

SCHEDULING STATUS: **S5**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

ZOLOFT® TABLETS 50 mg

Read all of this leaflet carefully before you start taking ZOLOFT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ZOLOFT 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 ZOLOFT CONTAINS:

The active ingredient of ZOLOFT is sertraline hydrochloride. Each tablet contains sertraline hydrochloride equivalent to 50 mg sertraline.

The other ingredients of ZOLOFT are: calcium hydrogen phosphate, microcrystalline cellulose, hydroxypropyl cellulose, sodium starch glycollate, magnesium stearate, hydroxypropyl methyl cellulose, polyethylene glycol, polysorbates, and titanium dioxide.

WHAT ZOLOFT IS USED FOR:

ZOLOFT 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 is used to treat

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

BEFORE YOU TAKE ZOLOFT:

Do not take ZOLOFT:

- If you are hypersensitive (allergic) to sertraline or any of the other ingredients of ZOLOFT
- If you are taking any medicines called monoamine oxidase inhibitors (MAOIs)

- 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 depression
- If you are pregnant, trying to become pregnant or are breastfeeding

Take special care with ZOLOFT:

- If you have suffered from serotonin syndrome (life-threatening medicine reaction) or neuroleptic malignant syndrome (neurological disorder) after taking certain medicines including 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 suffered from symptoms including fast heart beat or loss of consciousness
- If you are switching from another antidepressant medicine
- If you have suffered from a manic depressive illness or schizophrenia
- If you have epileptic fits or a history of seizures
- If you have or have had thoughts of harming or killing yourself
- If you have a history of bleeding disorders 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
- 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
- If you have angle-closure glaucoma or history of glaucoma (build-up of pressure behind the eye)
- If you have any diseases or conditions that affect your metabolism or your blood responses
- If you have a history of heart disease
- If you drink alcohol
- If you are being treated with electroconvulsive therapy (ECT)

Taking ZOLOFT with food and drink:

ZOLOFT can be taken with or without food.

Alcohol should be avoided whilst taking ZOLOFT.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

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

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

Driving and using machinery:

Special care should be taken when driving, operating machinery or performing any hazardous tasks.

Taking other medicines with ZOLOFT:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

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

Please consult your doctor, pharmacist or other healthcare professional 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 together with these medicines.
- Medicines to treat mental disorders such as psychosis (pimozide). Do not use ZOLOFT together with pimozide.
- Fenfluramine (used to treat weight loss) or the herbal medicine St. John's Wort
- 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
- Medicines that are known to affect your platelet function (e.g. atypical antipsychotics and phenothiazines, tricyclic antidepressants)
- Antipsychotics or antibiotics which could increase risk of underactive thyroid and/or heart contractions
- Lithium or another antidepressant or anti-obsessional medicine to treat mania and depression
- Phenytoin to treat epilepsy

- Sumatriptan to treat migraine headaches
- Warfarin (blood thinning medicine)
- Sedatives e.g. diazepam
- Medicines to treat diabetes e.g. tolbutamide
- Any medicines to regulate the rate and rhythm of your heart (e.g. flecainide, propenone)
- Cimetidine to treat excessive stomach acid and ulcers

HOW TO TAKE ZOLOFT:

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

Always take ZOLOFT exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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 will be increased to one 50 mg tablet daily.

For OCD in adults and children, the usual effective 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 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 is too strong or too weak, tell your doctor, pharmacist or healthcare professional.

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

If you take more ZOLOFT than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control 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: underactive thyroid, heart contractions, drowsiness, nausea and vomiting, rapid heart rate, shaking, agitation, dizziness and in rare cases unconsciousness.

If you forget to take ZOLOFT:

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 is stopped:

Do not stop taking ZOLOFT unless your doctor tells you to. Your doctor will gradually reduce your dose of ZOLOFT over several weeks before you finally stop taking this medicine. Symptoms such as dizziness, sweating, not being able to sleep, trembling, confusion, disturbed senses, agitation, anxiety and feeling sick may occur if ZOLOFT 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.

POSSIBLE SIDE EFFECTS:

ZOLOFT can cause side effects, although not everybody gets them.

Not all side effects reported for ZOLOFT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZOLOFT, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor, pharmacist or healthcare professional immediately:

If you experience any of the following symptoms after taking ZOLOFT, 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 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 ZOLOFT. 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 have a fit (seizure).
- If you have a manic episode (see Take special care with ZOLOFT).

