

PACKAGE LEAFLET:
INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

IN THIS LEAFLET

1. What Sertraline is and what it is used for
2. Before you take Sertraline
3. How to take Sertraline
4. Possible side effects
5. How to store Sertraline
6. Further information

1. WHAT SERTRALINE IS AND WHAT IT IS USED FOR

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

Sertraline can be used to treat:

- depression and to prevent recurrence of depression (in adults)
- panic disorder with or without agoraphobia (fear of open spaces) in adults
- Obsessive Compulsive Disorder (OCD) in adults and in children and adolescents aged 6-17 years old
- Social anxiety disorder (in adults)
- Post-Traumatic Stress Disorder (PTSD) 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).

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

Your doctor has decided that this situation for treating your illness. Talk to your doctor if you are unsure why you have been given Sertraline.

2. BEFORE YOU TAKE SERTRALINE

DO NOT take Sertraline if you:

- are allergic (hypersensitive) to sertraline hydrochloride or any of the other ingredients (see section 6)
- are taking or have taken in the past two weeks, monoamine oxidase inhibitors (MAOIs such as moclobemide and selegiline) or MAOI-like drugs (such as linezolid). If you stop treatment with sertraline, you must wait until at least one week before you start treatment with a MAOI. After stopping treatment with MAOI, you must wait at least 2 weeks before you can start treatment with sertraline.
- are taking another medicine called pimozide (an antipsychotic medicine)

Take special care with Sertraline

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

- Epilepsy or a history of seizures. If you have a fit (seizure), contact your doctor immediately.
- If you have suffered from manic depressive illness (bipolar disorder) or schizophrenia. If you have a mania episode, contact your doctor immediately.
- If you have or have previously had thoughts of harming or killing yourself (see below Thoughts of suicide and worsening of your depression or anxiety disorder).
- Serotonin Syndrome. In rare cases, this syndrome may occur when you are taking certain medicines at the same time as sertraline. (For symptoms, see section 4 Possible Side Effects). Your doctor will have told you whether you have suffered from this in the past.
- Neuroleptic malignant syndrome. In rare cases, this syndrome may occur when you are taking certain medicines at the same time as sertraline. (For symptoms, see section 4 Possible Side Effects). Your doctor will have told you whether you have suffered from this in the past.
- If you have low sodium level in your blood, since this can occur as a result of treatment with Sertraline. 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.
- Take special care if you are elderly as you may be more at risk of having low sodium level in your blood (see above)
- Liver disease; your doctor may decide that you should have a lower dose of Sertraline
- Diabetes; your blood glucose levels may be altered due to Sertraline and your diabetes medicines may need to be adjusted
- If you have suffered from bleeding disorders or have been taking medicines which thin the blood (e.g. acetylsalicylic acid (aspirin), or warfarin) or which may increase the risk of bleeding
- If you are a child or adolescent under 18 years old. Sertraline should only be used to treat children and adolescents aged 6-17 years old, suffering from Obsessive Compulsive Disorder. If you are being treated for this disorder, your doctor will want to monitor you closely (see use in children and adolescents below).
- If you are having electro-convulsive therapy (ECT)
- If you are suffering from increased eye pressure or have a previous history of increased eye pressure.

Restlessness/Akathisia

The use of sertraline has been linked to a distressing restlessness and need to move, often being unable to sit or stand still (akathisia). These problems are more likely to occur in the few weeks of treatment. Increasing the dose may be harmful, so you should tell your doctor if you experience these symptoms, so the best decision can be made as to how to continue your treatment.

Side effects relating to stopping treatment (withdrawal reactions) are common, particularly if the treatment is stopped suddenly (see section 3 If you stop taking Sertraline 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, it is recommended to reduce the dose gradually over a period of several weeks or months, and you should always discuss the best way of stopping treatment with your doctor.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants; since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this if you:

- have previously had thoughts about killing or harming yourself
- are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse or if they are worried about changes in your behaviour.

Use in children over 6 years old and adolescents under 18 years old:

Sertraline should normally not be used for children and adolescents under 18 years, except for patients with Obsessive Compulsive Disorder (OCD). Also, you should know that patients under 18 have an increased risk of side effects such as suicide attempt, thoughts of harming or killing themselves (suicidal thoughts) and hostility (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe Sertraline for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Sertraline for a patient under 18 years and you want to discuss this, please go back to your doctor. You should inform your doctor if any of the symptoms above develop or worsen when patients under 18 are taking Sertraline. Also, the long-term safety effects concerning growth, maturation and learning (cognitive) and behavioural development of Sertraline in this age group have not yet been demonstrated.

False-positive urine tests for benzodiazepines (drugs used to prevent mental problems) have been reported in patients taking sertraline.

