

Arrow – Venlafaxine XR

Venlafaxine (as hydrochloride) Modified Release Tablets 37.5mg, 75mg, 150mg

What is in this leaflet

This leaflet answers some common questions about ARROW – VENLAFAXINE XR.

It does not contain all of 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 ARROW – VENLAFAXINE XR 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 your medicine. You may need to read it again.

What ARROW – VENLAFAXINE XR is used for

ARROW – VENLAFAXINE XR is used in the treatment of major depression and anxiety, including avoidance or fear of social situations and the treatment of panic attacks. It is also used to prevent relapse and recurrence of major depression.

ARROW – VENLAFAXINE XR contains the active ingredient venlafaxine hydrochloride. It belongs to a group of medicines called serotonin-noradrenaline reuptake inhibitors (SNRIs). It increases the levels of serotonin and noradrenaline in the brain, which are involved in controlling mood.

Depression is longer lasting or more severe than the "low moods" everyone has from time to time due to the stress of everyday life. It is thought to be caused by chemical imbalance in some parts of the brain. This imbalance affects your whole body and can cause emotional and physical symptoms, such as feeling low in spirit, loss of interest in activities, being unable to enjoy life, poor appetite or over-eating, disturbed sleep, often waking up early, 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.

Your doctor may have prescribed ARROW – VENLAFAXINE XR for another reason. **Ask your doctor if you have any questions about why ARROW – VENLAFAXINE XR has been prescribed for you.**

There is no evidence that ARROW – VENLAFAXINE XR is addictive.

ARROW – VENLAFAXINE XR is available only with a doctor's prescription.

Before you take ARROW – VENLAFAXINE XR

When you must not take it

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

Do not take ARROW – VENLAFAXINE XR 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 ARROW – VENLAFAXINE XR to a patient under 18 years of age. The safety and effectiveness of ARROW - VENLAFAXINE XR in this age group has not been established.

Do not use ARROW - VENLAFAXINE XR 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 ARROW - VENLAFAXINE XR if the packaging is torn or shows signs of tampering.

Before you start to take ARROW - VENLAFAXINE XR

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. ARROW - VENLAFAXINE XR is not recommended for use during pregnancy. Your doctor will discuss the risks and benefits of using ARROW - VENLAFAXINE XR if you are pregnant. One of these risks is that newborn babies, whose mothers have been taking ARROW - VENLAFAXINE XR 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. ARROW - VENLAFAXINE XR passes into breast milk and there is a possibility that the breast-fed baby may be affected. For this reason, the use of ARROW - VENLAFAXINE XR is not recommended in breast-feeding women.

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

- A history of fits (seizures or convulsions)
- A personal history or family history of bipolar disorder
- A history of aggression
- Blood pressure problems
- Glaucoma (increased pressure in the eye)
- A tendency to bleed more than normal
- Raised cholesterol levels
- Problems with your heart, kidneys or liver
- Conditions that require treatment with anti-coagulants or platelet therapy
- 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 ARROW - VENLAFAXINE XR.

Taking other medicines

Tell your doctor or pharmacist if you take any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop, such as St Johns Wort or tryptophan supplements.

Do not start to take any other medicine while you are taking ARROW - VENLAFAXINE XR, unless it is prescribed or approved by your doctor.

Some medicines may interfere with ARROW - VENLAFAXINE XR or ARROW - VENLAFAXINE XR may interfere with these medicines. These include:

- Medications for depression known as monoamine oxidase inhibitors (such as 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 (a pain killer)
- Cimetidine (used to treat reflux and stomach ulcers)
- Triptans (used to treat migraine)
- Amiodarone or quinidine (used to treat irregular heart beats)
- 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 ARROW - VENLAFAXINE XR.

How to take ARROW – VENLAFAXINE XR

Swallow the tablets whole with a glass of water or other non-alcoholic liquid. Do not divide, crush, chew or dissolve the tablets in water.

Do not be concerned if you see a tablet in your stools after taking ARROW – VENLAFAXINE XR. As the tablet travels the length of your gastrointestinal tract, venlafaxine is slowly released. The shape of the tablet remains undissolved and is eliminated in your stools. Therefore, even though you may see a tablet in your stools, your dose of venlafaxine has been absorbed.

How much to take

The usual starting dose for the treatment of major depression and anxiety is 75mg taken once daily. If necessary, after two weeks, your doctor may increase your dose. The maximum daily dose is 375 mg per day.

For panic attacks, treatment is usually started with a dose of 37.5mg once daily for the first 4 to 7 days. After that time the dose should be increased to 75mg once daily. If necessary, after two weeks, your doctor may increase your dose. The maximum daily dose is 225mg per day.

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 ARROW - VENLAFAXINE XR.

When to take it

ARROW - VENLAFAXINE XR 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.

Avoid drinking alcohol while you are using ARROW - VENLAFAXINE XR.