The most frequent side effects experienced include the following:

- Sore throat
- Loss of appetite, decreased appetite, increased appetite*
- Difficulty sleeping, depression*, feeling strange, nightmare, agitation*, anxiety*, nervousness, decrease of sex drive (libido)*, grinding of the teeth, suicidal thoughts or behaviour, suicide attempt
- Dizziness, sleepiness, headache*, loss of sensation*, uncontrolled muscle movements, skin tingling*, shaking, muscle tension, abnormal taste, lack of attention
- Abnormal vision, visual disturbance
- Ringing of the ears*
- Palpitations*
- Hot flushes*
- Yawning*
- Diarrhoea, dry mouth, nausea, stomach pain*, constipation*, upset stomach/indigestion, vomiting*, excess amount of air/gas in the stomach
- Excessive sweat, rash*
- Joint pain, muscle pain
- Ejaculation disorder, problems with sexual function, menstrual irregularities
- Tiredness*, feeling unwell*, chest pain*

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, decrease in white blood cells, decrease in blood clotting cells
- Severe allergic reaction
- Underactive thyroid, increased secretion of a hormone which causes imbalance of salt and fluid levels (antidiuretic hormone), elevated prolactin levels in the blood
- Diabetes mellitus, low blood sodium, changes in blood sugar levels, increased blood cholesterol
- Hallucinations (seeing or hearing things that are not there)*, aggression*, feeling excited*, depressive symptoms, lack of caring, thinking abnormal, terrifying abnormal dreams, psychosis, psychotic disorder*, paranoia, sleep walking, premature ejaculation
- Confusion, coma*, convulsions (fits)*, fainting, uncontrolled muscle movements*, migraine*, abnormal coordination, moving a lot, amnesia, speech disorder, dizziness while standing up, abnormal movements, difficulty moving, increased sensation, sensory disturbance, sudden severe headache (which may be a sign of a serious condition known as reversible cerebral vasoconstriction syndrome)
- Dilation of pupils*, glaucoma, tear problem, spots in front of eyes, double vision, light hurts eye, blood in the eye, unequal sized pupils
- Ear pain
- Increased rate of heartbeat, heart attack, slow heart beat, heart contractions
- High blood pressure*, flushing, poor circulation of arms and legs, abnormal bleeding such as intestinal bleeding
- Constriction of air passages*, difficulty breathing, nose bleeds, closing up of throat, breathing fast, breathing slow, a harsh vibrating noise when breathing caused by an obstruction in the windpipe, difficulty talking, hiccups, progressive scarring of lung tissue (interstitial lung disease)
- 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, inflammation of the pancreas
- Problems with liver function, yellow skin and eyes (jaundice)

- Allergic skin reaction (dermatitis or hives*), itching, purpura (small, purple-coloured spots caused by bleeding into the skin)*, hair loss*, severe skin rash that causes blistering, swelling under the skin, dead skin cells, rash, skin sensitivity to sunlight, swelling of the face or around the eye*, cold sweat, dry skin, rash around hair follicles, abnormal hair texture, abnormal skin odour
- Muscle cramps, joint pain, muscular weakness, back pain, muscle twitching, bone disorder
- Urinary incontinence* and changes in frequency of urination* including bed wetting
- Vaginal bleeding, sexual dysfunction, female sexual dysfunction, abnormally heavy bleeding at menstruation, dry vaginal area, genital discharge, prolonged erection*, secretion of breastmilk in men or in women who are not breastfeeding*, breast enlargement in males
- Swelling of legs, chills, fever*, thirst, hernia, decreased medicine tolerance, changes in walking movement
- Increase in liver enzyme levels*, abnormal laboratory readings, changes in weight*, abnormal semen, abnormal platelet function test
- Injury, relaxation of blood vessels procedure
- Symptoms that can occur when ZOLOFT is stopped include agitation, anxiety, dizziness, headache, nausea, and pins and needles

*These adverse reactions also occurred in post-marketing experience (frequency not known)

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

STORING AND DISPOSING OF ZOLOFT:

Keep all medicines out of the reach of children. This medicine should be stored at or below 30 °C.

Do not use ZOLOFT 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).

PRESENTATION OF ZOLOFT:

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

IDENTIFICATION OF ZOLOFT:

ZOLOFT tablets 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.

REGISTRATION NUMBER:

ZOLOFT TABLETS 50 mg: 32/1.2/0381

NAME AND ADDRESS OF THE REGISTRATION HOLDER:

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton, 2196

South Africa

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