

Patient Information Leaflet for Medicines for Human Use: SERTRALINE AUSTELL

SCHEDULING STATUS: S5

SERTRALINE 50 mg AUSTELL tablets

SERTRALINE 100 mg AUSTELL tablets

Sertraline

Sugar free

Read all of this leaflet carefully before you start taking SERTRALINE AUSTELL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- SERTRALINE AUSTELL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What SERTRALINE AUSTELL is and what it is used for
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1. What SERTRALINE AUSTELL is and what it is used for



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

SERTRALINE AUSTELL is used to treat:

- Depression and recurrence of depression in adults.
- Obsessive-compulsive disorder (OCD) in adults and children aged 13 – 17 years.
- Panic disorder with or without agoraphobia (fear of open places) in adults.

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).

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 SERTRALINE AUSTELL.

2. What you need to know before you take SERTRALINE AUSTELL

Do not take SERTRALINE AUSTELL if you:

- are hypersensitive (allergic) to sertraline or any of the other ingredients of SERTRALINE AUSTELL (listed in section 6)
- are taking any medicines called monoamine oxidase inhibitors (MAOIs), including the antibiotic linezolid
- are taking any medicine called pimozide used to treat certain kinds of mental illness



- are under 18 years old and suffering from both a condition called obsessive-compulsive disorder along with depression
- suffer from liver or kidney impairment
- are pregnant or are breastfeeding.

Warnings and precautions

Take special care with SERTRALINE AUSTELL if you:

- have suffered from serotonin syndrome (SS) (life-threatening medicine reaction) or neuroleptic malignant syndrome (NMS) (neurological disorder) after taking certain medicines including amphetamines, triptans, fentanyl, tramadol, dextromethorphan, tapentadol, meperidine, methadone and pentazocine, MAOIs, antipsychotics and other dopamine antagonists. The symptoms of SS and NMS can include mental status changes (e.g. agitation, confusion, hallucinations, coma), damage to the nervous system (e.g. a pounding headache, fast heartbeat, low blood pressure, excessive and dangerously high body temperature, flushing of the skin, profuse sweating), abnormal muscle movements (e.g. twitching, muscle spasms, stiffness, lack of coordination) and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea) and can be life-threatening. Your doctor may wish to stop your treatment
- are taking, or have taken in the last two weeks, any medicines called monoamine oxidase inhibitors (MAOIs), like selegiline (to treat Parkinson's disease), moclobemide (to treat depression), linezolid (an antibiotic) and methylene blue
- have or have had 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. 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

- have a history of bleeding disorders (this is usually seen in an increased tendency to develop bruises in illnesses like von Willebrand disease, haemophilia A, deficiency in F VIII, and haemophilia B) or if you have any of the following conditions along with a bleeding disorder (e.g. multiple pregnancy, gestational hypertension or preeclampsia), or if you are pregnant (see Pregnancy, breastfeeding and fertility) or have been taking medicines which thin the blood (e.g. acetylsalicylic acid (aspirin), or warfarin) which may increase the risk of bleeding
- have taken medicines such as amphetamines, tryptophan, fentanyl or St. John's Wort (herbal medicine)
- have suffered from symptoms including fast heartbeat or loss of consciousness, or have been told that you have an abnormality of your heart tracing after an electrocardiogram (ECG) known as prolonged QT interval, or experienced a specific type of abnormal heart rhythm that can lead to sudden cardiac death (Torsades de pointes)
- 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
- unexpected and abnormal bleeding, e.g. bleeding gums, blood in the urine or in vomit, or the appearance of unexpected bruises or a rash of purple spots on the skin caused by internal bleeding from small blood vessels (purpura) to life-threatening bleeding from ruptured blood vessels in big organs (e.g. in your brain, stomach, intestines etc) where massive blood loss can lead to death
- are switching from another antidepressant medicine or anti-obsessional medicine (used to treat OCD)



