

Elaxine SR 37.5, 75, and 150

Modified Release Capsules

venlafaxine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Elaxine SR modified release capsules. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist or asking questions.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Elaxine SR against the expected benefits it will have for you.

If you have any questions about Elaxine SR, ask your doctor or pharmacist.

Keep this leaflet with your Elaxine SR modified release capsules.

You may need to read it again.

What Elaxine SR is for

The name of your medicine is Elaxine SR. It contains the active ingredient called venlafaxine hydrochloride.

Elaxine SR modified release capsules are used in the treatment and prevention of relapse of depression and panic attacks and in the treatment of anxiety, including avoidance or fear of social situations.

Depression can affect your whole body and may cause emotional and physical symptoms such as feeling low in spirit, being unable to enjoy life, poor appetite or overeating, disturbed sleep, loss of sex drive,

lack of energy and feeling guilty over nothing.

Excessive anxiety is a condition in which you feel constantly and uncontrollably worried and distressed. It may also make you feel irritable, and cause difficulty in thinking and sleeping. Other common symptoms associated with anxiety may include a dry mouth, a lump in the throat, cold clammy hands, diarrhoea and nausea.

Depression and anxiety are treatable illnesses. Anxiety or tension associated with the normal stress of everyday life usually does not require treatment with medicines.

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.

How Elaxine SR works

Elaxine SR modified release capsules belong to a class of medications for depression and anxiety, called Serotonin-Noradrenaline Reuptake Inhibitors (SNRIs).

Serotonin and noradrenaline are chemical messengers that allow certain nerves in the brain to work. Elaxine SR modified release capsules increase the level of these two messengers. Experts think this is how it helps to restore your feeling of wellness.

Elaxine SR is not addictive.

Before you take Elaxine SR

When you must not take Elaxine SR

Do not take Elaxine SR if you are taking other medications for depression known as monoamine oxidase inhibitors, even if you have stopped taking them now, but have taken them within the last 14 days.

Do not take Elaxine SR if you are allergic to it or to any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction include:

- Skin rash
- Itching or hives on the skin
- Swelling of the face, lips, tongue, throat or other parts of the body
- Shortness of breath, wheezing or troubled breathing; difficulty swallowing.

Do not give Elaxine SR to children or adolescents under 18 years of age.

The safety and effectiveness of Elaxine SR in this age group have not been established.

Do not use Elaxine SR after the expiry date (EXP) printed on the pack.

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

Do not use Elaxine SR if the packaging is torn or shows signs of tampering.

Before you start to take Elaxine SR

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

Tell your doctor or pharmacist if you have allergies to the active ingredient or any of the other ingredients listed at the end of this leaflet.

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

Elaxine SR is not recommended for use during pregnancy. Your doctor will discuss the risks and benefits of using Elaxine SR if you are pregnant. One of these risks is that newborn babies, whose mothers have been taking Elaxine SR in the last few months of pregnancy, may experience problems soon after delivery, including breathing difficulties, seizures and lack of oxygen in their blood.

Tell your doctor or pharmacist if you are breast-feeding or planning to breast-feed.

Elaxine SR passes into breast milk and there is a possibility that the breast-fed baby may be affected. For this reason, the use of Elaxine SR is not recommended in breast-feeding women.

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

- A history of fits (seizures or convulsions)
- A personal history or family history of bipolar disorder
- A history of aggression
- A history of restlessness or difficulty sitting still
- Diabetes
- Blood pressure problems
- Glaucoma (increased pressure in the eye)
- A tendency to bleed more than normal
- Raised cholesterol levels
- Problems with your kidneys or liver

- Problems with your heart

Your doctor may wish to do some heart tests such as an electrocardiogram (ECG) or blood tests during treatment with Elaxine SR.

Tell your doctor if you have or have had any other medical conditions.

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell them before you take Elaxine SR.

Taking other medicines

Tell your doctor or pharmacist if you take any other medicines, including

- All prescription medicines
- Medicines for weight loss
- All medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Do not start to take any other medicine while you are taking Elaxine SR, unless it is prescribed or approved by your doctor.