False-positive-test results may be expected for several days following discontinuation of sertraline therapy.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

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

- Medicines called monoamine oxidase inhibitors (MAOIs) e.g. moclobemide (to treat depression), selegiline (to treat Parkinson's disease) and the antibiotic linezolid. Do not use Sertraline together with MAO's.
- Medicines to treat mental disorders such as psychosis (pimozide). Do not use Sertraline together with pimozide.

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

- Medicines containing the amino acid, tryptophan
- Medicines to treat severe pain (e.g. tramadol)
- Medicines to treat migraines (e.g. sumatriptan)
- Blood thinning medicine (warfarin) Medicines to treat pain/arthritis
- (Non-steroidal anti-inflammatory drug (NSAID) acid (aspirin)) Sedatives (diazepam)
- Diuretics (also called 'water' tablets) Medicines to treat epilepsy (phenytoin, phenobarbital, carbamazepine)
- Medicines to treat diabetes (tolbutamide)
- Medicines to treat excessive stomach acid and ulcers (e.g. omeprazole, lansoprazole, pantoprazole, rabeprazole, cimetidine)
- Medicines to treat mania and depression (lithium)
- Other medicines to treat depression (such as amitriptyline, nortriptyline, nefazodone, fluoxetine, fluvoxamine)
- Medicines to treat schizophrenia and other mental disorders (such as perphenazine, levomepromazine and olanzapine)
- Medicines used to regulate the rate and rhythm of the heart (such as flecainide, propafenone)
- Fentanyl (painkiller)
- Medicines used to treat fungal infection (e.g. ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole)
- Medicines used to treat bacterial infection (e.g. clarithromycin, telithromycin, erythromycin, rifampicin)
- Medicines used to treat high blood pressure (e.g. verapamil and diltiazem)
- Aprepitant (used to treat sickness).

Taking Sertraline with food and drink

- Sertraline tablets can be taken with or without food
- Alcohol should be avoided whilst taking Sertraline
- Sertraline tablets should not be taken in combination with grapefruit

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking this medicine.

The safety of Sertraline has not been fully established in pregnant women. Sertraline should only be given to pregnant women if the doctor considers that the benefit to the mother is greater than any possible risk to the developing baby. Women of childbearing potential should use a reliable method of Contraception (such as the contraceptive pill) if taking Sertraline.

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

Some medicines like Sertraline may reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

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

Driving and using machines

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

3. HOW TO TAKE SERTRALINE

Always take Sertraline exactly as your doctor has told you. Sertraline tablets may be taken with or without food.

Take your medication once daily either in the morning or evening.
You should check with your doctor or pharmacist if you are not sure.

The usual dose is:

Adults:

• Depression and Obsessive Compulsive Disorder

Disorder

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

• Panic disorder, Social anxiety disorder and Post traumatic stress disorder

For panic disorder, social anxiety disorder and post-traumatic stress disorder, treatment should be started at 25 mg/day, and increased to 50 mg/day after one week. The daily dose then may be increased in 50mg increments over a period of weeks.

The maximum recommended dose is 200 mg/day.

Children and adolescents:

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

• Obsessive Compulsive Disorder

• **Children aged 6 to 12:** The recommended starting dose is 25 mg daily. After one week, your doctor may increase this to 50 mg daily. The maximum dose is 200 mg daily.

• **Adolescents aged 13 to 17 years:** The recommended starting dose is 50 mg daily. The maximum dose is 200 mg daily.

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

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

If you take more Sertraline than you should

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

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

If you forget to take Sertraline

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

If you stop taking Sertraline

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

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Sertraline can cause side effects, although not everybody gets them.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. Nausea is the most common side effect. The side effects depend on the dose and often 'disappear' or lessen with continued treatment.

Tell your doctor immediately:

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

- If you develop a severe skin rash that causes blistering (erythema multiforme), (this can affect the mouth and tongue). These may be signs of a condition known as Stevens Johnson 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, diarrhea, high temperature and blood pressure, excessive sweating and rapid heartbeat. These are symptoms of Serotonin Syndrome. In rare cases this syndrome may occur when you are taking certain medicines at the same time as sertraline. Your doctor may wish to stop your treatment.
- If you experience fever, stiff muscles, rapid or slow heartbeat, dizziness and confusion. These are symptoms of Neuroleptic Malignant Syndrome. In rare cases this syndrome may occur when you are taking certain medicines at the same time as sertraline. Your doctor may wish to stop your treatment.
- If you develop yellow skin and eyes which may mean liver damage.
- If you experience depressive symptoms with ideas of harming or killing yourself (suicidal thoughts)
- If you start to get feelings of restlessness and not be able to sit or stand still after you start to take Sertraline. You should tell your doctor if you start to feel restless.
- If you have a fit (seizure)
- If you have a manic episode (see section 2 Take special care with Sertraline).