- have suffered from a manic-depressive illness (bipolar disorder) or schizophrenia. If you have a manic episode, contact your doctor immediately
- have epileptic fits or a history of seizures. If you have a fit (seizure), contact your doctor immediately
- experience symptoms of sexual dysfunction. In some cases, these symptoms have continued after stopping treatment
- have low sodium level in your blood, since this can occur as a result of treatment with SERTRALINE AUSTELL. 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
- are elderly as you may be more at risk of having low sodium level in your blood (see above)
- experience side-effects when stopping treatment (withdrawal reactions). These side-effects are common, particularly if the treatment is stopped suddenly (see section 3 If you stop taking SERTRALINE AUSTELL 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 SERTRALINE AUSTELL, 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
- have any movement disorders or develop a distressing restlessness and need to move, are often 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

- suffer from a condition called osteoporosis (weak bones which are easily broken) or if you are taking medicines called corticosteroids (which can increase the risk of osteoporosis). Taking a SERTRALINE AUSTELL, may increase your risk of fracture in bones such as the hip, wrist or spine
- have any diseases or conditions that affect your metabolism or your blood responses such as having had a heart attack or have a condition in which your heart doesn't get enough blood flow and oxygen (unstable angina)
- have problems with your liver or kidneys
- have diabetes (high blood sugar); your blood glucose levels may be altered due to SERTRALINE AUSTELL and your diabetes medicines may need to be adjusted
- are having electro-convulsive therapy (ECT)
- have eye problems, such as certain kinds of glaucoma (increased pressure in the eye)
- have a laboratory reading for benzodiazepines (e.g., diazepam, alprazolam), as a false-positive reading can result if taking SERTRALINE AUSTELL
- have problems in your blood clotting (e.g., bruising easily, blood taking long to clot when you have an injury).

Children and adolescents

SERTRALINE AUSTELL 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 SERTRALINE AUSTELL to a patient under 18 if it is in the patient's interest. If your doctor has prescribed SERTRALINE AUSTELL 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 SERTRALINE AUSTELL, you should inform your doctor. Also, the long-term safety of SERTRALINE AUSTELL in regard to growth, maturation and learning (cognitive) and behavioural development in this age group has not yet been demonstrated.

Other medicines and SERTRALINE AUSTELL

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

SERTRALINE AUSTELL must not be taken together with the following medicines as it may cause serious side effects and death:

- 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 SERTRALINE AUSTELL together with these medicines.
- Medicines to treat mental disorders such as psychosis (pimozide). Do not use SERTRALINE AUSTELL together with pimozide.



SERTRALINE AUSTELL may cause very serious side effects and death due to Serotonin Syndrome (SS) or Neuroleptic Malignant Syndrome (NMS) (see section 4.4) when taken with some medicines. SERTRALINE AUSTELL should not be taken together with the following medicines:

- medicines containing amphetamines (used to treat attention deficit hyperactivity disorder (ADHD) (e.g., methylphenidate), narcolepsy, and obesity (e.g., fenfluramine))
- medicines to treat migraines (e.g., sumatriptan)
- medicines used in anaesthesia (fentanyl, mivacurium and suxamethonium) or to treat chronic pain
- medicines to treat severe pain (e.g., tramadol, dextromethorphan, tapentadol, meperidine, methadone and pentazocine)
- medicines called 5-HT antagonists that are used for the prevention and treatment of nausea and vomiting, (particularly that caused by chemotherapy, radiation therapy, or postoperatively)
- products containing the amino acid tryptophan (used to for problems such as sleep and depression)
- St. John's Wort (*Hypericum perforatum*) (a natural herbal product used to treat mild depression)
- medicines to treat schizophrenia and other mental disorders (such as perphenazine, levomepromazine, olanzapine and risperidone).

SERTRALINE AUSTELL may have effects on other medicine

SERTRALINE AUSTELL may strengthen the effect or side effects of the following medicines

- medicines known to increase the risk of changes in the electrical activity of the heart (QTc prolongation and/or ventricular dysrhythmias) e.g., some antipsychotics



and antibiotics. This can lead to sudden cardiac arrest (abrupt loss of heart function, breathing and consciousness) and death within minutes without emergency care