Some medicines may interfere with Elaxine SR or Elaxine SR may interfere with these medicines. These include:

- Medications for depression known as monoamine oxidase inhibitors (such as moclobemide, linezolid, phenelzine and tranylcypromine), even if you have stopped taking them now, but have taken them within the last 14 days. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.
- Any other medications for depression, anxiety, obsessive-compulsive disorder or premenstrual dysphoric disorder, including St John's Wort

- Haloperidol, risperidone, lithium or clozapine (used to treat mental disorders)
- Tramadol, fentanyl, tapentadol, pethidine and methadone (strong pain killers)
- Dexamphetamine and lisdexamphetamine (used to treat Attention Deficit Hyperactivity Disorder - ADHD)
- Cimetidine (used to treat reflux and stomach ulcers)
- Triptans (used to treat migraine)
- Amiodarone or quinidine (used to treat irregular heart beats)

Your doctor may wish to do some heart tests such as an electrocardiogram (ECG) or blood tests if you are using either of these medicines whilst taking Elaxine SR.

- Medicines used to prevent blood clotting such as anti-coagulants and platelet inhibitors
- Indinavir (an antiviral)
- Erythromycin and linezolid (used to treat infections)
- Ketoconazole or fluconazole (used as antifungal medicines)
- Medications for weight loss, including sibutramine
- Metoprolol (used to treat high blood pressure or angina).

You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

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

How to take Elaxine SR

Swallow the modified release capsules whole with a glass of water or other non-alcoholic liquid. Do not divide, crush, chew or place the modified release capsules in water.

How much to take

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

Depression and Anxiety

The usual starting dose is 75mg taken once daily. After 2 weeks, your doctor may increase the dose to 150mg a day.

Panic Attacks

The usual starting dose is 37.5 mg once daily for the first 4 to 7 days, and then increased to 75 mg once daily.

Do not change your dose unless your doctor tells you to.

If you have kidney or liver problems, you may need a lower dose of Elaxine SR.

If you have heart problems and your doctor wishes to increase your dose of Elaxine SR, your doctor may first do some blood tests or heart tests such as an electrocardiogram (ECG).

When to take it

Elaxine SR should be taken once daily with food, at approximately the same time each day.

This could be either in the morning or in the evening.

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

Avoid drinking alcohol while you are using Elaxine SR.

How long to take Elaxine SR

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

Although you may begin to feel better after two weeks, it may take several weeks before you feel much better. It is important to give Elaxine SR time to work.

This medicine helps to control your condition, but does not cure it. It is

important to keep taking your medicine even if you feel well.

If you forget to take Elaxine SR

If it is less than 12 hours until your next dose, skip the dose you missed and then take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking as you would normally.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of you getting an unwanted side effect.

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

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre for advice (Tel: 13 11 26), or go to Accident and Emergency at your nearest hospital if you or anyone else may have taken too much Elaxine SR.

Do this even if there are no signs of discomfort or poisoning.

If you take too many Elaxine SR modified release capsules you may:

- Feel sleepy
- Vomit
- Have an increased heart rate or changes in heart rhythm
- Have a seizure (fits)
- Have breathing difficulties
- Become unconscious
- Have dilated pupils.

While you are taking Elaxine SR

Things you must do

Visit your doctor regularly for a check up. Always discuss any

questions you have about Elaxine SR modified release capsules with your doctor.

Your doctor may do some tests [such as an electrocardiogram (ECG) or blood tests] from time to time to make sure the medicine is working and to prevent unwanted side effects.

If you are going to have surgery, tell your doctor that you are taking this medicine.

Some agents used to assist your doctor during surgery may interact with **Elaxine SR** leading to unwanted side effects.

Take Elaxine SR modified release capsules as your doctor has prescribed.

Keep enough Elaxine SR modified release capsules to last weekends and holidays. You need a prescription from your doctor to get more Elaxine SR modified release capsules.

