

ELEVA

sertraline hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ELEVA. 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 ELEVA against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What ELEVA is used for

ELEVA is used to treat:

- depression, panic disorder, obsessive compulsive disorder (OCD) and social phobia (social anxiety disorder) in adults
- premenstrual dysphoric disorder (PMDD) in women. PMDD affects some women in the days before their period. PMDD is different from premenstrual syndrome (PMS). The mood symptoms (e.g. anger, sadness, tension) in PMDD are more severe than in PMS and affect the woman's daily activities and relationships with others.
- obsessive compulsive disorder (OCD) in
 - children (aged 6-12 years)
 - adolescents (13-18 years).

ELEVA 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.

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

Your doctor may have prescribed it for another reason.

ELEVA should not be used in children and adolescents under the age of 18 for the treatment of any medical condition other than OCD.

The safety and efficacy of ELEVA for the treatment of medical conditions (other than OCD) in this age group have not been satisfactorily established.

For the treatment of OCD, ELEVA 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 available only with a doctor's prescription.

This medicine is not addictive.

Before you take ELEVA

When you must not take it

Do not take ELEVA if you have an allergy to:

- any medicine containing sertraline

- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

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

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

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

Taking ELEVA with a MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and convulsions (fits).

Some examples of MAOIs include moclobemide (e.g. Aurorix), phenelzine (Nardil), tranylcypromine (Parnate), selegiline (e.g. Eldepryl).

Do not take ELEVA if you are taking:

- phentermine, a medicine used to help weight loss
- tryptophan, an amino acid which may be found in protein-based foods, some sports and dietary supplements or multivitamin preparations
- methadone, a medicine used to treat drug addiction
- medicines used to treat migraine, e.g. sumatriptan
- dextromethorphan, a medicine used as a cough suppressant in some cold and flu medications

- pimozone, a medicine used to treat disturbances in thinking, feeling and behaviour
- medicines used for pain management such as fentanyl, tapentadol, tramadol or pethidine

These medicines can cause an exaggerated response to ELEVA.

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

Do not give ELEVA to:

- children younger than 6 years for the treatment of OCD
- children or adolescents under 18 years of age unless the doctor has prescribed it for the treatment of OCD

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- 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 plan to become pregnant.

There have been reports that babies exposed to ELEVA 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.

ELEVA passes into breast milk and may affect your baby.

Your doctor will discuss the risks and benefits of taking ELEVA when pregnant or breastfeeding.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and ELEVA may interfere with each other.

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

- MAOIs (monoamine oxidase inhibitors), a group of medicines used to treat depression and the symptoms of Parkinson's disease.
Taking ELEVA with a MAOI, 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 (fits).
- other MAOI drugs such as linezolid, an antibiotic used to treat pneumonia and certain skin infections
- other medicines for depression, panic disorder, social anxiety or obsessive illnesses (dothiepin, desipramine, fluoxetine, paroxetine, citalopram, venlafaxine)
- lithium, a medicine used to treat mood swings
- other medicines for PMDD
- 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, tramadol or pethidine
- methadone, a medicine 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)
- metimazole, which is an inducer of metabolising enzymes, as this may cause a reduction in plasma concentrations of sertraline thus efficacy.
- pimozone, a medicine 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, a medicine used to treat schizophrenia
- flecainide, a medicine used to treat an irregular heartbeats
- warfarin or other medicines used to prevent blood clots
- phenytoin, a medicine used to treat epilepsy
- sumatriptan, a medicine used to treat migraine
- diazepam or other medicines that act on the brain or nervous system
- cimetidine, a medicine used to treat reflux and ulcers
- tolbutamide, a medicine used to treat diabetes
- dexamphetamine and lisdexamphetamine, medicines used to treat Attention Hyperactivity Disorder (ADHD)
- antibiotics

These medicines may be affected by ELEVA 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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

How to take ELEVA

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many tablets you need to take each day. This will depend on your age, your condition and whether or not you are taking any other medicines.

Depression in Adults

The usual starting dose is one 50 mg tablet each day. Your doctor may increase the dose gradually up to 200 mg a day if necessary.

Obsessive Compulsive Disorder in Children (6-12 years)

The usual starting dose is 25 mg each day (half a 50 mg tablet). Your doctor may increase the dose to 50 mg per day after one week.

Obsessive Compulsive Disorder in Adolescents (13 - 18 years) and Adults

The usual starting dose is one 50 mg tablet each day.

Panic Disorder in Adults

The usual starting dose is 25 mg each day (half a 50 mg tablet). Your doctor may increase the dose to 50 mg per day after one week.

Social Phobia (Social Anxiety Disorder) in Adults

The usual starting dose is 25 mg each day (half a 50 mg tablet). Your doctor may increase the dose to 50 mg per day after one week.

Do not take more than 200 mg a day for the conditions listed above.

Premenstrual Dysphoric Disorder

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. The dose is increased in a step-wise fashion. If you are unsure how to do this, ask your doctor.