- medicines to treat mania and depression (lithium). You may experience more frequent side-effects of involuntary trembling and shaking
- medicines to treat epilepsy (phenytoin, phenobarbital, carbamazepine). Your doctor may need to monitor your blood levels of the epilepsy medicine and adjust the dose thereof to prevent unwanted side-effects
- medicines to treat diabetes (tolbutamide, glibenclamide)
- sedatives (diazepam)
- blood thinning medicine like warfarin or medicines acting on platelet function (e.g., medicines used to treat pain/arthritis (Non-steroidal anti-inflammatory drug (NSAID) such as ibuprofen, acetylsalicylic acid (aspirin) or ticlopidine) or other medicines that might increase bleeding, there can be an increased bleeding risk
- medicines used in anaesthesia (fentanyl, mivacurium and suxamethonium) or to treat chronic pain - their effects may be prolonged
- other medicines to treat depression (such as amitriptyline, nortriptyline, nefazodone, fluoxetine, fluvoxamine), their side-effects may become worse
- medicines to treat schizophrenia and other mental disorders (such as perphenazine, levomepromazine and olanzapine), their side-effects may become worse
- medicines used to treat high blood pressure, chest pain or regulate the rate and rhythm of the heart (such as verapamil, diltiazem, flecainide, propafenone), their blood levels may become too high and you may have too low blood pressure or too slow heart beat or worsening of side-effects.

Other medicines may interact with SERTRALINE AUSTELL



The following medicines may increase the blood levels of sertraline and strengthen the effect of SERTRALINE AUSTELL or lead to more unwanted side effects

- medicines used to treat fungal infections (such as ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole) and bacterial infections (such as clarithromycin, telithromycin, erythromycin)
- medicines used to treat HIV/AIDS and Hepatitis C (protease inhibitors such as ritonavir, telaprevir)
- some antidepressants (nefazodone, fluoxetine, fluvoxamine)
- medicines used to prevent nausea and vomiting after an operation or chemotherapy (aprepitant)
- medicines to treat excessive stomach acid, ulcers and heartburn (omeprazole, lansoprazole, pantoprazole, rabeprazole).

The following medicines may decrease the blood levels of sertraline and weaken the effect of SERTRALINE AUSTELL

- medicines to treat excessive stomach acid, ulcers and heartburn (cimetidine)
- medicines used to treat tuberculosis (TB) and other bacterial infections (rifampicin)
- medicines to treat epilepsy (phenytoin, phenobarbital, carbamazepine).

SERTRALINE AUSTELL with food, drink and alcohol

SERTRALINE AUSTELL tablets can be taken with or without food.

Alcohol should be avoided whilst taking SERTRALINE AUSTELL.

SERTRALINE AUSTELL should not be taken in combination with grapefruit juice, as this may increase the level of sertraline in your body and lead to unwanted side-effects.



Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You should not take SERTRALINE AUSTELL while you are pregnant. Women of childbearing potential should use adequate methods of contraception if taking SERTRALINE AUSTELL.

Please inform your doctor before taking SSRI such as SERTRALINE AUSTELL if you have history of bleeding disorders (this is usually seen in an increased tendency to develop bruises in illnesses like von Willebrand disease, haemophilia A, deficiency in F VIII, and haemophilia B) or if you have any of the following conditions along with a bleeding disorder (e.g., when you are carrying more than one baby at a time (multiple pregnancy), when you have high blood pressure in pregnancy (gestational hypertension) or if you have preeclampsia (a pregnancy complication characterised by mild to severe high blood pressure, protein in your urine, damage to another organ system, most often the liver and kidneys and swelling in your legs, feet, and hands which usually happens late in pregnancy, this can lead to seizures in the mom and be life-threatening to the mom and the baby).

If you take SERTRALINE AUSTELL 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 SERTRALINE AUSTELL so they can advise you.



You should not take SERTRALINE AUSTELL while you are breastfeeding your baby.

The effect of SERTRALINE AUSTELL on fertility is not known.

Driving and using machines

Special care should be taken when driving, operating machinery or performing any hazardous tasks. SERTRALINE AUSTELL may cause hypomania (feelings of unusual excitement, being very active and full of energy), dizziness, movement disorders, disturbance in attention, visual disturbance, tinnitus and loss of consciousness (coma).

It is not always possible to predict to what extent SERTRALINE AUSTELL may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which SERTRALINE AUSTELL affects you.

