

PATIENT INFORMATION LEAFLET
DYNA SERTRALINE RANGE

SCHEDULING STATUS

S5

DYNA SERTRALINE 50 film coated tablets

DYNA SERTRALINE 100 film coated tablets

Sertraline

DYNA SERTRALINE is sugar-free

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- DYNA SERTRALINE 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 DYNA SERTRALINE is and what it is used for
2. What you need to know before you use DYNA SERTRALINE
3. How to use DYNA SERTRALINE
4. Possible side effects
5. How to store DYNA SERTRALINE
6. Contents of the pack and other information

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

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.

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DYNA SERTRALINE is indicated for the treatment of:

- Depression and panic disorder in adults
- Obsessive compulsive disorder (OCD) in adults and children (aged 13-17 years).

A condition identified by unwanted, but stubbornly persistent thoughts, and/or unreasonable rituals you feel compelled to repeat.

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

Do not take DYNA SERTRALINE:

- if you are hypersensitive (allergic) to sertraline, or to any of the ingredients of DYNA SERTRALINE (see section 6)
- If you are taking other medicines for depression called monoamine oxidase inhibitors (MAOIs, e.g., selegiline, moclobemide and linezolid), or have taken them at any time within the last two weeks. Your doctor will advise you how you should begin taking DYNA SERTRALINE once you have stopped taking the MAOI. You should also not start taking MAOIs for at least 7 days after DYNA SERTRALINE treatment is terminated.
- If you are pregnant or breastfeeding your baby (see Pregnancy, breastfeeding and fertility).
- If you are taking a medicine called pimozide (to treat a mental disorder), as DYNA SERTRALINE may cause a serious irregular heartbeat when taken in combination with these medicines, which can be fatal.
- If you have a severe liver disorder or disease.
- If you have a condition called porphyria (an enzyme disorder with symptoms such as severe abdominal pain, pain in your chest, back or legs, vomiting or a rapid heartbeat).
- DYNA SERTRALINE should not be used for children and adolescents under the age of 18 years except for children between 13-17 years who are being treated for obsessive compulsive disorder (OCD) (see Take special care with DYNA SERTRALINE).

Warnings and precautions

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Take special care with DYNA SERTRALINE:

- If you take other medicines to treat mood disorders, as you may be at risk of serotonergic syndrome (a condition with symptoms such as agitation or restlessness, dilated pupils and heavy sweating).
- If you are taking other similar medicines for a mental condition, as this may lead to Neuroleptic Malignant Syndrome, a life-threatening condition with symptoms such as rigid muscles and fever.
- If you are taking other medicines containing tryptophan (a herbal supplement for depression), fenfluramine (used in the management of obesity), other 5-HT agonists (used for depression) or St John's Wort (a herbal supplement for depression).
- If you have been told that you have an abnormality of your heart rhythm known as prolonged QT interval (after an electrocardiogram (ECG)).
- If you have episodes of hypomania or mania (overactive behaviour or thoughts).
- If you have suffered from manic depressive illness (bipolar disorder) or schizophrenia.
- If you suffer from epilepsy or seizures (fits).
- 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, such as DYNA SERTRALINE, since these medicines take time to work (usually about two weeks but sometimes longer).
- If you have previously had thoughts about killing or harming yourself.
- If you have any thoughts of harming or killing yourself at any time, contact your doctor immediately or go to a hospital straight away. Your doctor will monitor your treatment and your progress carefully for the first few weeks.
- If you are taking medicine to prevent the clotting of blood, or are prone to bleeding easily, as DYNA SERTRALINE may increase the risk of bleeding.
- If you are pregnant and your doctor has prescribed DYNA SERTRALINE for you in the month before your baby is due, there is a risk of excessive bleeding after childbirth.

