

Package leaflet: Information for the user

Serimel 50 mg film-coated tablets Serimel 100 mg film-coated tablets

Sertraline

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

1. What Serimel is and what it is used for

Serimel contains the active ingredient sertraline. Sertraline is one of a group of medicines called Selective Serotonin Re-uptake Inhibitors (SSRIs); these medicines are used to treat depression and or anxiety disorders.

Serimel can be used to treat:

- depression and prevention of recurrence of depression (in adults)
- social anxiety disorder (in adults)
- post traumatic stress disorder (PTSD) (in adults)
- panic disorder (in adults)
- obsessive compulsive disorder (OCD) (in adults and children and adolescents aged 6-17 years old)

Depression is a clinical illness with symptoms like feeling sad, unable to sleep properly or to enjoy life as you used to.

OCD and panic disorders are illnesses linked to anxiety with symptoms like being constantly troubled by persistent ideas (obsessions) that make you carry out repetitive rituals (compulsions).

PTSD is a condition that can occur after a very emotionally traumatic experience, and has some symptoms that are similar to depression and anxiety. Social anxiety disorder (social phobia) is an illness linked to anxiety. It is characterised by feelings of intense anxiety or distress in social situations (for example: talking to strangers, speaking in front of groups of people, eating or drinking in front of others or worrying that you might behave in an embarrassing manner).

Your doctor has decided that this medicine is suitable for treating your illness.

You should ask your doctor if you are unsure why you have been given Serimel.

2. What you need to know before you take Serimel

DO NOT take Serimel

- If you are allergic to sertraline or any of the other ingredients of this medicine (listed in section 6).

- If you are taking or have taken medicines called monoamine oxidase inhibitors (MAOIs such as selegiline, moclobemide) or MAOI like drugs (such as linezolid). If you stop treatment with sertraline, you must wait until at least one week before you start treatment with a MAOI. After stopping treatment with a MAOI, you must wait at least 2 weeks before you can start treatment with sertraline.
- If you are taking another medicine called pimozide (a medicine for mental disorders such as a psychosis).

Warnings and precautions

Talk to your doctor or pharmacist before taking Serimel.

Medicines are not always suitable for everyone. Tell your doctor before you take Serimel, if you suffer from or have suffered in the past from any of the following conditions:

- If you have epilepsy (fit) or a history of seizures. If you have a fit (seizure), contact your doctor immediately.
- If you have suffered from manic depressive illness (bipolar disorder) or schizophrenia. If you have a manic episode, contact your doctor immediately.
- If you have or have previously had thoughts of harming or killing yourself (see below-Thoughts of suicide and worsening of your depression or anxiety disorder).
- If you have Serotonin syndrome. In rare cases this syndrome may occur when you are taking certain medicines at the same time as sertraline. (For symptoms, see section 4. Possible side effects). Your doctor will have told you whether you have suffered from this in the past.
- If you have low sodium level in your blood, since this can occur as a result of treatment with Serimel. You should also tell your doctor if you are taking certain medicines for hypertension, since these medicines may also alter the sodium level in your blood.
- If you are elderly as you may be more at risk of having low sodium level in your blood (see above).
- If you have liver disease; your doctor may decide that you should have a lower dose of Serimel.
- If you have diabetes; your blood glucose levels may be altered due to Serimel and your diabetes medicines may need to be adjusted.
- If you have suffered from bleeding disorders or have been taking medicines which thin the blood (e.g. acetylsalicylic acid, or warfarin) or may increase the risk of bleeding, or if you are pregnant (see 'Pregnancy, breast-feeding and fertility').
- If you are a child or adolescent under 18 years old. Serimel should only be used to treat children and adolescents aged 6-17 years old, suffering from obsessive compulsive disorder (OCD). If you are being treated for this disorder, your doctor will want to monitor you closely (see below - children and adolescents).
- If you are having electro-convulsive therapy (ECT).
- If you have eye problems, such as certain kinds of glaucoma (increased pressure in the eye).
- If you have been told that you have an abnormality of your heart tracing after an electrocardiogram (ECG) known as prolonged QT interval.
- If you have heart disease, low potassium levels or low magnesium levels, family history of QT prolongation, low heart rate and concomitant use of medications which prolong QT interval.