This medicine helps to control your condition, but not cure it. It is important to keep taking your medicine even if you feel well.

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

Watch carefully for signs that your depression or anxiety is getting worse, especially in the first few weeks of treatment or if your dose has changed.

Sometimes people with depression can experience a worsening of their depressive symptoms. This can happen even when taking an antidepressant.

Information from clinical trials has suggested that children, adolescents, and young adults (18-24 years), particularly those with depression, may be at increased risk of suicidal behaviour (including suicide attempts) if treated with venlafaxine, especially during initial treatment.

Tell your doctor immediately if you experience any of the following symptoms, especially if

they are severe, you have not had these symptoms before or they happen very suddenly.

- Anxiety or agitation
- Panic attacks
- Difficulty sleeping
- Irritability
- Aggressiveness
- Hostility or impulsiveness
- Restlessness
- Overactivity or uninhibited behaviour
- Other unusual changes in behaviour
- Thoughts of suicide.

Tell your doctor immediately if you have any thoughts about suicide or doing harm to yourself.

Warning signs of suicide

All thoughts or talk about suicide or violence are serious. If you or someone you know is showing the following warning signs, either contact your doctor or a mental health advisor right away or go to the nearest hospital for treatment:

- Thoughts or talk about death or suicide
- Thoughts or talk about self-harm or doing harm to others
- Any recent attempts of self-harm
- An increase in aggressive behaviour, irritability or agitation.

Things to be careful of

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

Elaxine SR modified release capsules may make you feel drowsy.

Things you must not do

Do not suddenly stop taking Elaxine SR modified release capsules if you have been taking it for some time.

Check with your doctor for the best way to slowly reduce the amount of

Elaxine SR you are taking before stopping completely.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects such as:

- Headache
- Nausea and vomiting
- Dizziness
- Insomnia
- Nervousness
- Anxiety
- Confusion and agitation
- Diarrhoea
- Sweating
- Loss of appetite
- Tremor
- Flu-like symptoms
- Impaired coordination and balance
- Tingling or numbness of the hands and feet.

Slowly reducing the amount of Elaxine SR being taken reduces the possibility of these effects occurring.

Some of these symptoms may impair driving, or the operation of dangerous machinery. These activities should be avoided if you experience these symptoms.

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

Side effects

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

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

Tell your doctor if you develop any of the following side effects and they worry you:

Stomach, bowel or urinary tract problems such as:

- Nausea or vomiting

- Loss of appetite
- Diarrhoea
- Constipation
- Difficulty passing urine, passing urine more frequently, or urinary incontinence.

Changes in your behaviour such as:

- Difficulty sleeping or abnormal dreams
- Paranoia
- Aggression
- Sexual function problems such as delayed ejaculation, problems with erection, decreased sex drive or difficulties achieving orgasm.
- Nervousness
- Teeth grinding
- Impaired coordination and balance

Difficulty thinking or working because of:

- Yawning
- Feeling sedated or drowsy
- Fainting and dizziness after standing up
- Restlessness or difficulty sitting still
- Headache
- Rapid heart beat
- Heavy or irregular menstrual periods.

Changes in your appearance such as:

- Sweating (including night sweats)
- Hot flushes
- Rash
- Hair loss
- Itchiness
- Weight loss or weight gain
- Flow of milk in women who are not breastfeeding

Changes in your sight, hearing, taste or touch such as:

- Blurred vision
- Ringing in the ears
- Altered taste or dry mouth

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

- Muscle tremors, spasms, twitching, jerky movements or sustained muscle contractions
- Abnormal facial movements such as tongue thrusting, repetitive chewing, jaw swinging, or grimacing
- A feeling of apathy or not caring about things
- Hallucinations
- Agitation
- Confusion
- Unusually overactive
- Changes in muscle tone, muscle weakness or fatigue
- Numbness or pins and needles
- Problems with breathing
- Cough
- Bleeding or bruising more easily than normal
- Sensitivity to sunlight.