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- If you are taking a water tablet (as in some medicines used for hypertension) tell your doctor, since these medicines may alter the sodium level in your blood.
- If you stop taking your DYNA SERTRALINE tablets suddenly, you may experience withdrawal effects (see POSSIBLE SIDE EFFECTS). Do not stop taking DYNA SERTRALINE without talking to your doctor.
- If you experience a feeling of restlessness, usually within the first few weeks of treatment (see POSSIBLE SIDE EFFECTS).
- If you have kidney or liver problems.
- If you have diabetes, as the dosage of your medicine may have to be adjusted.
- If you are having electro-convulsive therapy (brain stimulation with electric currents to treat depression).
- If you drink grapefruit juice, it may affect the way DYNA SERTRALINE works.
- If you need to undergo urine or blood tests, as DYNA SERTRALINE may affect the results (false positive banned substance results in urine tests).
- If you suffer from glaucoma (an eye condition that can result in the damage of the optic nerve).
- If you have a problem with low body weight.
- If you have a recent history of heart disease or had a heart attack.

Children and adolescents

DYNA SERTRALINE should not be used for children and adolescents under the age of 18 years and should only be used to treat children and adolescents aged 13-17 years old, suffering from obsessive compulsive disorder (OCD). If you are being treated for this disorder, your doctor will want to monitor you closely.

Other medicines and DYNA SERTRALINE

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

Do not take DYNA SERTRALINE with the following medicines:

- Medicines called monoamine oxidase inhibitors (MAOIs) including moclobemide, linezolid (an antibiotic), selegiline (used in the treatment of Parkinson's disease) and methylene blue (used in the treatment of certain blood disorders) (see Do not take DYNA SERTRALINE).
- Pimozide (used to treat schizophrenia) as DYNA SERTRALINE may cause a serious irregular heartbeat when taken in combination with these medicines.

Tell your doctor if you are taking any of the following medicines:

- Diazepam (used for the short-term relief of symptoms related to anxiety disorders).
- Tolbutamide (used in the treatment of high blood sugar or diabetes).
- Warfarin (used to thin the blood) or other medicines preventing blood clots, as the use of DYNA SERTRALINE may result in bleeding.
- Fenfluramine (used in the treatment of obesity).
- Fentanyl (used in general anaesthesia) and tramadol or pethidine (for pain).
- Tryptophan (an amino acid supplement), other SSRI's, or St John's Wort (a plant used to treat depression) as taking these medicines with DYNA SERTRALINE may lead to a condition called "serotonin syndrome" with symptoms such as fits, shaking, restlessness and irritability.
- Phenytoin, phenobarbital, carbamazepine (used in the treatment and prevention of seizures in epilepsy) may decrease the effect of DYNA SERTRALINE.
- Care should also be exercised when switching from one antidepressant to another, particularly when switching from long-acting medicines such as fluoxetine.
- Cimetidine (a medicine used to treat heart burn and stomach ulcers) may increase the

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effect of DYNA SERTRALINE.

- Lithium (used to treat depression) as DYNA SERTRALINE may increase the effect of this medicine.
- Sumatriptan (used to treat migraine).
- Anti-diabetic medicines, as blood sugar levels will need to be monitored.
- Aspirin, ibuprofen or other medicines called NSAIDs (non-steroidal anti-inflammatory medicines) used for pain and inflammation.
- Diuretics (water tablets) may result in reduced sodium levels in the blood, especially in the elderly.
- Medicines used to treat fungal infections (such as ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole, clarithromycin, telithromycin, nefazodone, aprepitant, erythromycin, verapamil and diltiazem) may increase the effect of DYNA SERTRALINE.
- Medicines to treat excessive stomach acid (omeprazole, lansoprazole, pantoprazole, rabeprazole).
- Fluoxetine, fluvoxamine (used to treat depression) as they may increase the effects of DYNA SERTRALINE.
- Ritonavir (used to treat HIV) may increase the effect of DYNA SERTRALINE.

DYNA SERTRALINE with food, drink and alcohol

DYNA SERTRALINE may be taken with or without food. Avoid drinking grapefruit juice.

Alcohol should be avoided while taking DYNA SERTRALINE.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before using DYNA SERTRALINE.