3. How to take SERTRALINE AUSTELL

Do not share medicines prescribed for you with any other person.

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



The usual dose unless otherwise recommended by your doctor is

- For depression, the starting dose is one 50 mg tablet daily. Your doctor may choose to increase your dosage at two weekly intervals.
- For panic disorder, the starting dose is one half 50 mg tablet daily (25 mg). After one week, the dose is increased to one 50 mg tablet daily.
- For OCD in adults and children, the usual dose is one 50 mg tablet daily; however, your doctor may choose to increase your dose.

Duration of administration

Your doctor will tell you how long your treatment with SERTRALINE AUSTELL will last. Do not change the dose yourself without your doctor's advice. Do not stop treatment early unless told to do so by your doctor. When discontinuing treatment, a gradual reduction in the dose rather than an abrupt stop is recommended.

If you have the impression that the effect of SERTRALINE AUSTELL is too strong or too weak, tell your doctor or pharmacist.

Method of administration

- Swallow your tablet/s whole with a drink of water.
- It is best to take your tablet/s once a day, every day, at the same time each day, with or without a meal.
- Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets
- Do not crush or chew your tablet/s.
- Keep taking your tablet/s every day.



If you take more SERTRALINE AUSTELL than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take along any tablets that are left, the container and the label so that the doctor can identify the medicine you are taking.

Possible signs and symptoms of overdose include drowsiness, nausea and vomiting, rapid heart rate, shaking, agitation, dizziness and unconsciousness.

If you forget to take SERTRALINE AUSTELL

Do not take a double dose to make up for forgotten individual doses.

If you forget to take a tablet, just take your usual dose the following day at the usual time. Do not take more tablets than your doctor has told you to.

If you stop taking SERTRALINE AUSTELL

Do not stop taking SERTRALINE AUSTELL unless your doctor tells you to. Your doctor will gradually reduce your dose of SERTRALINE AUSTELL over several weeks before you finally stop taking this medicine. Symptoms such as dizziness, sweating, not being able to sleep, trembling, confusion, disturbed senses, feeling of electric shock-like events, agitation, anxiety and feeling sick may occur if SERTRALINE AUSTELL treatment is stopped too quickly. These symptoms are generally not serious and disappear within a few days. If you experience symptoms on stopping treatment, contact your doctor.



4. Possible side effects

SERTRALINE AUSTELL can have side effects.

Not all side effects reported for SERTRALINE AUSTELL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SERTRALINE AUSTELL, please consult your health care provider for advice.

If any of the following happens, stop taking SERTRALINE AUSTELL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- severe allergic reaction which causes sudden wheezing, swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing or fainting (anaphylaxis)
- severe skin rash, reddening of the skin with blisters or peeling, itching, or hives (elevated patches of red or pale skin that often itch) with flushing or ulcers and bleeding in the lips, eyes, mouth, nose and genitals. This may be associated with a high fever and joint pains (these are signs and symptoms of a very serious condition called Stevens-Johnson syndrome) or a severe rash with reddening and swelling that may lead to blistering and peeling of the skin and resembles burns (toxic epidermal necrolysis)
- signs and symptoms of serotonin syndrome which may include agitation, confusion, diarrhoea, nausea, vomiting, high body temperature and fast changes in blood pressure, excessive sweating and rapid heartbeat, restlessness, hallucinations, loss of coordination, overactive reflexes, coma. These are symptoms of Serotonin Syndrome. In some cases this syndrome may occur when you are taking certain medicines at the same time as SERTRALINE AUSTELL. Your doctor may wish to stop your treatment. In its most severe form, serotonin



syndrome can resemble Neuroleptic Malignant Syndrome (NMS). Signs and symptoms of NMS may include a combination of fever, fast heartbeat, sweating, severe muscle stiffness, confusion, increased muscle enzymes (determined by a blood test)

- signs and symptoms of a heart attack such as pressure or tightness in the chest. pain in the chest, back, jaw, and other areas of the upper body that lasts more than a few minutes or that goes away and comes back, shortness of breath, sweating, nausea, vomiting, coughing and anxiety
- coma (loss of consciousness)
- experience depressive symptoms with ideas of harming or killing yourself (suicidal thoughts).