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

- Fits or seizures, which may be accompanied by a sudden fever
- Signs of allergy such as rash or hives, swelling of the face, lips, tongue or throat, wheezing or difficulty breathing or swallowing
- Symptoms of sudden fever with sweating, rapid heart beat and muscle stiffness, which may lead to loss of consciousness
- Palpitations, fainting, shortness of breath or chest pain
- Dark, red or cola coloured urine, muscle weakness and tenderness, stiffness or aching
- Stomach pain, yellowing of the skin, nausea, fever, clammy skin and sweating
- Yellowing of the skin or eyeballs, fever, fatigue, loss of appetite, dark coloured urine or light coloured bowel movements
- A severe skin reaction with painful red areas and large blisters, accompanied by fever

and chills, aching muscles and generally feeling unwell.

- Symptoms of a high fever, agitation, confusion, trembling and abrupt contractions of muscles
- Signs of an infection such as severe chills, fever, sore throat and mouth ulcers
- Black sticky bowel motions or bloody diarrhoea.

These symptoms are usually rare but may be serious and need urgent medical attention.

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.

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

Other side effects not listed above may also occur in some people. Some of these side effects (for example, increase in blood pressure or blood cholesterol) can only be found when your doctor does tests from time to time to check your progress.

After using Elaxine SR

Storage

Keep your Elaxine SR modified release capsules in their blister pack until it is time to take them.

The modified release capsules may not last as well if you take them out of the blister pack.

Keep Elaxine SR modified release capsules in a cool dry place where the temperature stays below 25°C.

Do not store Elaxine SR modified release capsules or any other medicine in the bathroom or near a sink. Do not leave Elaxine SR modified release capsules in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep Elaxine SR modified release capsules and all medication where young 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

Return any unused medicine to your pharmacist.

Product description

What Elaxine SR looks like

There are four strengths of Elaxine SR modified release capsules, containing 37.5 mg, 75 mg 150 mg or 225 mg of venlafaxine in a modified release formulation, which allows for once-a-day dosing. The modified release capsules have the following appearance:

Elaxine SR 37.5, grey cap/peach body with thick and thin radial circular bands on the cap and body in red ink.

Elaxine SR 75, peach cap and body with thick and thin radial circular bands on the cap and body in red ink.

Elaxine SR 150, dark orange cap and body with thick and thin radial circular bands on the cap and body in white ink.

Elaxine SR 225* pink opaque cap/pink opaque body size '00' hard capsule with thick and thin radial circular bands on both the cap and body in blue ink

Elaxine SR 37.5, 75 150 and 225 mg are available in blister packs containing 28 modified release capsules.

Ingredients

Elaxine SR modified release capsules contain venlafaxine hydrochloride as the active ingredient.

Elaxine SR 37.5 mg, 75 mg 150 mg and 225 mg modified release

capsules contain the following inactive ingredients:

- -Microcrystalline cellulose
- Povidone
- Purified talc
- colloidal anhydrous silica
- Magnesium stearate
- Ethyl cellulose
- Copovidone
- Gelatin
- Titanium dioxide.

In addition to these,

Elaxine SR 37.5 modified release capsules also contain black iron oxide E172, red iron oxide , yellow iron oxide and SB-1033 red ink;

Elaxine SR 75 modified release capsules also contain black iron oxide, red iron oxide and SB-1033 red ink;

Elaxine SR 150 modified release capsules also contain Brilliant Blue FCF, Allura Red AC, Sunset Yellow FCF and SB-0007P white ink.

Elaxine SR 225: gelatin, titanium dioxide, Carmoisine. The printing uses TekPrint SB-6018 blue Ink (PI 2653).

Elaxine SR does not contain gluten, sucrose, tartrazine or any other azo dyes.

May contain trace amounts of phenylalanine and sulphites.

Sponsor

Arrow Pharma Pty Ltd
15-17 Chapel Street
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Australian registration numbers:

Elaxine SR 37.5:
AUST R 285314

Elaxine SR 75:
AUST R 285315

Elaxine SR 150:
AUST R 285316

Elaxine SR 225*
AUST R 292634

* not marketed

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