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The safe use of DYNA SERTRALINE during pregnancy and breastfeeding has not been established. Do not take DYNA SERTRALINE if you are pregnant or breastfeeding your baby (see Do not take DYNA SERTRALINE). If you take DYNA SERTRALINE 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 DYNA SERTRALINE so they can advise you (see Warnings and precautions).

Driving and using machines:

DYNA SERTRALINE is not expected to affect your ability to drive or use machines. It is not always possible to predict to what extent DYNA SERTRALINE 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 DYNA SERTRALINE affects you.

3. How to take DYNA SERTRALINE

Do not share medicines prescribed for you with any other person. Always use DYNA SERTRALINE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The dose of DYNA SERTRALINE will be different for each patient and depends on what the medicine is being used, for and if other medicines are also being used at the same time. Your doctor will decide the appropriate dose for your condition. The tablets should be swallowed whole with a glass of water and should be taken the same time each day.

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Children:

The use of DYNA SERTRALINE in children is not recommended, other than in children between 13 and 17 years with OCD.

Your doctor will tell you how long your treatment with DYNA SERTRALINE will last. Do not stop treatment early because you may experience withdrawal symptoms (see If you stop taking DYNA SERTRALINE). If you have the impression that the effect of DYNA SERTRALINE is too strong or too weak, tell your doctor or pharmacist.

If you take more DYNA SERTRALINE than you should:

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

Take this leaflet and the rest of the remaining tablets with you so the doctor will know what you have taken.

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 DYNA SERTRALINE:

If you miss a dose, take it as soon as you remember. Do not take DYNA SERTRALINE if it has been more than 12 hours since you missed your last dose. Wait and take the next dose at your regular time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking DYNA SERTRALINE

Do not stop taking DYNA SERTRALINE unless your doctor tells you to. Your doctor will want to gradually reduce your dose of DYNA SERTRALINE over several weeks, before you finally stop taking this medicine. If you suddenly stop taking-DYNA SERTRALINE you may

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experience side effects such as dizziness, numbness, sleep disturbances, agitation or anxiety, headaches, feeling sick (nausea), being sick (vomiting) and shaking.

4. Possible side effects

DYNA SERTRALINE can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DYNA SERTRALINE. 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:

- yellowing of the skin and eyes, also called jaundice
- fast irregular or slow heartbeat, chest pain
- high blood pressure or low blood pressure (feeling dizzy when standing up)
- increased infections
- lack of ability to urinate, loss of bladder control, passing more or less urine than is normal for you

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- abnormal bleeding of skin, eye or stomach
- feeling anxious (especially children)
- panic attacks
- thinking of killing yourself (suicidal ideation) and suicidal behaviour
- blurred or abnormal vision, dilated pupils or glaucoma (high eye pressure)
- feeling confused
- having hallucinations (strange visions or sounds)
- seizures, shivering, excessive sweating
- liver damage or failure, inflammation of the liver (hepatitis), with symptoms such as fatigue, loss of appetite and muscle or joint ache
- memory loss, impaired concentration, coma.

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:

- sore throat
- increased or decreased appetite, weight loss
- nervousness, depression, depersonalisation (a feeling where your thoughts and feelings seem unreal or not to belong to yourself), inability to sit still, decreased sex drive
- headache, feeling dizzy or shaky (tremors), not sleeping well (insomnia) or feeling sleepy, tingling or pricking sensation (pins and needles), stiff muscles, metallic taste
- ringing or buzzing in the ears
- hot flush
- yawning
- feeling sick, diarrhoea, constipation, abdominal pain, excessive gas (wind), dry mouth, indigestion, anorexia (eating disorder, characterised by low weight, fear of gaining weight)

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and strong desire to be thin), being sick

- rash, increased sweating
- muscle and joint pain
- ejaculation delay or failure to ejaculate
- fever, generally feeling tired or unwell.