Restlessness/ Akathisia

The use of Serimel/sertraline has been linked to a distressing restlessness and need to move, often being unable to sit or stand still (akathisia). This is most likely to occur during the first few weeks of treatment. Increasing the dose may be harmful so if you develop such symptoms you should talk to your doctor.

Withdrawal reactions

Side effects relating to stopping treatment (withdrawal reactions) are common, particularly if the treatment is stopped suddenly (see section 3 If you stop taking Serimel and section 4 Possible side effects). The risk of withdrawal symptoms depends on the length of treatment, dosage, and the rate at which the dose is reduced. Generally, such symptoms are mild to moderate. However, they can be serious in some patients. They normally occur within the first few days after stopping treatment. In general, such symptoms disappear on their own and wear off within 2 weeks. In some patients they may last longer (2-3 months or more). When stopping treatment with Serimel/sertraline it is recommended to

reduce the dose gradually over a period of several weeks or months, and you should always discuss the best way of stopping treatment with your doctor.

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.

Sexual problems:

Medicines like Serimel (so called SSRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

Children and adolescents

Sertraline should not usually be used in children and adolescents less than 18 years old, except for patients with Obsessive Compulsive Disorder (OCD). Patients under 18 have an increased risk of undesirable effects, such as suicide attempt, thoughts of harming or killing themselves (suicidal thoughts) and hostility (mainly aggressiveness, oppositional behaviour and anger) when they are treated with this class of medicines. Nevertheless, it is possible that your doctor decides to prescribe Serimel to a patient under 18 if it is in the patient's interest. If your doctor has prescribed Serimel to you and you are less than 18 years old and you want to discuss this, please contact him/her. Furthermore, if any of the symptoms listed above appear or worsen while you are taking Serimel, you should inform your doctor. Also, the long-term safety of Serimel in regard to growth, maturation and learning (cognitive) and behavioural development in this age group has not yet been demonstrated.

Other medicines and Serimel

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

Some medicines can affect the way Serimel works, or Serimel itself can reduce the effectiveness of other medicines taken at the same time.

Taking Serimel together with the following medicines may cause serious side effects:

- Medicines called monoamine oxidase inhibitors (MAOIs), like moclobemide (to treat depression) and selegiline (to treat Parkinson's disease), the antibiotic linezolid and methylene blue (to treat high levels of methaemoglobin in the blood). Do not use Serimel together with these medicines.
- Medicines to treat mental disorders such as psychosis (pimozide). Do not use Serimel together with pimozide.

Talk to your doctor if you are taking the following medicines:

- Medicines containing amphetamines (used to treat attention deficit hyperactivity disorder (ADHD), narcolepsy, and obesity).
- Herbal medicine containing St. John's Wort (*Hypericum perforatum*). The effects of St. John's Wort may last for 1-2 weeks.
- products containing the amino acid tryptophan
- medicines to treat severe pain (e.g. tramadol)

- medicines used in anaesthesia or to treat chronic pain (fentanyl, mivacurium and suxamethonium)
- medicines to treat migraines (e.g. sumatriptan)
- blood thinning medicine (warfarin)
- medicines to treat pain/arthritis (Non-steroidal anti-inflammatory drug (NSAID) such as ibuprofen, acetylsalicylic acid)
- sedatives (diazepam)
- diuretics (also called ‘water’ tablets)
- medicines to treat epilepsy (phenytoin, phenobarbital, carbamazepine)
- medicines to treat diabetes (tolbutamide)
- medicines to treat excessive stomach acid, ulcers and heartburn (cimetidine, omeprazole, lansoprazole, pantoprazole, rabeprazole)
- medicines to treat mania and depression (lithium)
- other medicines to treat depression (such as amitriptyline, nortriptyline, nefazodone, fluoxetine, fluvoxamine)
- medicines to treat schizophrenia and other mental disorders (such as perphenazine, levomepromazine and olanzapine)
- medicines used to treat high blood pressure, chest pain or regulate the rate and rhythm of the heart (such as verapamil, diltiazem, flecainide, propafenone)
- Medicines used to treat bacterial infections (such as rifampicin, clarithromycin, telithromycin, erythromycin)
- Medicines used to treat fungal infections (such as ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole).
- Medicines used to treat HIV/AIDS and Hepatitis C (protease inhibitors such as ritonavir, telaprevir).
- Medicines used to prevent nausea and vomiting after an operation or chemotherapy (aprepitant).
- Medicines known to increase the risk of changes in the electrical activity of the heart (e.g. some antipsychotics and antibiotics).