How long to take ARROW - VENLAFAXINE XR

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 ARROW - VENLAFAXINE XR time to work.

Even when you feel well again, you may need to keep taking ARROW - VENLAFAXINE XR for several months to make sure the benefits last. Discuss this with your doctor and don't stop taking ARROW - VENLAFAXINE XR unless your doctor tells you to.

If you forget to take ARROW - VENLAFAXINE XR

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. Contact your doctor if you have missed more than two doses in a row.

Always finish the tablets you are taking in the current pack before you start a new pack.

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

If you take too much (overdose)

It is important that you do not take more ARROW - VENLAFAXINE XR than your doctor has prescribed. If you do take more than you have been prescribed, contact your doctor immediately for advice.

Immediately telephone your doctor or 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 ARROW – VENLAFAXINE XR. Do this even if there are no signs of discomfort or poisoning.

If you take too many ARROW - VENLAFAXINE XR tablets you may notice the following: feeling sleepy to becoming unconscious, vomit, rapid heart beat, seizure (fit), breathing difficulties or dilated pupils/blurred vision.

While you are taking ARROW – VENLAFAXINE XR

Things you must do

Visit your doctor regularly for a check up. Always discuss any questions you have about ARROW - VENLAFAXINE XR with your doctor.

Take ARROW - VENLAFAXINE XR as your doctor has prescribed.

Keep enough ARROW - VENLAFAXINE XR to last weekends and holidays. You need a prescription from your doctor to get more ARROW - VENLAFAXINE XR.

Watch carefully for signs that your depression or anxiety is getting worse, especially in the first few weeks of treatment, or if your dose is 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) when treated with ARROW - VENLAFAXINE XR, 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

ARROW - VENLAFAXINE XR may make you feel drowsy. Be careful driving or operating dangerous machinery until you know how it affects you.

Things you must not do

Do not suddenly stop taking ARROW - VENLAFAXINE XR if you have been taking it for some time.

Check with your doctor for the best way to slowly reduce the amount of ARROW - VENLAFAXINE XR you are taking before stopping completely.

Side effects from stopping treatment with ARROW - VENLAFAXINE XR may include:

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

Slowly reducing the amount of ARROW - VENLAFAXINE XR being taken reduces the possibility of these effects occurring. Some of these symptoms may impair driving, or the operation of dangerous machinery.

Avoid these activities if you experience these symptoms.

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

Side effects

All medicines can have side effects. Sometimes they are serious; often they are not.

Tell your doctor if you develop any of the following side effects or if they become troublesome.

Stomach, bowel or urinary tract problems such as:

- Nausea or vomiting
- Loss of appetite
- Diarrhoea
- Constipation
- Difficulty passing urine.

Changes in your behaviour such as:

- Difficulty sleeping or abnormal dreams
- Sexual function problems such as delayed ejaculation, problems with erection, decreased sex drive or difficulties achieving orgasm.
- Nervousness
- Teeth grinding
- Muscle tremors, spasms, twitching, jerky movements or sustained muscle contractions
- Impaired coordination and balance
- 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.

Difficulty thinking or working because of:

- Yawning
- Feeling sedated or drowsy
- Fainting or dizziness after standing up
- Changes in muscle tone
- Muscle weakness or fatigue
- Restlessness or difficulty sitting still
- Headache
- Rapid heart beat
- Problems with breathing
- 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
- Bleeding or bruising more easily than normal
- Flow of milk in women who are not breastfeeding.

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

- Blurred vision
- Dilated pupils
- Visual disturbances
- Sensitivity to sunlight.
- Ringing in the ears
- Altered taste
- Dry mouth
- Numbness or pins and needles.

Other changes you may not be aware of:

- Increased blood pressure
- Increase in blood cholesterol levels.

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, 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.

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.

After taking ARROW – VENLAFAXINE XR

Storage

Keep ARROW – VENLAFAXINE XR 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 tablets in a cool dry place where the temperature stays below 25 °C.

Do not store ARROW – VENLAFAXINE XR 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.

Disposal

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

Product Description

What it looks like

ARROW – VENLAFAXINE XR comes in 3 strengths of tablets and all are white, round, film coated tablets.

Ingredients

The active ingredient in ARROW – VENLAFAXINE XR is venlafaxine (as hydrochloride).

The tablets also contain:

- mannitol
- povidone
- macrogol 400
- microcrystalline cellulose
- colloidal anhydrous silica
- magnesium stearate

The film coat also contains cellulose acetate, macrogol 400 and opadry white Y-30-18037 (hypromellose, lactose monohydrate, titanium dioxide, triacetin).

The tablets do not contain gluten.

Supplier

ARROW – VENLAFAXINE XR is distributed in New Zealand by:

Arrow Pharmaceuticals (NZ) Limited

33a Normanby Road, Mt Eden
Auckland, New Zealand.

Date of preparation

24 March 2011