

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S5**

ZOLOFT® TABLETS 50 mg

Sertraline

Sugar free

Read all of this leaflet carefully before you start taking ZOLOFT TABLETS 50 mg

- 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.
- ZOLOFT TABLETS 50 mg 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 ZOLOFT TABLETS 50 mg is and what it is used for
2. What you need to know before you take ZOLOFT TABLETS 50 mg
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1. What ZOLOFT TABLETS 50 mg is and what it is used for

ZOLOFT TABLETS 50 mg 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.

ZOLOFT TABLETS 50 mg 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.

2. What you need to know before you take ZOLOFT TABLETS 50 mg

Do not take ZOLOFT TABLETS 50 mg

- If you are hypersensitive (allergic) to sertraline or any of the other ingredients of ZOLOFT TABLETS 50 mg (listed in section 6).
- If you are taking any medicines called monoamine oxidase inhibitors (MAOIs), including the antibiotic linezolid.
- If you are taking any medicine called pimozide used to treat certain kinds of mental illness.
- If you are under 18 years old and suffering from both a condition called obsessive-compulsive disorder along with depression.
- If you suffer from liver or kidney impairment.
- If you are pregnant or are breastfeeding.

Warnings and precautions

Take special care with ZOLOFT TABLETS 50 mg:

- If you have suffered from serotonin syndrome (life-threatening medicine reaction) or neuroleptic malignant syndrome (neurological disorder) after taking certain medicines including amphetamines, triptans, fentanyl, tramadol, dextromethorphan, tapentadol, meperidine, methadone and pentazocine, MAOIs, antipsychotics and other dopamine antagonists.
- If you 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.
- If you have taken medicines such as amphetamines, tryptophan, fentanyl or St. John's Wort (herbal medicine).
- If you have suffered from symptoms including fast heartbeat or loss of consciousness.
- If you are switching from another antidepressant medicine.
- If you have suffered from a manic depressive illness.
- If you have epileptic fits or a history of seizures.
- If you have or have had thoughts of harming or killing yourself.

- If you experience symptoms of sexual dysfunction. In some cases, these symptoms have continued after stopping treatment.
- If you have a history of bleeding disorders, or if you are pregnant (see Pregnancy and breastfeeding) or have been taking medicines which thin the blood.
- If you have low sodium levels in your blood since this can occur as a result of taking ZOLOFT TABLETS 50 mg.
- If you take ZOLOFT TABLETS 50 mg, you may be at an increased risk of bone fractures.
- If you have any diseases or conditions that affect your metabolism or your blood responses.
- If you have problems with your liver or kidneys.
- If you suffer from diabetes mellitus as your blood sugar levels may alter and your dose of diabetic medicines may need to be adjusted.
- If you have a laboratory reading for benzodiazepines (e.g. diazepam, alprazolam), as a false reading can result if taking ZOLOFT TABLETS 50 mg.
- If you have angle-closure glaucoma or history of glaucoma (build-up of pressure behind the eye).

Other medicines and ZOLOFT TABLETS 50 mg

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

Some medicines can affect the way ZOLOFT TABLETS 50 mg works, or ZOLOFT TABLETS 50 mg itself can reduce the effectiveness of other medicines taken at the same time.

Please consult your doctor, pharmacist or other health care provider if you are taking the following medicines:

- 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 ZOLOFT TABLETS 50 mg together with these medicines.
- Medicines to treat mental disorders such as psychosis (pimozide). Do not use ZOLOFT TABLETS 50 mg together with pimozide.
- Medicines which may affect the way your heart beats.
- Alcohol, or medicines containing alcohol.

- Lithium, another antidepressant or anti-obsessional medicine to treat mania and depression.
- Phenytoin to treat epilepsy.
- Sumatriptan to treat migraine headaches.
- Tryptophan (used to treat depression); fentanyl (used to treat pain) or the herbal medicine St. John's Wort (used to treat depression).
- Warfarin (blood thinning medicine).
- Sedatives e.g. diazepam.
- Medicines to treat diabetes e.g. tolbutamide.
- Cimetidine to treat excessive stomach acid and ulcers.
- Any medicines to regulate the rate and rhythm of your heart (e.g. flecainide, propafenone).
- Medicines that are known to affect your platelet function (e.g. atypical antipsychotics, phenothiazines, tricyclic antidepressants, aspirin or other pain killers known as NSAIDs (non-steroidal anti-inflammatory drugs)).
- Diuretics (known as water tablets) as they may alter the sodium levels in your blood.

ZOLOFT TABLETS 50 mg with food, drink and alcohol

ZOLOFT TABLETS 50 mg can be taken with or without food.

Alcohol should be avoided whilst taking ZOLOFT TABLETS 50 mg.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, 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 ZOLOFT TABLETS 50 mg while you are pregnant. Women of childbearing potential should use adequate methods of contraception if taking ZOLOFT TABLETS 50 mg.

If you take ZOLOFT TABLETS 50 mg 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 ZOLOFT TABLETS 50 mg so they can advise you.