These are very serious side effects. If you have them, you may have had a serious reaction to SERTRALINE AUSTELL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- heavy vaginal bleeding shortly after birth (postpartum haemorrhage), See section 2, Pregnancy, breastfeeding and fertility for more information
- blood in the urine
- unexpected and abnormal bleeding, e.g., the appearance of unexpected bruises or a rash of purple spots on the skin caused by internal bleeding from small blood vessels (purpura) to life-threatening bleeding from ruptured blood vessels in big organs (e.g., in your brain, stomach, intestines etc) where massive blood loss can lead to death (see section 2, Warnings and precautions)



- a heart problem called “prolonged QT interval” (which is an abnormality of your heart tracing and is shown on your electrocardiogram, ECG (see section 2, Warnings and precautions)
- abnormal and unusual elevated or irritable mood, intense energy, feeling overexcited, experiencing racing thoughts, and other extreme and exaggerated behaviours (mania - see section 2, Warnings and precautions)
- impairment of thoughts and emotions so that contact is lost with external reality (psychosis - see section 2, Warnings and precautions), hearing or seeing things that are not real (hallucinations)
- unjustified suspicion and mistrust of people, belief that you are being persecuted despite being contradicted by reality or rational argument, unwarranted jealousy, or exaggerated self-importance (paranoia)
- seizures or fits (see section 2, Warnings and precautions)
- loss of vision, double vision, sensitivity to light, limb weakness or paralysis, loss of voice, slurred or stuttered speech, trouble coordinating movements caused by a condition in which the brain and body's nerves are unable to send and receive signals properly (conversion disorder)
- excess of morbid dreams and nightmares
- feeling that you cannot function normally without SERTRALINE AUSTELL (medicine dependence)
- lower than normal level of sodium in the bloodstream. This may cause nausea or vomiting, headache, confusion, or excessive tiredness and loss of energy, low blood pressure. muscle weakness, twitching, or cramps, restlessness or bad temper, seizures or coma (see section 2, Warnings and precautions)
- shaking, muscular movement problems (such as moving a lot, tense muscles, difficulty walking and stiffness, spasms and involuntary movements of muscles),



extreme restlessness with an uncontrollable urge to move (see section 2, Warnings and precautions), numbness and tingling, tense muscles

- abnormal and involuntary movements
- bone diseases such as the degeneration of joint cartilage and the underlying bone which causes pain and stiffness, especially in the hip, knee, and thumb joints (osteoarthritis) and bone fractures (see section 2, Warnings and precautions)
- unexplained muscle pain, tenderness or weakness caused by muscle breakdown and muscle death in which whereby damaged muscle fibres enter the bloodstream, leading to kidney failure and other problems which can be life-threatening (rhabdomyolysis)
- liver problems such as liver inflammation (hepatitis), which may include jaundice which can cause yellow skin and eyes, dark urine and tiredness; liver failure (see section 2, Warnings and precautions)
- kidney problems (see section 2, Warnings and precautions) which may cause less urine than is normal for you and swelling of your legs, ankles, and feet
- problems with blood sugar control (causing too high or too low levels of glucose in the blood) (see section 2, Warnings and precautions)
- severe eye pain and decreased or blurred vision (glaucoma) (see section 2, Warnings and precautions)
- symptoms such as severe (bloody or repeated watery) diarrhoea, with or without fever, abdominal pain or tenderness (you may have bowel inflammation caused by a bacterial infection)
- heart problems (these can include a variety of conditions that include how well your heart works such as problems with the arteries to the heart, problems with how the heart valves function to regulate blood flow in and out of the heart, problems with the heart muscle's ability to squeeze, heart rhythm disturbances (dysrhythmias) that affect the electrical conduction)



