

Eleva

contains the active ingredient 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 benefits and risks. Your doctor has weighed the risks of you taking Eleva against the benefits expected for you.

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

Keep this leaflet with your 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
- obsessive compulsive disorder (OCD) in
 - children (aged 6-12 years), and
 - 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.

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.

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

Your doctor may have prescribed Eleva for another reason.

Eleva 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 of Eleva for the treatment of medical conditions (other than OCD) in this age group has 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.

Eleva is available only with a doctor's prescription.

There is no evidence that Eleva is addictive.

Before you take Eleva

When you must not take it

Do not take Eleva if you are allergic to medicines containing sertraline hydrochloride or any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

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

Do not take Eleva if you are currently taking a medicine that belongs to the group of medicines called monoamine oxidase inhibitors (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).

MAOIs are medicines used to treat depression and Parkinson's disease. 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:

- tryptophan, an amino acid which may be found in some sports and dietary supplements or multivitamin preparations
- methadone, a medicine used to treat drug addiction

- medicines used to treat migraine, e.g. sumatriptan (Imigran)
- pimozide (Orap), a medicine used to treat mental illness with disturbances in thinking, feeling and behaviour
- phentermine (Duromine) for weight loss
- dextromethorphan, used as a cough suppressant in cold and flu medications
- medicines used for pain management such as fentanyl (Durogesic), tapentadol (Palexia), tramadol (e.g. Tramal), 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 and adolescents under 18 years of age for the treatment of depression, panic disorder, social phobia or premenstrual dysphoric disorder.

The safety and effectiveness of this medicine in the above age groups for these conditions have not been established.

If you are not sure whether you should be taking Eleva, talk to your doctor.

Do not take Eleva if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take Eleva if the packaging shows signs of tampering or the tablets do not look quite right.

Before you start to take it

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

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

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

Your doctor will discuss the risks and benefits of taking Eleva during pregnancy.

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 breastfeeding.

Tell your doctor if you have any medical conditions, especially the following:

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

Your doctor may want to take special care if you have any of these conditions.

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 if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some 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 will advise you.

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

- 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.
- 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 (Prothiaden, Pertofran, Prozac, Aropax, Luvox, Cipramil, Efexor)
- lithium (e.g. Lithicarb), a medicine used to treat mood swings
- other medicines for PMDD (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, 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)
- pimozide (Orap) a medicine used to treat mental illness with disturbances in thinking, feeling and behaviour
- St John's Wort, a herbal remedy used to treat mood disorders
- clozapine (e.g. Clozaril), a medicine used to treat schizophrenia

- flecainide (Tambocor), a medicine used to treat an irregular heart beat
- warfarin (Coumadin, Marevan) or other medicines used to prevent blood clots
- sumatriptan (e.g. Imigran), a medicine used to treat migraine
- diazepam (e.g. Valium) or other medicines that act on the brain or nervous system (e.g. Serepax)
- cimetidine (e.g. Tagamet), a medicine used to treat reflux and ulcers
- phenytoin (Dilantin) or carbamazepine (e.g. Tegretol), medicines used to treat epilepsy
- tolbutamide (e.g., Rastinon), a medicine used to treat diabetes
- antibiotics

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Not all brand names are given for the medicines listed above. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Eleva.

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

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

How to take Eleva

Follow all directions given to you by your doctor.

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.

How much to take

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. 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. 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 known as PMDD

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 your menstrual periods (to a maximum of 100 mg daily). Your doctor will tell you how to increase the dose gradually if necessary.

Do not take more than the maximum doses recommended above for PMDD.

However, depending on your condition and how you react to the medicine, your doctor may ask you to take some other dose. The maximum recommended dose of Eleva is 200 mg per day.

How to take it

Swallow the tablets with a glass of water.

When to take it

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

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

Eleva can be taken with or without food.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

If you are not sure what to do or have any questions about this, ask your doctor or pharmacist.

How long to take it for

Keep taking Eleva for as long as your doctor recommends.