You should not take ZOLOFT TABLETS 50 mg while you are breastfeeding your baby.

The effect of ZOLOFT TABLETS 50 mg on fertility is not known.

Driving and using machines

Special care should be taken when driving, operating machinery or performing any hazardous tasks. ZOLOFT TABLETS 50 mg may cause hypomania (feelings of unusual excitement, being very active and full of energy).

It is not always possible to predict to what extent ZOLOFT TABLETS 50 mg may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ZOLOFT TABLETS 50 mg affects them.

3. How to take ZOLOFT TABLETS 50 mg

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

Always take ZOLOFT TABLETS 50 mg exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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.

- Swallow your tablet/s whole with a drink of water.
- It is best to take your tablet/s at the same time each day, with or without a meal.
- Do not crush or chew your tablet/s.
- Keep taking your tablet/s every day.

Do not change the dose yourself without your doctor's advice. Your doctor will tell you how long your treatment with ZOLOFT TABLETS 50 mg will last. Do not stop treatment early unless told to do so by your doctor. If you have the impression that the effect of ZOLOFT TABLETS 50 mg is too strong or too weak, tell your doctor or pharmacist.

When discontinuing treatment, a gradual reduction in the dose rather than an abrupt stop is recommended.

If you take more ZOLOFT TABLETS 50 mg than you should

In the event of overdosage, 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 overdosage include drowsiness, nausea and vomiting, rapid heart rate, shaking, agitation, dizziness and unconsciousness.

If you forget to take ZOLOFT TABLETS 50 mg

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.

Effects when treatment with ZOLOFT TABLETS 50 mg is stopped

Do not stop taking ZOLOFT TABLETS 50 mg unless your doctor tells you to. Your doctor will gradually reduce your dose of ZOLOFT TABLETS 50 mg 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 ZOLOFT TABLETS 50 mg 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

ZOLOFT TABLETS 50 mg can have side effects.

Not all side effects reported for ZOLOFT TABLETS 50 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZOLOFT TABLETS 50 mg, please consult your health care provider for advice.

If any of the following happens, stop taking ZOLOFT TABLETS 50 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- If you develop a severe skin rash that causes blistering called erythema multiforme (this can affect the mouth and tongue). These may be signs of a condition known as Stevens-Johnson 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 (closing up of throat, a harsh vibrating noise when breathing caused by an obstruction in

the windpipe, wheezing, difficulty swallowing), 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 ZOLOFT TABLETS 50 mg. Your doctor may wish to stop your treatment.
- If you develop yellow skin and eyes (jaundice) which may mean liver damage.
- If you experience depressive symptoms with ideas of harming or killing yourself (suicidal thoughts).
- If you experience or suffer from psychosis (hearing or seeing things that are not real).
- If you have a manic episode (see Warnings and precautions).
- If you slip into a coma.
- If you have a fit (seizure).
- If you have a heart attack.
- If you experience chest pain.
- Sudden severe headache (which may be a sign of a serious condition known as reversible cerebral vasoconstriction syndrome).
- Prolonged erection.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ZOLOFT TABLETS 50 mg. 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:

Frequent side effects experienced include the following:

- Sore throat.
- Loss of appetite.
- Decreased appetite.
- Difficulty sleeping.
- Feeling strange.
- Nervousness.
- Suicidal thoughts or behaviour, suicide attempt.

- Dizziness.
- Sleepiness.
- Shaking.
- Abnormal taste.
- Lack of attention.
- Abnormal vision.
- Visual disturbance.
- Diarrhoea.
- Dry mouth.
- Nausea (feeling sick).
- Upset stomach/indigestion.
- Excess amount of air/gas in the stomach.
- Excessive sweat.
- Muscle pain.
- Ejaculation failure and disorder.
- Impotence.
- Problems with sexual function.

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

Tell your doctor if you notice any of the following:

Less frequent side effects may include the following:

- Chest cold.
- Runny nose.
- Intestinal problems.
- Ear infection.
- A new and abnormal growth of tissue in some parts of the body (neoplasm).
- Swollen glands.
- Increased blood cholesterol.
- Lack of caring.

- Thinking abnormal.
- Terrifying abnormal dreams.
- Blindness or paralysis that cannot be explained medically.
- Dependence on medicine.
- Paranoia.
- Sleep walking.
- Premature ejaculation.
- Abnormal coordination.
- Amnesia.
- Speech disorder.
- Dizziness while standing up.
- Abnormal movements.
- Difficulty moving.
- Increased sensation.
- Sensory disturbance.
- Glaucoma.
- Tear problem.
- Spots in front of eyes.
- Double vision.
- Light hurts eye.
- Blood in the eye.
- Ear pain.
- Slow heartbeat.
- Heart contractions.
- Flushing.
- Poor circulation of arms and legs.
- Breathing fast.
- Breathing slow.

