

SETRONA

sertraline (as hydrochloride)

50 mg and 100 mg tablets

What is in this leaflet

Please read this leaflet carefully before you start taking SETRONA.

This leaflet answers some common questions about SETRONA. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SETRONA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What SETRONA is used for

SETRONA is used to treat:

- Depression and prevention of recurrence of depression (in adults).
- Obsessive compulsive disorder (OCD) (in adults and children and adolescents aged 6-17 years old).
- Panic disorder (in adults).
- Post-traumatic stress disorder (PTSD) (in adults).
- Social anxiety disorder (in adults).
- Premenstrual dysphoric disorder (PMDD) (in adults).

SETRONA belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). They are thought to work by blocking the uptake of serotonin (a chemical involved in controlling mood) into nerve cells in the brain.

Your doctor may have prescribed SETRONA for another reason. **Ask your doctor if you have any**

questions about why SETRONA has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you take SETRONA

When you must not take it

Do not take SETRONA if you have an allergy to:

- any medicine containing sertraline or
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- difficulty in breathing or wheezing.
- shortness of breath.
- swelling of the face, tongue, lips, or other parts of the body.
- hives on the skin, rash, or itching.

Do not take SETRONA if:

- If you are taking or have taken medicines called monoamine oxidase inhibitors (MAOIs such as moclobemide, phenelzine, selegiline or tranylcypromine), within the last 14 days. If you stop treatment with SETRONA, you must wait until at least 2 weeks before you start treatment with an MAOI. After stopping treatment with an MAOI, you must wait at least 2 weeks before you can start treatment with sertraline.
- If you are taking another medicine called pimozide (a medicine for mental health disorders such as psychosis).

Do not give this medicine to a child under the age of 18 years unless they are between the ages of 6 to 17 years old and SETRONA is being used for the treatment of obsessive-compulsive disorder (OCD).

Do not take it after the expiry date (EXP) printed on the back. If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking SETRONA, talk to your doctor.

Before you start to take it

Tell your doctor if:

- 1. you have any allergies to any foods, dyes, preservatives, or any other medicines.**
- 2. you have, or have had, the following medical conditions:**
 - If you have been told that you have an abnormality of your heart tracing after an electrocardiogram (ECG) known as prolonged QT interval.
 - If you have heart disease, low potassium levels or low magnesium levels, family history of QT prolongation, low heart rate and concomitant use of medications which prolong QT interval.
 - Serotonin Syndrome or Neuroleptic Malignant Syndrome (potentially life-threatening conditions). In rare cases these syndromes may occur when you are taking certain medicines at the same time as sertraline (see "Taking other medicines" below).
 - If you have suffered from manic depressive illness (bipolar disorder) or schizophrenia. If you have a manic episode, contact your doctor immediately.
 - Epilepsy or a history of seizures. If you have a fit (seizure), contact your doctor immediately.
 - If you have or have previously had thoughts of harming or killing yourself (see below "While you are taking SETRONA" "Thoughts of suicide and worsening of your depression or anxiety disorder").
 - If you have suffered from bleeding disorders or have been taking medicines which thin the blood (e.g., aspirin or warfarin), or may increase the risk of bleeding or if you are pregnant.
 - If you have low sodium level in your blood since this can occur because of treatment with SETRONA. You should also tell your doctor if you are taking certain medicines for high blood pressure (hypertension), since these medicines may also alter the sodium level in your blood.

- Diabetes- your blood glucose levels may be altered due to SETRONA, and your diabetes medicines may need to be adjusted.
- If you have a history of glaucoma (increased pressure in the eye).
- If you are having electro-convulsive (ECT) therapy.
- Liver disease: your doctor may decide that you should have a lower dose of SETRONA.
- Kidney problems.
- Acute or chronic pain, or other conditions that are treated with opioid medicines.

3. you are pregnant or intend to become pregnant.

The safety of SETRONA has not fully been established in pregnant women. SETRONA should only be given to pregnant women if the doctor considers that the benefit for the mother exceeds any possible risk to the unborn baby. Women of childbearing potential should employ an adequate method of contraception if taking SETRONA. There have been reports that babies exposed to SETRONA and other antidepressants during the third trimester of pregnancy may develop complications after birth.

If you take SETRONA 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 SETRONA so they can advise you.

4. you are breastfeeding or planning to breastfeed.

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

If you have not told your doctor about any of the above, tell them before you start taking SETRONA.