Serimel with food, drink and alcohol

Serimel film-coated tablets can be taken with or without food.

Alcohol should be avoided whilst taking Serimel.

Sertraline STADA should not be taken in combination with grapefruit juice, as this may increase the level of sertraline in your body.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

The safety of sertraline has not fully been established in pregnant women. Sertraline will only be given to you when pregnant if your doctor considers that the benefit for you is greater than any possible risk to the developing baby.

Make sure your midwife and/or doctor know you are on Serimel. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Serimel may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

If you take Serimel near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking Serimel so they can advise you.

Your newborn baby might also have other conditions, which usually begin during the first 24 hours after birth. Symptoms include:

- trouble with breathing,
- a blueish skin or being too hot or cold,
- blue lips,
- vomiting or not feeding properly,
- being very tired, not able to sleep or crying a lot,
- stiff or floppy muscles,
- tremors, jitters or fits,
- increased reflex reactions,
- irritability,
- low blood sugar.

If your baby has any of these symptoms when it is born, or you are concerned about your baby's health, contact your doctor or midwife who will be able to advise you.

Breast-feeding

There is evidence that sertraline passes into human milk. Sertraline should only be used in women during breast-feeding, if the doctor considers that the benefit for the mother exceeds any possible risk to the baby.

Fertility

Some medicines like sertraline may 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

Psychotropic drugs such as sertraline may influence your ability to drive or use machines. You should therefore not drive or operate machinery, until you know how this medication affects your ability to perform these activities.

Serimel contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Serimel

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

The recommended dose is

Adults:

Depression and obsessive compulsive disorder

For depression and OCD, the usual effective dose is 50 mg/day. The daily dose may be increased in 50 mg increments and at intervals of at least one week over a period of weeks. The maximum recommended dose is 200 mg/day.

Panic disorder, social anxiety disorder and post-traumatic stress disorder:

For panic disorder, social anxiety disorder and post-traumatic stress disorder, treatment should be started at 25 mg/day, and increased to 50 mg/day after one week.

The daily dose then may be increased in 50 mg increments over a period of weeks. The maximum recommended dose is 200 mg/day.

Use in children and adolescents

Serimel must only be used to treat children and adolescents suffering from OCD aged 6-17 years old.

Obsessive compulsive disorder:

Children aged 6 to 12: The recommended starting dose is 25 mg daily.

After one week, your doctor may increase this to 50 mg daily. The maximum dose is 200 mg daily.

Adolescents aged 13 to 17: The recommended starting dose is 50 mg daily.

The maximum dose is 200 mg daily.

Hepatic and/or renal impairment

If you have liver or kidney problems, please tell your doctor and follow the doctor's instructions.

Method of administration

Serimel film-coated tablets may be taken with or without food.

Take your medication once daily either in the morning or evening.

The film-coated tablet can be divided into equal doses.

Your doctor will advise you on how long to take this medication for. This will depend on the nature of your illness and how well you are responding to the treatment. It may take several weeks before your symptoms begin to improve. Treatment of depression should usually continue for 6 months after improvement.

If you take more Serimel than you should

If you accidentally take too much Serimel contact your doctor at once or go to the nearest hospital casualty department. Always take the labelled medicine package with you, whether there is any medication left or not.

Symptoms of overdose may include drowsiness, nausea and vomiting, rapid heart rate, shaking, agitation, dizziness and in rare cases unconsciousness.

If you forget to take Serimel

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, do not take the missed dose. Just take the next dose at the right time.

If you stop taking Serimel

Do not stop taking Serimel unless your doctor tells you to. Your doctor will want to gradually reduce your dose of Serimel over several weeks, before you finally stop taking this medicine. If you suddenly stop taking this medicine you may experience side effects such as dizziness, numbness, sleep disturbances, agitation or anxiety, headaches, feeling sick, being sick and shaking. If you experience any of these side effects, or any other side effects whilst stopping taking Serimel, please speak to your doctor.