- a new and abnormal growth of tissue in some parts of the body which may be cancerous or non-cancerous (tumours/ neoplasm)
- symptoms of an underactive thyroid gland (hypothyroidism) such as excessive tiredness, increased sensitivity to cold, constipation, dry skin, weight gain, puffy face, muscle weakness, aches, tenderness and stiffness, thinning hair
- the retention of water in the body and decrease of certain electrolytes in the blood (such as sodium) due to excessive levels of antidiuretic hormones (hormones that help the kidneys, and body that conserve the correct amount of water)
- changes in the way your heart beats, for example, if you notice it beating faster or slower
- difficulty breathing, constriction of air passages
- progressive scarring of lung tissue (interstitial lung disease) which can cause symptoms like shortness of breath, a dry, hacking cough, extreme tiredness and weakness, mild chest pain, difficulty breathing. This scarring is seen on lung function tests and imaging tests (such as X-rays or CT scans) conducted by your health care professional
- signs of infection, such as high temperature, chills, shivering, sore throat, mouth ulcers, headaches, sweating, flu-like symptoms or weakness, bleeding or bruising easily, slow blood clotting after injury, pale skin and/or breathlessness. This may be the result of a blood disorder (such as leukopenia (lower-than-normal levels of white blood cells) and low counts and abnormal function of platelets in the blood (thrombocytopenia))
- sudden severe headache (which may be a sign of a serious condition known as reversible cerebral vasoconstriction syndrome)
- dark sticky faeces containing partly digested blood, as a result of internal bleeding or the swallowing of blood (melaena)



- inflammation of the pancreas which can cause moderate to severe upper abdominal pain that may spread to your back, pain that comes on suddenly or builds up over a few days, pain that worsens when eating, swollen, tender abdomen, nausea and vomiting
- rapid and sudden swelling of the area beneath the skin (angioedema) affecting the deeper layers of the skin, especially in areas with loose areas of tissue, such as the face and throat, as well as the limbs and genitals. In serious cases, there may be a severe allergic reaction known as anaphylaxis
- a rash of round, red welts on the skin that itch intensely, sometimes with dangerous swelling, caused by an allergic reaction (urticaria) or a rash of purple spots on the skin caused by internal bleeding from small blood vessels (purpura)
- large, fluid-filled blisters that develop on areas of skin that often flex -such as the lower abdomen, upper thighs or armpits
- urinary incontinence (inability to control the bladder)
- disturbances of the urine storage function of the bladder or the emptying function
- when your bladder doesn't empty all the way or at all when you urinate
- menstrual irregularities or menstrual periods with abnormally heavy or prolonged bleeding
- sexual problems in men (such as inability to obtain or maintain an erection (erectile dysfunction), ejaculation failure)
- sexual dysfunction in men and in women (see section 2, Warnings and precautions)
- vaginal bleeding
- secretion of breastmilk in men or in women who are not breastfeeding
- the thinning and drying of the lining of the vagina. This results in itching, burning and pain during sex, among other symptoms
- pain and inflammation (swelling and irritation) of the head of the penis



- breast enlargement in males
- prolonged erection
- hernia (a bulge or lump formed when part of an organ or fatty tissue squeezes through a weak spot in the wall of the cavity, surrounding muscle or tissue that holds it in place)
- partial loss of vision.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- chest cold, sore throat, runny nose
- decreased appetite, increased appetite
- difficulty sleeping, anxiety, depression, agitation, decreased sexual interest, nervousness, feeling strange, nightmare, teeth grinding
- dizziness, headache, sleepiness, lack of attention
- abnormal taste
- visual disturbance
- ringing in ears
- feeling like your heart is beating too hard or too fast, skipping a beat, or fluttering (palpitations)
- hot flush
- yawning
- nausea (feeling sick), upset stomach (diarrhoea), dry mouth, indigestion, constipation, abdominal pain, vomiting (being sick), gas
- increased sweating
- skin rash



- back pain, joint pain, muscle pain
- tiredness and a feeling of overall discomfort, illness, or generally not feeling well, chest pain, weakness, fever
- weight increased
- injury.

