

PATIENT INFORMATION LEAFLET

Sertraline Tablets IP (25/50/100 mg)

SERWELL 25/50/100

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- ◆ 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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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.

What is in this leaflet:

1. What SERWELL is and what it is used for
2. What you need to know before you take SERWELL
3. How to take SERWELL
4. What are the possible side effects of SERWELL
5. How to store SERWELL
6. Contents of the pack and other information

1. What SERWELL is and what it is used for

SERWELL contains the active substance Sertraline Hydrochloride. 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 prevention of recurrence of depression (in adults).
- ◆ Social anxiety disorder (in adults).
- ◆ Post traumatic stress disorder (PTSD) (in adults).
- ◆ Panic disorder (in adults).
- ◆ Obsessive compulsive disorder (OCD) (in adults and children and adolescents aged 6-17 years old).

2. What you need to know before you take SERWELL

Do not take SERWELL

- ◆ If you are allergic to Sertraline Hydrochloride.
- ◆ If you are taking or have taken medicines called monoamine oxidase inhibitors (MAOIs) such as Selegiline, Moclobemide) or MAOI like drugs (such as Linezolid). If you stop treatment with SERWELL, you must wait until at least one week before you start treatment with a MAOI. After stopping treatment with a MAOI, you must wait at least 2 weeks before you can start treatment with SERWELL.
- ◆ If you are taking another medicine called Pimozide (a medicine for mental disorders such as psychosis).

Warnings and precautions

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

- ◆ If you have epilepsy (fit) 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 manic 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).
- ◆ If you have Serotonin Syndrome. In rare cases this syndrome may occur when you are taking certain medicines at the same time as SERWELL.
- ◆ If you have low sodium level in your blood, since this can occur as a result of treatment with SERWELL. 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.
- ◆ If you have liver disease, your doctor may decide that you should have a lower dose of SERWELL.
- ◆ If you have diabetes; your blood glucose levels may be altered due to SERWELL 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 may increase the risk of bleeding.
- ◆ If you are having electro-convulsive therapy (ECT).
- ◆ If you have eye problems, such as certain kinds of glaucoma (increased pressure in the eye).

Children and adolescents

SERWELL should not usually be used in children and adolescents less than 18 years old, except for patients with Obsessive Compulsive Disorder (OCD).

Other medicines and SERWELL

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines can affect the way SERWELL works, or SERWELL itself can reduce the effectiveness of other medicines taken at the same time. Taking SERWELL together with the following medicines may cause serious side effects:

- ◆ Do not use SERWELL together with 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 SERWELL together with medicines to treat mental disorders such as psychosis (Pimozide).

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

- ◆ Medicines containing Amphetamines (used to treat attention deficit hyperactivity disorder (ADHD), narcolepsy, and obesity).
- ◆ Herbal medicine containing St. John's Wort (Hypericum perforatum). The effects of St. John's Wort may last for 1-2 weeks.
- ◆ Products containing the amino acid Tryptophan.
- ◆ Medicines to treat severe pain (e.g. Tramadol).
- ◆ Medicines used in anaesthesia or to treat chronic pain (e.g. Fentanyl, Mivacurium and Succinylcholine).
- ◆ Medicines to treat migraines (e.g. Sumatriptan).
- ◆ Blood thinning medicine (Warfarin).
- ◆ Medicines to treat pain (arthritis) (Non steroidal anti-inflammatory drug (NSAID) such as Ibuprofen, Acetylsalicylic 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, ulcers and heartburn (Cimetidine, Omeprazole, Lansoprazole, Pantoprazole, Rabeprazole).
- ◆ 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 treat high blood pressure, chest pain or regulate the rate and rhythm of the heart (such as Verapamil, Diltiazem, Flecainide, Propafenone).
- ◆ Medicines used to treat bacterial infections (such as Rifampicin, Clarithromycin, Telithromycin, Erythromycin).
- ◆ Medicines used to treat fungal infections (such as Ketoconazole, Itraconazole, Posaconazole, Voriconazole, Fluconazole).
- ◆ Medicines used to treat HIV/AIDS and Hepatitis C (protease inhibitors such as Ritonavir, Telaprevir).
- ◆ Medicines used to prevent nausea and vomiting after an operation or chemotherapy (Aprepitant).
- ◆ Medicines known to increase the risk of changes in the electrical activity of the heart (e.g. some anti-psychotics and antibiotics).