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.

Nausea is the most common side effect. The side effects depend on the dose and often disappear or lessen with continued treatment.

Tell your doctor immediately:

If you experience any of the following symptoms after taking this medicine, these symptoms can be serious.

- If you develop a severe skin rash that causes blistering (erythema multiforme), (this can affect the mouth and tongue). These may be signs of a condition known as Stevens-Johnson's syndrome, or Toxic Epidermal Necrolysis (TEN). Your doctor will stop your treatment in these cases.
- Allergic reaction or allergy, which may include symptoms such as an itchy skin rash, breathing problems, wheezing, swollen eyelids, face or lips.
- If you experience agitation, confusion, diarrhoea, high temperature and blood pressure, excessive sweating and rapid heartbeat. These are symptoms of serotonin syndrome. In rare cases this syndrome may occur when you are taking certain medicines at the same time as sertraline. Your doctor may wish to stop your treatment.
- If you develop yellow skin and eyes which may mean liver damage.

- If you experience depressive symptoms with ideas of harming or killing yourself (suicidal thoughts).
- If you start to get feelings of restlessness and are not able to sit or stand still after you start to take Serimel. You should tell your doctor if you start to feel restless.
- If you have a fit (seizure).
- If you have a manic episode (see section 2 “Warnings and precautions”).

The following side effects were seen in clinical trials in adults and after marketing.

Very common (may affect more than 1 in 10 people):

Insomnia, dizziness, sleepiness, headache, diarrhoea, feeling sick, dry mouth, ejaculation failure, fatigue.

Common (may affect up to 1 in 10 people):

- chest cold, sore throat, runny nose,
- decreased appetite, increased appetite,
- anxiety, depression, agitation, decreased sexual interest, nervousness, feeling strange, nightmare, teeth grinding,
- shaking, muscular movement problems (such as moving a lot, tense muscles, difficulty walking and stiffness, spasms and involuntary movements of muscles)*, numbness and tingling, muscle tense, lack of attention, abnormal taste,
- visual disturbance,
- ringing in ears,
- palpitations,
- hot flush,
- yawning,
- upset stomach, constipation, abdominal pain, vomiting, gas,
- increased sweating, rash,
- back pain, joint pain, muscle pain,
- menstrual irregularities, erectile dysfunction,
- malaise, chest pain, weakness, fever
- weight increased,
- injury.

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

- gastroenteritis, ear infection,
- tumour,
- hypersensitivity, seasonal allergy,
- low thyroid hormones,
- suicidal thoughts, suicidal behaviour*, psychotic disorder, thinking abnormal, lack of caring, hallucination, aggression, euphoric mood, paranoia,
- amnesia, decreased feeling, involuntary muscle contractions, passing out, moving a lot, migraine, convulsion, dizziness while standing up, abnormal coordination, speech disorder,
- enlarged pupils,
- ear pain,
- fast heartbeat, heart problem,
- bleeding problems (such as stomach bleeding)*, high blood pressure, flushing, blood in urine,
- shortness of breath, nose bleed, breathing difficulty, possible wheezing,
- tarry stools, tooth disorder, inflammation of the oesophagus, tongue problem, haemorrhoids, increased saliva, difficulty swallowing, burping, tongue disorder,
- eye swelling, hives, hair loss, itching, purple spots on skin, skin problem with blisters, dry skin, face oedema, cold sweat,
- osteoarthritis, muscle twitching, muscle cramps*, muscular weakness,
- increase in frequency of urination, problem urinating unable to urinate, urinary incontinence, increase in urination, nighttime urination,
- sexual dysfunction, excessive vaginal bleeding, vaginal haemorrhage, female sexual dysfunction,

- swelling in legs, chills, difficulty walking, thirst,
- increase in liver enzyme levels, weight decreased.
- **Cases of suicidal ideation and suicidal behaviours have been reported during sertraline therapy or early after treatment discontinuation (see section 2).**