Less frequent side effects:

- runny or blocked nose
- neoplasm (abnormal growth of tissue)
- abnormal blood, heart and urine test results
- underactive thyroid (you may feel depressed, tired or experience memory loss)
- increased or decreased blood sugar levels, increased cholesterol
- aggression, intense excitement or happiness, lack of interest, thinking abnormally, paranoia, medicine dependence, sleep walking
- increase or decrease in sense of touch, twitching, speech disorder, loss of coordination, migraine (very severe headache)
- inability to produce tears, discomfort, or pain of the eyes due to light exposure
- ear pain
- sinusitis, bronchitis, coughing, nose bleeds, difficulty speaking due to a disorder of the mouth, tongue, throat or vocal cords, hiccups
- difficulty swallowing, haemorrhoids, excessive saliva, bloody or black, tarry stools, inflamed tongue, tongue and mouth ulcer, tooth disorders
- hair loss or abnormal texture of hair, skin odour, cold sweats, dry skin, swelling of the face, purple spots on the skin, rash, itching, blisters
- muscle weakness, back pain, muscle twitching, bone disorders
- urinating more at night or after waking, burning sensation when urinating

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- sexual dysfunction or spontaneous flow of milk from the breasts, inflamed vagina or inflamed penis in uncircumcised males, painful erection, painful or abnormal menstruation, abnormal discharge, premature ejaculation
- thirst, chills, hernia (a condition by which part of an organ is displayed and protrudes on the outside of the body, usually the intestine), decrease of tolerance to medicine, swelling of the legs
- injury

The following side effects have been reported but the frequency for them to occur is not known:

- heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy in section 2 for more information
- morbid dreams and nightmares, teeth grinding
- absence of, or decrease in, body movements
- unequal pupils, optic neuritis (eye pain or problems seeing colours), cataract (clouding of the eyes which affects vision)
- pancreatitis (inflammation of the pancreas characterised by abdominal pain that feels worse after eating, tenderness when touching the abdomen, nausea and vomiting)
- sensitivity of the skin to sunlight
- muscle cramps, bone fractures
- breast enlargement in men

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

Reporting of side effects

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If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug 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 DYNA SERTRALINE.

5. How to store DYNA SERTRALINE

Store all medicines out of reach of children.

Store at or below 25 °C. Store in a cool dry place.

Do not remove the blisters from the carton until required for use.

Do not use 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 DYNA SERTRALINE contains

The active substance is sertraline.

DYNA SERTRALINE 50: Each film coated tablet contains sertraline hydrochloride equivalent to 50 mg sertraline.

DYNA SERTRALINE 100: Each film coated tablet contains sertraline hydrochloride equivalent to 100 mg sertraline.

The other ingredients are:

Tablet core:

Dibasic calcium phosphate anhydrous, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose and sodium starch glycollate.

Film coating:

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Opadry Blue (containing FD&C Blue #2/indigo carmine aluminium lake, hypromellose, macrogol, polysorbate, titanium dioxide) as the colouring agent for DYNA SERTRALINE 50 and Opadry Yellow (containing hypromellose, iron oxide yellow, macrogol, polysorbate, titanium dioxide) as the colouring agent for DYNA SERTRALINE 100.

What DYNA SERTRALINE looks like and contents of the pack

DYNA SERTRALINE 50 is a blue coloured, capsule shaped, biconvex, film coated tablet, debossed with 'SER' on one side, and '5' and '0' on either side of the break-line on the other side.

DYNA SERTRALINE 100 is a yellow coloured, capsule shaped, biconvex, film coated tablet, debossed with 'SER' on one side, and '100' on other side.

DYNA SERTRALINE tablets are packed in white opaque PVC/PVDC and aluminium blister strips containing 30 tablets. The blister will be placed in an outer carton bearing the labelling requirements.

Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd
1st Floor, Grapevine House, Steenberg Office Park
Silverwood Close
Westlake, Cape Town
7945, South Africa

This leaflet was last revised in

30 September 2021

Registration numbers

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DYNA SERTRALINE 50: A43/1.2/0339

DYNA SERTRALINE 100: A43/1.2/0340

NAMIBIA:

DYNA SERTRALINE 50: NS3 14/1.2/0627

DYNA SERTRALINE 100: NS3 14/1.2/0628