SERWELL with food and drink

SERWELL can be taken with or without food.

Alcohol should be avoided whilst taking SERWELL.

SERWELL should not be taken in combination with grapefruit juice, as this may increase the level of Sertraline in your body.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Psychotropic drugs such as SERWELL 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 SERWELL

The recommended dose is:

Adults:

Depression and Obsessive Compulsive 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 50 mg increments over a period of weeks. The maximum recommended dose is 200 mg/day.

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: The recommended starting dose is 50 mg daily.

The maximum dose is 200 mg daily.

If you take more SERWELL than you should

If you accidentally take too much SERWELL contact your doctor at once or go to the nearest 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 SERWELL

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

If you stop taking SERWELL

Do not stop taking SERWELL unless your doctor tells you to. Your doctor will want to gradually reduce

your dose of SERWELL 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 SERWELL, please speak to your doctor.

4. What are the possible side effects of SERWELL

Like all prescription medicines, SERWELL may cause side effects, although not everyone gets them. Nausea is the most common side effect. The side effects depend on the dose and often disappear or lessen with continued treatment.

Stop taking SERWELL and tell your doctor immediately

- ❖ 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.
- ❖ 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 SERWELL. 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 are not able to sit or stand still after you start to take SERWELL. You should tell your doctor if you start to feel restless.
- ❖ If you have a fit (seizure).

Other side effects may include

Talk to your doctor if you get any side effects.

Very common side effects (may affect more than 1 in 10 people):

Insomnia, dizziness, sleepiness, headache, diarrhoea, feeling sick, dry mouth, ejaculation failure, fatigue.

Common side effects (may affect up to 1 in 10 people):

- ❖ Chest cold, sore throat, runny nose.
- ❖ Decreased appetite, increased appetite.
- ❖ Anxiety, depression, agitation, decreased sexual interest, nervousness, feeling strange, nightmare, teeth grinding.
- ❖ Shaking, muscular movement problems (such as moving a lot, tense muscles, difficulty walking and stiffness, spasms and involuntary movements of muscles), numbness and tingling, muscle tense, lack of attention, abnormal taste.
- ❖ Visual disturbance,
- ❖ Ringing in ears,
- ❖ Palpitations,
- ❖ Hot flush,
- ❖ Yawning,
- ❖ Upset stomach, constipation, abdominal pain, vomiting, gas,
- ❖ Increased sweating, rash,
- ❖ Back pain, joint pain, muscle pain,
- ❖ Menstrual irregularities, erectile dysfunction,
- ❖ Malaise, chest pain, weakness, fever,
- ❖ Weight increased,
- ❖ Injury

Uncommon side effects (may affect up to 1 in 100 people):

- ❖ Gastroenteritis, ear infection,
- ❖ Tumour,
- ❖ Hypersensitivity, seasonal allergy,
- ❖ Low thyroid hormones,
- ❖ Suicidal thoughts, suicidal behaviour, psychotic disorder, thinking abnormal, lack of caring, hallucination, aggression, euphoric mood, paranoia,
- ❖ Amnesia, decreased feeling, involuntary muscle contractions, passing out, moving a lot, migraine, convulsion, dizziness while standing up, abnormal coordination, speech disorder,
- ❖ Enlarged pupils,
- ❖ Ear pain,
- ❖ Fast heartbeat, heart problem
- ❖ Bleeding problems (such as stomach bleeding), high blood pressure, flushing, blood in urine,
- ❖ Shortness of breath, nose bleed, breathing difficulty, possible wheezing.
- ❖ Tarry stools, tooth disorder, inflammation of the oesophagus, tongue problem, haemorrhoids, increased saliva, difficulty swallowing, burping, tongue disorder,
- ❖ Eye swelling, hives, hair loss, itching, purple spots on skin, skin problem with blisters, dry skin, face oedema, cold sweat,
- ❖ Osteoarthritis, muscle twitching, muscle cramps, muscular weakness,
- ❖ Increase in frequency of urination, problem urinating unable to urinate, urinary incontinence, increase in urination, nighttime urination,
- ❖ Sexual dysfunction, excessive vaginal bleeding, vaginal haemorrhage, female sexual dysfunction,
- ❖ Swelling in legs, chills, difficulty walking, thirst,

