulant drugs). Your doctor may want to monitor your clotting time when starting or stopping SECITA® to confirm that your anticoagulant dose is appropriate.
- Mefloquine (used in malaria treatment), bupropion (used in depression treatment), and tramadol (used in severe pain) due to the risk of lowering the seizure threshold.

- Antipsychotics (used in schizophrenia and psychosis treatment) and antidepressants (tricyclic antidepressants and SSRIs) due to the risk of lowering the seizure threshold.
- Flecainide, propafenone, and metoprolol (used in cardiovascular diseases), clomipramine and nortriptyline (antidepressants), and risperidone, thioridazine, and haloperidol (antipsychotics). Dose adjustment of SECITA® may be necessary when taken with these medications.
- If you are using medications for heart rhythm problems, or medications that can affect heart rhythm such as Class IA and III antiarrhythmics, antipsychotics (e.g., phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial compounds (e.g., sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, especially halofantrine among antimalarial drugs), and certain effective drugs against allergy diseases (astemizole, hydroxyzine, mizolastine), do not use SECITA®.
- Medications that lower potassium and magnesium levels increase the risk of life-threatening cardiac arrhythmias.

If you are currently using or have recently used any prescription or non-prescription medication, please inform your doctor or pharmacist about these.

3. How to use SECITA® ?

• Instructions for appropriate use and dose/frequency of administration:

SECITA® should always be used as prescribed by your doctor. If you are unsure, consult your doctor or pharmacist.

For adults:

Depression:

The recommended dose of SECITA® is 10 mg once daily. Your doctor may increase the dose to a maximum of 20 mg per day.

Panic Disorder(These are sudden and occasionally recurring episodes of intense distress or fear.):

The initial dose of SECITA® is 5 mg once daily for one week before increasing to 10 mg once daily. Your doctor may then increase the dose to a maximum of 20 mg per day.

Social Anxiety Disorder(Intensely feeling anxiety and fear of being negatively evaluated by others in social situations.):

The recommended dose of SECITA® is 10 mg once daily. Depending on your response to the medication, your doctor may decrease the dose to 5 mg once daily or increase it to a maximum of 20 mg per day.

Generalized Anxiety Disorder(A persistent, excessive, and situationally inappropriate state of anxiety.):

The recommended dose of SECITA® is 10 mg once daily. Your doctor may increase the dose to a maximum of 20 mg per day based on your individual response.

Obsessive-Compulsive Disorder(Repetitive behaviors and mental actions accompanied by obsessive thoughts, ideas, and impulses):

The recommended dose of SECITA® is 10 mg once daily. Your doctor may increase the dose to a maximum of 20 mg per day depending on your response to the treatment.

Always follow your doctor's instructions carefully regarding the dosage of SECITA® for your specific condition.

- **Administration route and method:** You can take SECITA® with or without food. Swallow the tablets whole with water. Do not chew them as they have a bitter taste.

If necessary, the tablets can be split by placing them on a flat surface with the score line facing up, and pressing down with your index fingers at both ends to divide them into two.



- **Different age groups:**

- **Use in children and adolescents:**

- SECITA® should not be used in children and adolescents (under 18 years of age). For more information, please refer to section 2 "Before using SECITA®" in the product information.

- **Use in elderly:**

- The recommended starting dose of SECITA® is 5 mg once daily. Your doctor may increase the dose to a maximum of 10 mg per day based on your individual response and needs. It's important to follow your doctor's instructions carefully regarding the dosage adjustments.

- **Special usage conditions:**

Kidney Insufficiency:

Adjustment of dose is not necessary in patients with mild to moderate kidney insufficiency. Caution should be exercised in patients with severely reduced kidney function. Take SECITA® as prescribed by your doctor.

Liver Insufficiency:

For patients with mild to moderate liver insufficiency, it is recommended to start with a dose of 5 mg once daily for the first two weeks of treatment. The dose may be increased to 10 mg per day. Caution should be exercised in patients with severely reduced liver function. Take SECITA® as prescribed by your doctor.

Patients Known to Poorly Metabolize CYP2C19 Enzyme:

Patients with this known genotype should not exceed a daily dose of 10 mg. Take SECITA® as prescribed by your doctor.

Duration of Treatment:

It may take several weeks to feel better. Even if you notice improvement in your condition, continue using SECITA®. Do not change the dose of your medication without consulting your doctor.

Use SECITA® for the duration recommended by your doctor. If you stop the treatment early, your symptoms may recur. It is recommended to continue treatment for at least 6 months after you start feeling well.

If you have the impression that SECITA®'s effect is too strong or too weak, talk to your doctor or pharmacist.

If you have taken more SECITA® than you should:

If you have taken more SECITA® than you should, talk to a doctor or pharmacist immediately, or go to the nearest emergency department, even if you do not feel unwell.

Some symptoms of overdose include dizziness, tremors, agitation, seizures (convulsions), coma, nausea, vomiting, abnormal heartbeat (either slower or faster than usual), decreased blood pressure, and changes in the body's water/electrolyte balance.

When you visit the doctor or hospital, take the SECITA® box with you.

If you forget to take SECITA®:

Do not take a double dose to make up for a missed dose.

If you forget to take a dose and remember it before bedtime, take it immediately. Continue with your regular schedule the next day. If you remember it later on the same day or the next day, skip the missed dose and continue with your normal treatment.

Effects when discontinuing treatment with SECITA®:

Do not stop SECITA® without your doctor's advice. If you have completed your treatment, it is generally recommended to gradually reduce the dose of SECITA® over a few weeks before stopping.