Medicines like SETRONA may cause symptoms of sexual dysfunction (see "Side effects" section). In some cases, these symptoms have continued after stopping treatment.

Restlessness: The use of sertraline has been linked to a distressing restlessness and need to move, often being unable to sit or stand still. This is most likely to occur during the first few weeks of treatment. Increasing the dose may be harmful so if you develop such symptoms you should talk to your doctor.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket, or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking SETRONA.

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

- Medicines called monoamine oxidase inhibitors (MAOIs), like moclobemide (to treat depression) and selegiline (to treat Parkinson's disease). Do not use SETRONA together with these medicines. Taking together may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and convulsions.
- Medicines to treat mental disorders such as psychosis (pimozide). Do not use SETRONA together with pimozide.

Some medicines may interfere with SETRONA. These include:

- Medicines containing amphetamines (used to treat attention deficit hyperactivity disorder (ADHD), narcolepsy, and obesity).
- Medicines to treat diabetes (tolbutamide).
- Medicines used to treat chronic and severe pain such as tramadol, methadone, fentanyl, pethidine.
- Herbal medicine containing St. John's wort (*Hypericum perforatum*).
- Medicines to treat migraines (e.g., sumatriptan).
- Blood thinning medicines (e.g., warfarin).
- Medicines to treat pain/arthritis (non-steroidal anti-inflammatory drugs (NSAID) such as ibuprofen, aspirin).
- Diuretics (also called 'water' tablets).
- Medicines to treat epilepsy (phenytoin, phenobarbital, carbamazepine).

- Medicines to treat diabetes (tolbutamide).
- Lithium, a medicine used to treat mania and depression.
- Other medicines to treat depression (such as amitriptyline, nortriptyline, fluoxetine).
- Medicines used to treat high blood pressure chest pain or regulate the rate and rhythm of the heart (such as flecainide, verapamil and diltiazem).
- Medicines to treat fungal infections (such as fluconazole, ketoconazole, itraconazole, posaconazole, voriconazole).
- Medicines to treat excessive stomach acid, ulcers and heartburn (cimetidine, omeprazole, lansoprazole, pantoprazole, rabeprazole).
- Antibiotics (such as clarithromycin, erythromycin, telithromycin).
- Tryptophan, contained in protein-based foods or dietary proteins.
- Dextromethorphan (used in cold and 'flu medicines to suppress cough).
- Metamizole, a medicine used to treat pain and fever
- Tapentadol, pentazocine, medicines used to treat moderate to severe pain.
- Fenfluramine, a medicine used to treat seizures.
- 5-HT antagonists, medicines used to treat nausea and vomiting.

These medicines may be affected by SETRONA or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking SETRONA.

How to take SETRONA

How much to take

Follow all directions given to you by your doctor or pharmacist carefully. Your doctor may have prescribed a different dose. A 25 mg dose may be obtained by halving the 50 mg tablet.

Tell your doctor if you have liver or kidney problems.

Adults:

Depression and Obsessive-Compulsive Disorder

For depression and OCD, the recommended effective dose is 50 mg tablet each day. The daily dose may be increased gradually and at intervals of at least one week over a period of weeks. The maximum recommended dose is 200 mg a 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 a day, and increased to 50 mg/day after one week. The daily dose then may be increased gradually and at intervals of at least one week over a period of weeks. The maximum recommended dose is 200 mg a day.

Premenstrual Dysphoric Disorder (PMDD)

If taking throughout the menstrual cycle

The usual starting dose is one 50 mg tablet a day. This may be increased to a maximum of 150 mg a day if needed. Increase the dose in a step wise fashion. If you are unclear how to do this ask your doctor or pharmacist for advice.

If taking in the last 14 days of the menstrual cycle

The usual starting dose is one 50 mg tablet a day. This may be increased to a maximum of 100 mg a day. **Do not take more than the maximum doses recommended above for PMDD.**

Use in 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, the 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 do not understand the instructions on the box, ask your doctor or pharmacist for help.

How to take it

Swallow the tablets with a glass of water. SETRONA tablets may be taken with or without food. The tablets can be divided into equal doses.

When to take it

Try to take your tablet at the same time each day, either morning or evening. Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.

How long to take it

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.

Continue taking your medicine for as long as your doctor tells you. Do not stop taking Sertraline unless your doctor tells you to. Your doctor will want to gradually reduce your dose of SETRONA over several weeks, if possible, 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. **If you experience any of these side effects, or any other side effects whilst stopping taking SETRONA, please talk to your doctor.**

If you forget to take it

Do not take a double dose to make up for the dose that you missed. This may increase the chance of unwanted side effects.