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

- diverticulitis, swollen lymph glands, decrease in clotting cells*, decrease in white blood cells*,
- severe allergic reaction,
- endocrine problems*,
- high cholesterol, problems controlling blood sugar levels (diabetes), low blood sugar, increase in blood sugar levels*, low blood salt*,
- physical symptoms due to stress or emotions, terrifying abnormal dreams*, drug dependence, sleep walking, premature ejaculation,
- coma, abnormal movements, difficulty moving, increased sensation, sudden severe headache (which may be a sign of a serious condition known as Reversible Cerebral Vasoconstriction Syndrome (RCVS))* , sensory disturbance,
- spots in front of eyes, glaucoma, double vision, light hurts eye, blood in the eye, unequal sized pupils*, vision abnormal*, tear problem,
- heart attack, light-headedness, fainting, or chest discomfort which could be signs of changes in the electrical activity (seen on electrocardiogram) or abnormal rhythm of the heart*, slow heartbeat,
- poor circulation of arms and legs,
- breathing fast, progressive scarring of lung tissue (Interstitial Lung Disease)*, closing up of throat, difficulty talking, breathing slow, hiccups,
- mouth ulceration, pancreatitis*, blood in stool, tongue ulceration, sore mouth,
- problems with liver function, serious liver function problems*, yellow skin and eyes (jaundice)*,
- skin reaction to sun*, skin oedema*, hair texture abnormal, skin odour abnormal, hair rash,
- breakdown of muscle tissue*, bone disorder,
- urinary hesitation, decreased urination,
- breast discharge, dry vaginal area, genital discharge, red painful penis and foreskin, breast enlargement*, prolonged erection,
- hernia, drug tolerance decreased,
- increase in blood cholesterol levels, abnormal laboratory tests*, semen abnormal, problems with clotting*,
- relaxation of blood vessels procedure.

Not known (frequency cannot be estimated from the available data):

- lockjaw*
- bedwetting*
- partial loss of vision
- inflammation of the colon (causing diarrhoea).
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy, breast-feeding and fertility in section 2 for more information.

***Side effect reported after marketing.**

Additional side effects in children and adolescents

In clinical trials with children and adolescents, the side effects were generally similar to adults (see above). The most common side effects in children and adolescents were headache, insomnia, diarrhoea and feeling sick.

Symptoms that can occur when treatment is discontinued

If you suddenly stop taking this medicine you may experience side effects such as dizziness, numbness, sleep disturbances, agitation or anxiety, headaches, feeling sick, being sick and shaking (see section 3. “If you stop taking Serimel”).

An increased risk of bone fractures has been observed in patients taking this type of medicines.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Serimel

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

Do not use this medicine after the expiry date, which is stated on the carton and blister. The expiry date refers to the last day of that month.

There are no special storage conditions.

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 Serimel contains:

The active substance is sertraline.

Serimel 50 mg film-coated tablets

1 film-coated tablet contains 50 mg of sertraline (as sertraline hydrochloride).

Serimel 100 mg film-coated tablets

1 film-coated tablet contains 100 mg of sertraline (as sertraline hydrochloride).

The other ingredients are:

Tablet core:

cellulose, microcrystalline, calcium hydrogen phosphate dihydrate, sodium starch glycolate (type A), hydroxypropylcellulose and magnesium stearate.

Tablet coat:

hypromellose, titanium dioxide (E 171), macrogol 400 and talc.

What Serimel looks like and contents of the pack

Serimel 50 mg film-coated tablets

Serimel 50 mg film-coated Tablets are white film-coated caplet shaped tablets debossed with “50” on one side and break-line on the other side. The film-coated tablet can be divided into equal doses.

Serimel 100 mg film-coated tablets

Serimel 100 mg film-coated Tablets are white film-coated caplet shaped tablets debossed with “100” on one side and break-line on the other side. The film-coated tablet can be divided into equal doses.

Pack containing 10, 14, 15, 20, 28, 30, 50, 56, 60, 98 or 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:

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

Manufacturer:

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

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

Germany: Sertralin STADA 50 mg and 100 mg Filmtabletten
Austria: Sertralin STADA 50 mg Filmtabletten
Belgium: Sertraline EG 50 mg and 100 mg filmomhulde tabletten
Luxembourg: Sertraline EG 50 mg and 100 mg filmomhulde tabletten
Ireland: Serimel 50 mg and 100 mg Tablets
Portugal: Sertralina CICLUM 50 mg and 100 mg comprimidos revestidos por pelicula

This leaflet was last revised in February 2021.