- Difficulty talking.
- Hiccups.
- Inflammation of the oesophagus.
- Difficulty swallowing.
- Haemorrhoids.
- Increased saliva.
- Tongue disorder.
- Burping.
- Blood in stool.
- Inflammation of the mouth or tongue.
- Mouth or tongue ulceration.
- Tooth disorder.
- Problems with liver function.
- Cold sweat.
- Dry skin.
- Skin condition with large, fluid filled blisters.
- Rash around hair follicles.
- Abnormal hair texture.
- Abnormal skin odour.
- Muscle cramps.
- Joint pain.
- Muscular weakness.
- Back pain.
- Muscle twitching.
- Bone disorder.
- Changes in frequency of urination.
- Bed wetting.
- Vaginal bleeding.

- Female sexual dysfunction.
- Abnormally heavy bleeding at menstruation.
- Dry vaginal area.
- Genital discharge.
- Chills.
- Thirst.
- Hernia (when an organ or fatty tissue squeezes through a weak spot in a surrounding muscle or tissue that holds it in place).
- Decreased medicine tolerance.
- Abnormal semen.
- Injury.
- Relaxation of blood vessels procedure.
- Symptoms that can occur when ZOLOFT TABLETS 50 mg is stopped include agitation, anxiety, dizziness, headache, nausea, and pins and needles.

Other side effects reported include the following:

- Decrease in blood clotting cells.
- Decrease in white blood cells.
- Abnormal platelet function test.
- Increased secretion of a hormone which causes imbalance of salt and fluid levels (antidiuretic hormone).
- Elevated prolactin levels in the blood.
- Underactive thyroid.
- Increased appetite.
- Diabetes mellitus.
- Low blood sodium.
- Changes in blood sugar levels.
- Depressive symptoms.
- Depression.

- Anxiety.
- Agitation.
- Grinding of the teeth.
- Nightmare.
- Decrease of sex drive (libido).
- Hallucinations (seeing or hearing things that are not there).
- Aggression.
- Confusion.
- Feeling excited.
- Headache.
- Muscle tension.
- Skin tingling.
- Fainting.
- Uncontrolled muscle movements.
- Loss of sensation.
- Migraine.
- Moving a lot.
- Unequal sized pupils.
- Weakened vision.
- Dilation of pupils.
- Swelling around the eye.
- Ringing of the ears.
- Palpitations (feeling of abnormal heartbeat).
- Increased rate of heartbeat.
- Irregular heart rhythm.
- Hot flushes.
- Abnormal bleeding.
- High blood pressure.

- Sudden severe headache (which may be a sign of a serious condition known as reversible cerebral vasoconstriction syndrome).
- Progressive scarring of lung tissue (interstitial lung disease).
- Yawning.
- Constriction of air passages.
- Nose bleeds.
- Vomiting.
- Constipation.
- Stomach pain.
- Intestinal bleeding.
- Inflammation of the pancreas.
- Increase in liver enzyme levels.
- Rash.
- Allergic skin reaction (dermatitis or hives).
- Purpura (small, purple-coloured spots caused by bleeding into the skin).
- Itching.
- Hair loss.
- Swelling under the skin.
- Dead skin cells.
- Skin sensitivity to sunlight.
- Joint pain.
- Sharp, sudden muscle pain.
- Rhabdomyolysis (breakdown of muscle tissue that releases a damaging protein into the blood).
- Decreased ability to open the mouth fully.
- Inability to completely empty the bladder.
- Blood in the urine.
- Urinary incontinence (inability to control the bladder).
- Menstrual irregularities.

- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage) (see Pregnancy and breastfeeding).
- Secretion of breastmilk in men or in women who are not breastfeeding.
- Breast enlargement in males.
- Lack of energy.
- Fever.
- Feeling unwell.
- Tiredness.
- Changes in walking movement.
- Swelling of legs.
- Swelling of the face.
- Changes in weight.
- Abnormal laboratory readings.
- Fracture.

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 or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions 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 ZOLOFT TABLETS 50 mg.

5. How to store ZOLOFT TABLETS 50 mg

Store all medicines out of reach of children.

Stored at or below 30 °C.

Do not use ZOLOFT TABLETS 50 mg after the expiry date stated on the carton.

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 ZOLOFT TABLETS 50 mg contains

The active substance is sertraline hydrochloride. Each tablet contains sertraline hydrochloride equivalent to 50 mg sertraline.

The content of the tablet core is calcium hydrogen phosphate, hydroxypropylcellulose, magnesium stearate, microcrystalline cellulose and sodium starch glycollate.

The content of the tablet coat is methylhydroxypropyl cellulose, polyethylene glycol, polysorbates and titanium dioxide (E171).

What ZOLOFT TABLETS 50 mg looks like and contents of the pack

ZOLOFT TABLETS 50 mg are white, film-coated, capsule-shaped tablets, with “Pfizer” coded on the one side and the trade name abbreviation “ZLT” and “50” on the other side, with a functional score line between the two.

ZOLOFT TABLETS 50 mg are packed in opaque PVC/aluminium blister packs containing 30, 60, 90, 120, 240 and 500 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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