

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SERTRA.

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 SERTRA against the benefits it is expected to have for you.

Ask your doctor or pharmacist if you have any concerns about taking this medicine.

Keep this leaflet with the medicine.

You may need to read it again.

What SERTRA is used for

SERTRA is used to treat depression and conditions called obsessive compulsive disorder (OCD), panic disorder, social phobia (social anxiety disorder) and premenstrual dysphoric disorder (PMDD). PMDD affects some women in the days before their period. PMDD is different from premenstrual syndrome (PMS). The mood symptoms (anger, sadness, tension, etc) in PMDD are more severe than in PMS and affect the woman's daily activities and relationships with others.

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

Your doctor, however, may prescribe SERTRA for another purpose.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

SERTRA should not be used in children and adolescents under the age of 18 years for the treatment of any medical condition other than obsessive compulsive disorder (OCD). The safety and efficacy for the treatment of medical conditions (other than OCD) in this age group has not been satisfactorily established.

For the treatment of OCD, this medicine is not recommended for use in children under the age of 6, as the safety and efficacy in children of this age group has not been established.

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

There is no evidence that it is addictive.

Before you take it

When you must not take it

Do not take SERTRA if you have ever had an allergic reaction to sertraline hydrochloride or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include a skin rash, itchiness, hives on the skin, shortness of breath, wheezing, difficulty breathing and swelling of the face.

Do not take SERTRA if you have epilepsy not properly controlled by medication. Do

not take it if you are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking it within the last 14 days.

Taking this medicine with a MAOI (eg Aurorix, Eldepryl, Nardil, Parnate) may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and convulsions (fits).

Do not take SERTRA if you are taking phentermine (used to help weight loss), tryptophan (contained in protein-based foods or dietary proteins), methadone (used to treat drug addiction), medicines used to treat migraine, e.g. sumatriptan (Imigran), dextromethorphan (used as a cough suppressant in cold and 'flu medications), medicines used for pain management such as fentanyl, tapentadol (Palexia), tramadol or pethidine.

These medicines can cause an exaggerated response to SERTRA.

Do not take it if you are taking pimozide (used to treat disturbances in thinking, feeling and behaviour).

Ask your doctor or pharmacist if you are not sure if you have been taking one of these medicines.

Do not give SERTRA to children or adolescents under the age of 18 unless the doctor has prescribed it for the treatment of OCD. Do not give it to children under the age of 6 for the treatment of OCD.

Talk to your doctor if you are not sure whether you should be taking this medicine.

Do not take this medicine if the expiry date marked on the packaging has passed, even though the tablets may look alright.

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

If this is the case, take the tablets to your pharmacist.

Before you start to take it

Tell your doctor if you are allergic to any foods, dyes, preservatives or any other medicines.

Tell your doctor if you have any health problems, including:

- any other mental illness
- epilepsy or seizures
- liver or kidney problems
- heart conditions causing irregular heartbeats
- a tendency to bleed more than normal
- diabetes mellitus
- glaucoma, an eye condition.

Tell your doctor if you are pregnant or intend to become pregnant.

There have been reports that babies exposed to SERTRA and other antidepressants during the third trimester of pregnancy may develop complications immediately after birth.

Tell your doctor if you are breastfeeding or wish to breastfeed.

This medicine passes into breast milk and may affect your baby.

Your doctor will discuss the risks and benefits of using SERTRA when pregnant or breastfeeding.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by SERTRA or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

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

- other medicines for the treatment of depression called monoamine oxidase inhibitors (MAOIs).

Taking SERTRA with, or within 14 days of stopping a MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and convulsions.

- other MAOI drugs such as linezolid, an antibiotic used to treat pneumonia and certain skin infections
- other medicines for depression, panic disorder, social anxiety disorder or obsessive illnesses (e.g. Prothiaden, Prozac, Aropax, Luvox, Cipramil, Efexor XR, Xydep)
- lithium (e.g. Lithicarb), a medicine used to treat mood swings
- other medicines for PMDD (e.g. Prozac, Lovan, Xydep)
- tryptophan (contained in protein based foods or dietary proteins)
- phentermine (weight-reducing medicines)
- dextromethorphan (used in cold and 'flu medicines to suppress cough)
- medicines for strong pain management such as fentanyl, tapentadol (Palexia), tramadol or pethidine
- methadone (used to treat drug addiction)
- other medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis (e.g. aspirin or NSAIDs such as ibuprofen or diclofenac)
- pimozide (used to treat disturbances in thinking, feeling and behaviour)
- St John's wort, a herbal remedy used to treat mood disorders
- medicines for treating psychotic illness such as clozapine (e.g. Clozaril) which is used to treat schizophrenia
- medicines for irregular heartbeats (e.g. Tambocor)
- warfarin (e.g. Marevan, Coumadin) or other medicines that stop the blood from clotting
- phenytoin (e.g. Dilantin), a medicine used to treat epilepsy
- sumatriptan (e.g. Imigran), a medicine used to treat migraine
- diazepam or other medicines that act on the brain or nervous system (e.g. Serepax, Valium)