- ❖ Increase in liver enzyme levels, weight decreased.
- ❖ Cases of suicidal ideation and suicidal behaviours have been reported during SERWELL therapy or early after treatment discontinuation.

Rare (may affect up to 1 in 1,000 people):

- ❖ Diverticulitis, swollen lymph glands, decrease in clotting cells, decrease in white blood cells,
- ❖ Severe allergic reaction,
- ❖ Endocrine problems,
- ❖ High cholesterol, problems controlling blood sugar levels (diabetes), low blood sugar, increase in blood sugar levels, low blood salt,
- ❖ Physical symptoms due to stress or emotions, terrifying abnormal dreams, drug dependence, sleep walking, premature ejaculation,
- ❖ Coma, abnormal movements, difficulty moving, increased sensation, sudden severe headache (which may be a sign of a serious condition known as Reversible Cerebral Vasoconstriction Syndrome (RCVS)), sensory disturbance,
- ❖ Spots in front of eyes, glaucoma, double vision, light hurts eye, blood in the eye, unequal sized pupils, vision abnormal, tear problem,
- ❖ Heart attack, light-headedness, fainting, or chest discomfort which could be signs of changes in the electrical activity (seen on electrocardiogram) or abnormal rhythm of the heart, slow heartbeat,
- ❖ Poor circulation of arms and legs,
- ❖ Breathing fast, progressive scarring of lung tissue (Interstitial Lung Disease), closing up of throat, difficulty talking, breathing slow, hiccups,
- ❖ Mouth ulceration, pancreatitis, blood in stool, tongue ulceration, sore mouth,
- ❖ Problems with liver function, serious liver function problems, yellow skin and eyes (jaundice),
- ❖ Skin reaction to sun, skin oedema, hair texture abnormal, skin odour abnormal, hair rash,
- ❖ Breakdown of muscle tissue, bone disorder,
- ❖ Urinary hesitation, decreased urination,
- ❖ Breast discharge, dry vaginal area, genital discharge, red painful penis and foreskin, breast enlargement, prolonged erection,
- ❖ Hernia, drug tolerance decreased,
- ❖ Increase in blood cholesterol levels, abnormal laboratory tests, semen abnormal, problems with clotting,
- ❖ Relaxation of blood vessels procedure.

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 SERWELL

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.

Store this medicine below 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What SERWELL contains

The active ingredient is Sertraline Hydrochloride.

SERWELL 25

Each film coated tablet contains:

Sertraline Hydrochloride IP equivalent to Sertraline 25 mg

Colours: Erythrosine Lake & Titanium Dioxide

SERWELL 50

Each film coated tablet contains:

Sertraline Hydrochloride IP equivalent to Sertraline 50 mg

Colours: Erythrosine Lake & Titanium Dioxide

SERWELL 100

Each film coated tablet contains:

Sertraline Hydrochloride IP equivalent to Sertraline 100 mg

Colours: Erythrosine Lake & Titanium Dioxide

What SERWELL looks like and contents of the pack

SERWELL is pink coloured, round, biconvex, film coated tablets with breakline on one side. SERWELL tablets are packed in PVC Blister. The pack size is 10 x 10 tablets in a printed paper carton with packing insert.



Manufactured by :
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