Less frequent side effects:

- inflammation and irritation of your stomach and intestines (gastroenteritis)
- inflammation of the middle ear
- intestinal pain, due to inflammation of the intestine lining, which may be constant and persist for several days, usually in the lower left side of the abdomen, nausea, vomiting, fever, abdominal tenderness, constipation and less commonly, diarrhoea
- enlargement of one or more lymph nodes, the bean-shaped glands found in the neck, armpits, chest, groin and abdomen
- seasonal allergy
- thinking abnormal, lack of caring, sleep walking
- sexual problems in men and women (such as premature ejaculation and sexual dysfunction)
- a partial or total loss of memory (amnesia), decreased feeling, involuntary muscle contractions, passing out, moving a lot, migraine, dizziness while standing up, abnormal coordination, speech disorder
- excessive physical sensitivity, especially of the skin
- enlarged pupils, a partial loss of vision or blind spot in an otherwise normal visual field, double vision, light sensitivity, accumulation of blood in the space between the cornea (front clear surface of the eye) and iris (coloured part of the eye), problems with tear production and drainage



- ear pain
- high blood pressure, flushing, blood in urine
- deficient blood distribution to the limbs which may cause symptoms such as painful cramping in one or both of your hips, thighs or calf muscles after certain activities, leg numbness or weakness, coldness in your lower leg or foot, sores on your toes, feet or legs that won't heal
- nose bleeds
- breathing fast, closing up of throat, a harsh vibrating noise when breathing, caused by obstruction of the windpipe, involuntary spasms in the muscles of the voice box causing the voice to break and have a tight, strained or strangled sound, difficulty talking, breathing slow, hiccups
- inflammation and/or sores (ulceration) of the mouth or tongue
- tooth disorder
- inflammation of the oesophagus (the part of the alimentary canal which connects the throat to the stomach)
- difficulty swallowing, increased saliva.
- tongue disorder
- burping
- a swollen vein or group of veins in the region of the anus (haemorrhoids), rectal bleeding when blood passes from the rectum or anus. The bleeding may be noted on the stool or be seen as blood on toilet paper or in the toilet. The blood may be bright red
- swelling around the eyes, hair loss, itching, redness and swelling of the skin, dry skin, swelling of the face, cold sweat, skin sensitivity to sunlight, abnormal hair texture and skin odour, rash that occurs in the hair follicles
- frequent, abnormal urination during the day or night
- production of abnormally large volumes of dilute urine



- production of less urine than what is normal for you
- muscle cramps, twitching and weakness
- genital discharge
- swelling of your lower legs or hands
- chills
- thirst
- decreased medicine tolerance
- increased liver enzymes
- decreased weight
- abnormal semen
- increased blood cholesterol
- abnormal laboratory readings
- abnormal platelet function test
- relaxation of blood vessels procedure.

Side effects with frequency unknown:

- lockjaw i.e., the uncontrolled inability to open the mouth or jaw
- bedwetting.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of SERTRALINE AUSTELL.



5. How to store SERTRALINE AUSTELL

Store all medicines out of reach of children.

Store at or below 25 °C

Keep blister in outer carton until required for use.

Do not use after the expiry date stated on the blister/carton after EXP. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What SERTRALINE AUSTELL contains

- The active ~~substance~~ ingredient is sertraline.

Each SERTRALINE 50 mg AUSTELL tablet contains sertraline hydrochloride equivalent to 50 mg sertraline.

Each SERTRALINE 100 mg AUSTELL tablet contains sertraline hydrochloride equivalent to 100 mg sertraline.

- The other ingredients are

Tablet core

Anhydrous calcium hydrogen phosphate

Microcrystalline cellulose

Hydroxypropyl cellulose

Sodium starch glycollate

Magnesium stearate



Tablet film coating

Hydroxypropyl methyl cellulose (Hypromellose)

Polyethylene glycol

Polysorbate 80

Titanium dioxide.

What SERTRALINE AUSTELL looks like and contents of the pack

SERTRALINE 50 mg AUSTELL tablets are white to off-white, caplet shaped, biconvex, film-coated tablets with break line on one side and “50” and “BL” embossed on either side of the break line. The tablet can be divided into equal halves.

SERTRALINE 100 mg AUSTELL tablets are white to off-white, caplet shaped, biconvex, film-coated tablets with “100” and “BL” embossed on one side.

SERTRALINE 50 mg AUSTELL tablets are packed in white opaque PVC/Aluminium blister packs containing 30 tablets.

SERTRALINE 100 mg AUSTELL tablets are packed in white opaque PVC/Aluminium blister packs containing 30 tablets.



Holder of Certificate of Registration

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