- cimetidine (e.g. Tagamet), a medicine used to treat reflux and ulcers
- medicines used to treat Attention Deficit Hyperactivity Disorder (ADHD) such as dexamphetamine and lisdexamphetamine
- antibiotics.

Not all brand names are given for the medicines listed above. Your doctor or pharmacist has more information on these medicines or other medicines to be careful with or avoid while taking SERTRA.

If you have not told your doctor or pharmacist about these things, tell them before you start taking SERTRA.

Some combinations of medicines may increase the risk of serious side effects and are potentially life threatening.

How to take it

Take SERTRA exactly as your doctor has prescribed.

Follow all directions given to you by your doctor. They may differ from the information contained in this leaflet.

How much to take

For DEPRESSION IN ADULTS the usual starting dose is one 50 mg tablet each day. The dose can be increased gradually up to 200 mg a day if necessary.

For OBSESSIVE COMPULSIVE DISORDER IN CHILDREN (6-12 YEARS) the usual starting dose for SERTRA is 25 mg/day (half a 50 mg tablet), increasing to 50 mg/day after one week.

For OBSESSIVE COMPULSIVE DISORDER IN ADULTS AND ADOLESCENTS (13-18 YEARS) the usual starting dose is one 50 mg tablet each day.

For PANIC DISORDER IN ADULTS the usual starting dose is 25 mg per day, increasing to 50 mg per day after one week.

For SOCIAL PHOBIA (SOCIAL ANXIETY DISORDER) IN ADULTS the usual starting dose is 25 mg per day, increasing to 50 mg per day after one week.

The maximum recommended dose for the conditions listed above is 200 mg per day.

For PREMENSTRUAL DYSPHORIC DISORDER the usual starting dose is one 50 mg tablet each day, either throughout the menstrual cycle (to a maximum of 150 mg daily) or for the last 14 days before the start of menses (to a maximum of 100 mg daily).

However, depending on your condition and how you react to the medicine, your doctor may ask you to take some other dose.

How to take it

Swallow the tablets with a glass of water.

Try to take your tablet at the same time each day, either morning or evening.

This medicine can be taken with or without food.

How long to take it for

Most medicines for depression and obsessive illnesses take time to work, so do not be discouraged if you do not feel better straight away.

It may take 2 to 4 weeks or even longer to feel the full benefit of SERTRA.

Occasionally the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing

suicide. It is possible that these symptoms may continue or increase until the full anti-depressant effect of your medicine becomes apparent (i.e. one to two months).

You or anyone close to you or caring for you should watch for these symptoms and tell your doctor immediately or go to the nearest hospital if you have any distressing thoughts or experiences during this initial period or at any other time.

Also contact your doctor if you experience any worsening of your depression or other symptoms at any time during your treatment. Even when you feel well, you may need to take SERTRA for several months or longer. Continue taking your medicine until your doctor tells you to stop.

If you have PMDD, your doctor may ask you to take this medicine only at certain times of the month.

Do not stop taking it, or change the dose, without first checking with your doctor.

If you forget to take it

Do not take an extra dose. Wait until the next day and take your normal dose then.

Do not try to make up for the dose you missed by taking more than one dose at a time.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much SERTRA. Do this even if there are no signs of discomfort or poisoning.

Keep telephone numbers for these places handy.

If you take too many tablets, you may feel drowsy, sick in the stomach, have a fast heart beat, suffer from tremors, feel agitated or dizzy. Coma has also been reported with overdose.

While you are taking it

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking SERTRA.

Tell all doctors, dentists and pharmacists who are treating you that you are taking this medicine.

Tell your doctor if you become pregnant while taking it.

If you are a woman of child-bearing age, you should avoid becoming pregnant while taking this medicine.

Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.

A worsening of depressive symptoms including thoughts of suicide or self-harm may occur in the first one or two months of you taking SERTRA or when the doctor changes your dose. These symptoms should subside when the full effect of SERTRA takes place.

Children, adolescents or young adults under 24 years of age are more likely to experience these effects during the first few months of treatment.

Patients and caregivers should be alert and monitor for these effects.