If you are not sure what to do, ask your doctor or pharmacist.

While you are taking SETRONA

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking SETRONA.

If you become pregnant while taking this medicine, tell your doctor immediately.

Tell your doctor immediately if you have any suicidal thoughts or other mental or mood changes. A worsening of depressive symptoms including thoughts of suicide or self-harm may occur at the beginning of a course of treatment with SETRONA or when the doctor changes your dose.

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. All mention of suicide or violence must be taken seriously.

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

Children should have regular check-ups with the doctor to monitor growth and development.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you are about to have any urine tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Things you must not do

Do not give SETRONA to anyone else, even if they have the same condition as you.

Do not stop taking SETRONA, or lower the dosage, without checking with your doctor. Your doctor may want you to gradually reduce the amount you are taking before stopping completely. This may help reduce the possibility of experiencing side effects such as dizziness, numbness, sleep disturbances, agitation, or anxiety.

Things to be careful of

Be careful driving or operating machinery until you know how SETRONA affects you. Psychotropic medicines 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.

Be careful if you are over 65 or very dehydrated (e.g., if you have been sick or had severe diarrhoea). You may be more at risk of having low sodium level in your blood (see "Before you start to take it- Tell your doctor if").

Alcohol should be avoided whilst taking SETRONA.

If you feel light-headed or incoordination when getting out of bed or standing up, get up slowly. An increased risk of bone fractures has been observed in patients taking this type of medicine.

You should wait at least 14 days after stopping SETRONA before starting medicines for depression or obsessive illnesses from the monoamine oxidase inhibitors (MAOIs) group (MAOIs such as moclobemide, phenelzine, selegiline or tranylcypromine)

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much SETRONA.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SETRONA.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- insomnia (trouble sleeping), dizziness, drowsiness, fatigue, headache, shaking, nausea, diarrhoea.
- fever, general feeling of being unwell (malaise), muscle twitching, muscle tense, muscle pain.
- abnormal taste, vomiting, dry mouth, upset stomach such as indigestion or heartburn.
- rash, increased sweating.
- menstrual irregularities, sexual dysfunction, decreased sexual interest, ejaculation failure.
- hot flush, yawning.
- visual disturbance, ringing in ears.
- inflammation of the colon (causing diarrhoea).

Tell your doctor as soon as possible if you notice any of the following symptoms:

- agitation, anxiety, nervousness, teeth grinding, paranoia, thinking abnormal, depersonalisation, nightmare.
- uncontrollable muscle spasms affecting the eyes, head, neck and body.
- palpitations, chest pain, irregular heartbeats.
- abnormal bleeding.
- heavy vaginal bleeding shortly after birth.

If any of the following happen, stop taking SETRONA and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing.
- hives.
- fainting.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to SETRONA. You may need urgent medical attention or hospitalisation. These side effects are very rare.

- fits or seizures.
- symptoms of sudden fever with sweating, fast heartbeat and muscle stiffness, agitation, confusion, diarrhoea.
- thoughts of suicide or attempting suicide or self-harm.

These may be serious side effect of SETRONA. You may need urgent medical attention. Serious side effects are uncommon.

Tell your doctor if you notice any other effects. Other adverse effects not listed above may also occur in some patients.

After taking SETRONA

Storage

Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the pack, they may not keep well.

Keep your tablets in a cool dry place where the temperature stays at or below 25°C.

Do not store SETRONA in the bathroom or near a sink. Do not leave it in the car or on a windowsill. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or they have passed their expiry date, ask your pharmacist what to do with any unused medicine. **Return any unused medicine to your pharmacist.**

Product description

What it looks like

SETRONA 50 mg tablets are white film-coated caplet shaped tablets embossed with '50' on one side and break line on the other. Pack size 30 tablets.

SETRONA 100 mg tablets are white film-coated caplet shaped tablets embossed with '100' on one

side and break line on the other. Pack size 30 tablets.

Ingredients

Active ingredient(s): sertraline (as sertraline hydrochloride)

Inactive ingredients: calcium hydrogen phosphate dihydrate; hypolose; magnesium stearate; microcrystalline cellulose; sodium starch glycolate; Opadry white OY-S-58910 (containing hypromellose, titanium dioxide, macrogol and talc)

Sponsor details

SETRONA is supplied in New Zealand by:
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