The length of treatment will depend on how quickly your symptoms improve. Most medicines for depression and obsessive illnesses take time to work, so do not be discouraged if you do not feel better right away. Some of your symptoms may improve in 7 days but it may take 2 to 4 weeks or even longer to feel the full benefit of Eleva. Even when you feel well, you may need to take Eleva for several months or even longer to make sure the benefits last.

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

Do not stop taking Eleva, 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 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 you or anyone else may have taken too much Eleva, even if there are no signs of discomfort or poisoning. Keep telephone numbers for these places handy.

You may need urgent medical attention.

If you take too much Eleva, you may feel drowsy, dizzy, sick in the stomach; have a fast or irregular heartbeat, convulsions or hallucinations (seeing, feeling or hearing things that are not there). You may also have high or low blood pressure, feel agitated or even lose consciousness.

While you are taking Eleva

Things you must do

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

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Eleva.

Avoid becoming pregnant while taking Eleva, but tell your doctor immediately if you do become pregnant. Do not stop taking your tablets until you have spoken to your doctor.

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 Eleva or when the doctor changes your dose. These symptoms should be controlled when the full effect of Eleva takes place.

Children, adolescents or young adults under 25 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:

- worsening of symptoms such as depression
- 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 any other unusual changes in behaviour or mood.

All mentions 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 right away.

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

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

Stopping Eleva suddenly may cause discontinuation symptoms such as dizziness, unusual tingling feelings or electric shock sensations. Your doctor may want you to gradually reduce the amount of Eleva you are taking before stopping completely.

Do not use Eleva to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

Be careful driving or operating machinery until you know how Eleva 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 Eleva, your doctor may suggest avoiding alcohol while you are taking Eleva.

If you are feeling drowsy or are 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, Nardil, Parnate, Eldepryl.

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 it.

Side effects

Check with your doctor as soon as possible if you have any problems while taking Eleva, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Eleva can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Do not be alarmed by the 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, shakiness, muscle stiffness or weakness, decrease or loss of touch or other senses

- dry mouth, increased sweating, feeling sick, diarrhoea, indigestion, vomiting, stomach pain
- tiredness, pain, hot flushes, fever, feeling unwell
- weight increase or loss
- sleeping difficulties, sleepiness
- sexual problems
- vision disturbance
- irregular menstrual periods in women
- difficulty in passing urine, or increased frequency
- unusually overactive
- shaking or tremors.

These side effects are usually mild.

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

- agitation, nervousness, anxiety, frightening dreams, yawning, abnormal thinking, teeth grinding, loss of appetite, impaired concentration
- 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
- uncontrollable movements of the body, shuffling walk
- palpitations, fainting or chest pain
- irregular heartbeats
- abnormal bleeding.
- sudden onset of severe headache

Tell your doctor immediately, or go to 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 heart beat and muscle stiffness, which may lead to loss of consciousness
- thoughts of suicide or attempting suicide or self-harm.

These symptoms may be serious and need urgent medical attention or hospitalisation.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

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.

Ask your doctor or pharmacist if you do not understand anything in this list.

After taking Eleva

Storage

Keep Eleva 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.

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 Eleva in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

What it looks like

Eleva is available in two strengths:

- Eleva 50 - white to off-white, capsule shaped, film-coated tablets with "ST" over score line "50" on one side and "G" on the other side.
- Eleva 100 - white to off-white, capsule shaped, film-coated tablets with "ST" over score line "100" on one side and "G" on the other side.

Each blister pack contains 30 tablets.

Ingredients

The active ingredient in:

- Eleva 50 - 50 mg sertraline per tablet
- Eleva 100 - 100 mg sertraline per tablet.

The tablets also contain:

- cellulose - microcrystalline
- calcium hydrogen phosphate anhydrous
- sodium starch glycollate
- magnesium stearate
- Opadry II White Y-22-7719

Eleva tablets do not contain sugar, gluten or lactose.

Supplier

Eleva is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

ABN 93 002 359 739

www.alphapharm.com.au

Medical Information Phone:

1800 028 365

Australian Registration Numbers:

Eleva 50 blister pack AUST R 95581

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This leaflet was prepared on 22

January 2015.