Signs and symptoms of suicide include:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of suicide or self-harm
- increase in aggressive behaviour, irritability or agitation
- worsening of depression.

All mention of suicide or violence must be taken seriously.

If you or someone you know is demonstrating these warning signs of suicide while taking SERTRA, contact your doctor or a mental health professional right 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 interact with other medicines used during surgery and cause unwanted side effects.

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 stop taking SERTRA, or change the dose, without first checking with your doctor. Do not let yourself run out of tablets over the weekend or on holidays.

Suddenly stopping this medicine may cause dizziness, lightheadedness, numbness, unusual tingling feelings or shakiness.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use it to treat any other complaints unless your doctor says so.

Things to be careful of

Be careful driving or operating machinery until you know how SERTRA affects you. Some medicines for depression may affect your ability to drive or operate machinery or do things that could be dangerous if you are not alert.

Although drinking moderate amounts of alcohol is unlikely to affect your response to SERTRA, your doctor may suggest avoiding alcohol.

If you are feeling drowsy or are uncoordinated, be careful that you do not fall over.

SERTRA, like other medicines in this class, may increase your risk of bone fracture.

You should wait at least 14 days after stopping SERTRA before starting medicines for depression or obsessive illnesses from the MAOI group, such as Aurorix, Eldepryl, Nardil, Parnate.

All of the above precautions are important even after you have stopped taking SERTRA.

The effects of this medicine may last for some days after you have stopped taking it.

Side effects

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

Like all other medicines, it may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. It can be difficult to tell whether side effects are the result of taking SERTRA, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

Tell your doctor if...

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

- headache, dizziness, shaking or tremors, unusually overactive, muscle stiffness or weakness, decrease or loss of touch or other senses, sleepiness, drowsiness, impaired concentration
- dry mouth, nausea, feeling sick, diarrhoea, indigestion, vomiting, stomach pain, constipation
- increased sweating, rash and hives
- tiredness, , fever, feeling unwell
- hot flush, high blood pressure
- weight increase or loss
- increased or decreased appetite
- sleeping difficulties, sexual problems,
- vision disturbance
- menstrual irregularities, sexual dysfunction including impaired sexual function in males difficulty in passing urine, or increased frequency
- persistent noise in the ears
- tingling and numbness of hands and feet

Tell your doctor as soon as possible if...

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

- agitation, nervousness, anxiety, frightening dreams, yawning, abnormal thinking, teeth grinding, symptoms of agitation, anxiety dizziness, headache, nausea and tingling or numbness of the hands and feet after stopping SERTRA
- uncontrollable muscle spasms affecting the eyes, head, neck and body, temporary paralysis or weakness of muscles
- lockjaw
- painful, swollen joints
- difficulty in breathing, wheezing or coughing
- uncontrollable movements of the body, shuffling walk, unusual weakness
- palpitations, fainting or chest pain
- irregular heartbeats
- abnormal bleeding including vaginal bleeding, sudden onset of severe headache.

Go to hospital if...

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- fits or seizures

- signs of allergy such as rash or hives, swelling of the face, lips or tongue, wheezing or difficulty breathing
- symptoms of sudden fever with sweating, fast heartbeat and muscle stiffness, which may lead to loss of consciousness
- thoughts of suicide or attempting suicide or self-harm. The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people. Some of these side effects (e.g., changes in thyroid function, liver function or glucose control) can only be found when your doctor does tests from time to time to check your progress.

After using it

Storage

Keep SERTRA 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.

Keep your medicine in a cool, dry place where the temperature stays below 25 degrees Celsius.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep your tablets in their blister pack until it is time to take them.

Disposal

If your doctor tells you to stop taking this medicine, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

SERTRA tablets come in two strengths:

- SERTRA 50 – oval, white film-coated tablets, scored on one side
- SERTRA 100 – oval, white film-coated tablet.

Each blister pack contains 30 tablets.

Ingredients

The active ingredient in SERTRA is sertraline (as hydrochloride).

- each SERTRA 50 tablet contains 50 mg of sertraline
- each SERTRA 100 tablet contains 100 mg of sertraline.

The tablets also contain:

- microcrystalline cellulose
- dibasic calcium phosphate dihydrate
- hydroxypropylcellulose
- sodium starch glycolate
- magnesium stearate
- Opadry White YS-1R-7003 (contains colour 171)
- Opadry Clear YS-1R-7006.

The tablets are gluten free.

Sponsor

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

Australian registration numbers:

SERTRA 50 mg - AUST R 107067

SERTRA 100 mg - AUST R 107071

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