If you have abruptly stopped using SECITA®, you may experience withdrawal symptoms. These symptoms are common when SECITA® treatment is suddenly discontinued, especially after long-term use, high doses, or rapid dose reduction. In many patients, symptoms are mild and resolve spontaneously within two weeks. However, in some patients, symptoms may be more severe or last longer (2-3 months or more). If you experience severe withdrawal symptoms after stopping SECITA®, please inform your doctor. Your doctor may advise you to restart your medication and taper off more slowly over a longer period.

Withdrawal symptoms may include dizziness (lightheadedness or imbalance), tingling sensation, burning sensation, and sensation of electric shock, including in the head area (less commonly), sleep disturbances (vivid dreams, nightmares, insomnia), feelings of anxiety, headaches, nausea, sweating (including night sweats), feeling restless or agitated, tremors, confusion, emotional instability or irritability, diarrhea (loose stools), vision disturbances, palpitations, or sensations of excessive heartbeat.

If you have any questions about the use of this medication, ask your doctor or pharmacist

4. Possible side effects of SECITA®:

Like all medicines, SECITA® can cause side effects in people who are sensitive to its ingredients. Side effects are categorized as follows:

Very common: affects more than 1 in 10 users.

Common: affects 1 to 10 users in 100.

Uncommon: affects 1 to 10 users in 1,000. Rare: affects 1 to 10 users in 10,000.

Not known: frequency cannot be estimated from the available data.

Side effects usually disappear after a few weeks of treatment. Please consider that many of these effects may be related to your condition and may resolve as you begin to recover.

Stop using SECITA® and IMMEDIATELY inform your doctor or go to the nearest hospital if you notice any of the following:

Uncommon:

- Abnormal bleeding, including gastrointestinal bleeding.

Rare:

- Swelling of the skin, tongue, lips, throat, or face; hives; difficulty breathing or swallowing (allergic reaction). Inform your doctor or go to the hospital immediately if these occur.
- High fever, agitation, dizziness, tremors, and sudden muscle contractions may indicate symptoms of a rare condition called serotonin syndrome. Inform your doctor if you experience these symptoms.

These are all serious side effects and may require urgent medical intervention, including hospitalization.

If you notice any of the following, immediately inform your doctor or go to the emergency department of the nearest hospital:

Not known:

- Difficulty urinating.
- Seizures (also see "Use SECITA® with caution in the following cases").
- Yellowing of the skin or whites of the eyes, indicating liver function impairment/hepatitis symptoms.
- Rapid, irregular heartbeat, fainting. These may be symptoms of a life-threatening condition known as Torsades de pointes.
- Thoughts of harming yourself or suicide, also see "Use SECITA® with caution in the following cases."
- Sudden swelling of the skin or mucosa (angioedema).

These are serious side effects and may require urgent medical intervention.

Other side effects:

Very common:

- Nausea.
- Headache.

Common:

- Nasal congestion or runny nose (sinusitis).
- Decreased or increased appetite.
- Anxiety, restlessness, abnormal dreams, difficulty falling asleep, drowsiness, yawning, tremors, tingling sensation in the skin.
- Diarrhea, constipation, vomiting, dry mouth.
- Increased sweating.
- Muscle and joint pain (arthralgia and myalgia).
- Sexual disorders (delayed ejaculation, erectile dysfunction, decreased libido, and orgasm disorders in women).
- Fatigue, fever.
- Weight gain.

Uncommon:

- Hives (urticaria), rash, itching (pruritus).
- Teeth grinding, agitation, irritability, panic attacks, dizziness, confusion.
- Sleep disorders, taste disturbances, fainting (syncope).
- Pupil dilation (mydriasis), vision disturbances, ringing in the ears (tinnitus).
- Hair loss.
- Excessive menstrual bleeding, irregular menstruation.
- Weight loss.
- Increased heart rate.
- Swelling in the arms and legs.
- Nosebleeds.

Rare:

- Aggression, depersonalization (feeling detached from one's body), hallucinations (seeing or hearing things that are not there).
- Slowing of the heartbeat.
- Postural dizziness due to low blood pressure (orthostatic hypotension).
- Abnormal liver function tests (increased liver enzymes in the blood).
- Movement disorders (involuntary muscle movements).
- Painful erection (priapism).
- Signs of abnormal bleeding, e.g., bruises on the skin and mucosa (ecchymosis) and low platelet levels (thrombocytopenia).
- Sudden swelling of the skin or mucosa (angioedema).

- Increased body water retention and dilution of blood due to increased secretion of a hormone called ADH (inappropriate ADH secretion).
- Breast milk production in men and non-breastfeeding women.
- Mania (a state of abnormally elevated arousal).
- Increased risk of bone fractures in patients using this group of drugs.
- Changes in heart rhythm (prolonged QT interval seen on electrocardiogram).
- Severe vaginal bleeding shortly after childbirth (postpartum hemorrhage). For more information, see Section 2 "Pregnancy."

Additionally, there are some side effects reported with medications that work similarly to escitalopram (the active ingredient in SECITA®), including:

- Motor restlessness (akathisia).
- Loss of appetite.

If you experience any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

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. Storage of SECITA®

Store SECITA® in a place where children cannot see or reach, in its original packaging.

Store below 30°C.

Use in accordance with the expiry date.

Store in the original packaging.

Do not use SECITA® after the expiration date printed on the packaging. The expiration date indicates the last day of the specified month.

Do not dispose of expired or unused medications in the trash! Dispose of them according to the collection system established by the Ministry of Environment, Urbanization, and Climate Change

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