If taking ELEVA in the last 14 days of the menstrual cycle:

The usual starting dose is one 50 mg tablet each 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.

How to take it

Swallow the tablets with a glass of water.

When to take it

Try to take your tablet at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

ELEVA can be taken with or without food.

For women with PMDD, your doctor may ask you to take this medicine only at certain times of the month.

How long to take it

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

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

Continue taking your medicine for as long as your doctor tells you to.

Even when you feel well, you may need to take ELEVA for several months or even longer.

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

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

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.

Contact your doctor if you experience any worsening of your depression or your symptoms at any time during your treatment.

If you forget to take it

Do not take a double dose to make up for the dose you missed. Wait until the next day and take your normal dose then.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at

your nearest hospital, if you think that you or anyone else may have taken too much ELEVA. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose include:

- feeling drowsy
- nausea, diarrhoea, vomiting
- fast or irregular heartbeats
- tremors
- feeling agitated or dizzy

While you are taking ELEVA

Things you must do

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

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately. Do not stop taking this medicine until you have spoken to your doctor.

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

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.

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 to two months of taking ELEVA or when the doctor changes your dose. These symptoms should subside when the full effect of ELEVA 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 ELEVA, contact your doctor or a mental health professional immediately.

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

Keep all of your doctor's appointments so that your progress can be checked.

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 take ELEVA to treat any other complaints unless your doctor tells you to.

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

Do not suddenly stop taking your medicine, or change the dose, without checking with your doctor.

Stopping ELEVA suddenly may cause dizziness, light headedness, numbness, unusual tingling feelings or shakiness.

Things to be careful of

Be careful driving or operating machinery until you know how ELEVA affects you.

If you do not feel alert, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful when riding bicycles or climbing trees.

Although drinking moderate amounts of alcohol is unlikely to affect your response to ELEVA, your doctor may suggest avoiding alcohol while you are taking ELEVA.

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

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

You should wait at least 14 days after stopping ELEVA before starting any other medicines for depression or obsessive illnesses from a MAOI group, e.g. Aurorix (moclobemide), Nardil (phenelzine), Parnate (tranylcypromine), Eldepryl (selegiline).

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

The effects of ELEVA 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 ELEVA.

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

It can be difficult to tell whether side effects are the result of taking ELEVA, 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 the following list of side 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:

- 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, hives
- tiredness, fever, feeling unwell
- hot flush, high blood pressure
- weight increase or loss
- increased or decreased appetite
- sleeping difficulties
- sexual problems
- vision disturbance
- irregular menstrual periods in women
- sexual dysfunction including impaired sexual function in males
- difficulty in passing urine, or increased frequency
- persistent noise in the ears
- tingling and numbness of the hands and feet
- inflammation of the colon (causing diarrhoea)

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 ELEVA

- 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

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

- 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 following symptoms are signs of side effects named Serotonin Syndrome (SS) or Neuroleptic Malignant Syndrome (NMS). SS is caused by medications which build up high levels of serotonin in the body. NMS is a life-threatening emergency associated with the use of antipsychotic medicines. The risk of SS and NMS with SSRI's is increased with combined use of other SSRIs, MAOIs and other antipsychotic medicines.

- agitation
- hallucinations
- coma
- fast heartbeat
- fluctuating blood pressure readings
- high body temperature

- twitching and spastic body movements
- lack of body co-ordination
- nausea
- vomiting
- diarrhoea

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 taking ELEVA

Storage

Keep your tablets in the 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 below 25°C.

Do not store ELEVA or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metre above the ground is a good place to store medicines.

Disposal

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

Product description

What it looks like

ELEVA is available in two strengths:

- ELEVA 50 - 4.2-4.5 mm x 10.3-10.7 mm, white to off-white, capsule shaped, film-coated tablets with “ST|50” on one side and “G” on the other side.
- ELEVA 100 - 5.2-5.6 mm x 13.0-13.4 mm, white to off-white, capsule shaped, film-coated tablets with “ST|100” on one side and “G” on the other side.

Each blister pack contains 30 tablets.

Ingredients

ELEVA contains either 50 mg or 100 mg of sertraline as the active ingredient.

The tablets also contain:

- microcrystalline cellulose
- calcium hydrogen phosphate
- sodium starch glycolate type A
- magnesium stearate
- purified water
- Opadry II Complete film coating system Y-22-7719 white (ARTG PI No: 2578)

Supplier

ELEVA is supplied in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
Phone: (02) 9298 3999
www.viatris.com.au

Australian registration numbers:

AUST R 95581 – ELEVA 50
sertraline hydrochloride 50 mg
tablet blister pack

AUST R 95582 - ELEVA 50
sertraline hydrochloride 50 mg
tablet bottle

AUST R 95583 - ELEVA 100
sertraline hydrochloride 100 mg
tablet blister pack

AUST R 95584 - ELEVA 100
sertraline hydrochloride 100 mg
tablet bottle

This leaflet was prepared in
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