Very common (occurs in more than 1 out of 10 patients):

- Insomnia, dizziness, sleepiness, headache, fatigue
- Diarrhea, feeling sick, dry mouth
- Ejaculation failure

Common side effects (occurs in between 1 and 10 out of 100 patients):

- Depression, feeling strange, nightmare, anxiety, agitation, nervousness, lack of attention, teeth grinding
- Numbness and tingling, shaking, muscle tense
- Rash, increased sweating, chest pain, muscle pain
- Abnormal taste, visual disturbance, ringing in ears

- Decreased sexual interest, sexual dysfunction, erectile dysfunction.

Uncommon (occurs in between 1 and 10 out of 1000 patients)

- Hallucination, feeling too happy, lack of caring, thinking abnormal thoughts
- Convulsion, involuntary muscle contractions, abnormal coordination, moving a lot, amnesia
- Decreased feeling, speech disorder, migraine, ear pain, eye swelling
- Fast heartbeat, high blood pressure, flushing, dizziness while standing up
- Breathing difficulty, possible wheezing, shortness of breath, nose bleed, chest cold, runny nose
- Inflammation of the oesophagus (throat), difficulty swallowing, haemorrhoids, increased saliva, tongue disorder, burping, purple spots on skin
- Hair loss, cold sweat, dry skin, hives
- Osteoarthritis, muscular weakness, back pain, muscle twitching
- Night time urination, unable to urinate, increase in urination, increase in frequency of urination, problem urinating
- Vaginal haemorrhage, female sexual dysfunction
- Weight decreased, weight increased
- Malaise, chills, fever, weakness, thirst

Rare side effects (occurs in between 1 and 10 out of 10000 patients)

- Intestine problem, ear infection, cancer, swollen glands
- High cholesterol, low blood sugar
- Physical symptoms due to stress or emotions, drug dependence, psychotic disorder, aggression, paranoia, suicidal thoughts, sleep walking, premature ejaculation
- coma, 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, enlarged pupils
- heart attack, slow heart beat, heart problem, poor circulation of arms and legs
- closing up of throat, breathing fast, breathing slow, difficulty talking,
- blood in stool, sore mouth, tongue ulceration, tooth disorder, tongue problem, mouth ulceration, problems with liver function
- skin problem with blisters, hair rash, hair texture abnormal, skin odour abnormal, bone disorder
- decreased urination, urinary incontinence, urinary hesitation
- excessive vaginal bleeding, dry vaginal area, red painful penis and foreskin, genital discharge, prolonged erection, breast discharge
- hernia, drug tolerance decreased, difficulty walking
- abnormal laboratory tests, semen abnormal, injury, relaxation of blood vessels procedure
- **Cases of suicidal ideation and suicidal behaviours have been reported during sertraline therapy or early after treatment discontinuation (see section 2).**
After marketing sertraline, the following side effects have been reported:
 - decrease in white blood cells, decrease in clotting cells
 - low thyroid hormones, endocrine problem, low blood salt
 - terrifying abnormal dreams
 - muscular movement problems (such as moving a lot, tense muscles and difficulty walking)
 - passing out, vision abnormal
 - bleeding problems (such as nose bleed, stomach bleeding, or blood in urine)
 - pancreatitis, serious liver function problems, yellowing of skin and/or eyes (jaundice)
 - skin oedema, skin reaction to sun, itching
 - joint pain, muscle cramps
 - breast enlargement, menstrual irregularities
 - swelling in legs, problems with clotting, bedwetting and severe allergic reaction
 - increased blood sugar level
 - abnormal muscle rigidity
 - unequal pupils
 - brain dysfunction related to the blood
 - vessels supplying the brain
 - lung problems.

Side effects in children and adolescents

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

Symptoms that occur when treatment is discontinued:

If you suddenly stop taking this medicine you may experience certain side effects such as dizziness, numbness, sleep disturbances, agitation of anxiety, headaches, feeling sick, being sick and shaking (see section 3 if you stop taking Sertraline)

Other Effects

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE SERTRALINE

Keep reach out of children. Store in a cool dry place protected from light below 30°C.

The tablet should be stored in the package or container supplied. Do not transfer them to another container.

Do not use Amtripyline after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Sertraline Tablets contain:

The active ingredient is sertraline hydrochloride

The other ingredients include microcrystalline cellulose, croscarmellose sodium, magnesium stearate.

Presentation: 10 x 3 x 10 or Jar 1000

Shelf Life: 2 years

Made in Ghana by

- Kinapharma Ltd.
B920/10 Mausoleum Lane
North Industrial Area - Accra.