



### VENLAFAXINE GENERICHEALTH XR

Venlafaxine Hydrochloride, Modified Release Capsules

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#### What is in this leaflet

This leaflet answers some common questions about VENLAFAXINE GENERICHEALTH XR 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 VENLAFAXINE GENERICHEALTH XR against the expected benefits it will have for you.

If you have any questions about VENLAFAXINE GENERICHEALTH XR, ask your doctor or pharmacist.

Keep this leaflet with your VENLAFAXINE GENERICHEALTH XR capsules. You may need to read it again.

#### What VENLAFAXINE GENERICHEALTH XR is for

The name of your medicine is VENLAFAXINE GENERICHEALTH XR. It contains the active ingredient called venlafaxine hydrochloride.

VENLAFAXINE GENERICHEALTH XR capsules are used in the treatment and prevention of relapse of depression.

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.

Depression is a treatable illness. Anxiety or tension associated with the normal stress of everyday life usually does not require treatment with medicines.

VENLAFAXINE GENERICHEALTH XR 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.

VENLAFAXINE GENERICHEALTH XR capsules increase the level of these two messengers. Experts think this is how it helps to restore your feeling of wellness.

VENLAFAXINE GENERICHEALTH XR is not addictive.

Your doctor may have prescribed VENLAFAXINE GENERICHEALTH XR capsules for another purpose. Ask your doctor if you have any questions about why VENLAFAXINE GENERICHEALTH XR capsules has been prescribed for you.

## **Before you take VENLAFAXINE GENERICHEALTH XR**

### *When you must not take VENLAFAXINE GENERICHEALTH XR*

Do not take VENLAFAXINE GENERICHEALTH XR 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 VENLAFAXINE GENERICHEALTH 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 or other parts of the body
- Shortness of breath, wheezing or troubled breathing.

Do not give VENLAFAXINE GENERICHEALTH XR to children or adolescents under 18 years of age. The safety and effectiveness of VENLAFAXINE GENERICHEALTH XR in this age group have not been established.

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

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

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 VENLAFAXINE GENERICHEALTH 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 VENLAFAXINE GENERICHEALTH XR, unless it is prescribed or approved by your doctor.

Some medicines may interfere with VENLAFAXINE GENERICHEALTH XR or VENLAFAXINE GENERICHEALTH 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)

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 VENLAFAXINE GENERICHEALTH XR:

- Warfarin (used to prevent blood clotting)
- 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 VENLAFAXINE GENERICHEALTH XR.

### **How to take VENLAFAXINE GENERICHEALTH XR**

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

Inside VENLAFAXINE GENERICHEALTH XR capsules are tablets that contain the venlafaxine active ingredient. As the medicine travels the length of your gastrointestinal tract, venlafaxine is slowly released.

### *How much to take*

The usual starting dose is 75mg taken once daily. If necessary, after two weeks, your doctor may increase your dose.

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

### *When to take it*

VENLAFAXINE GENERICHEALTH 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 VENLAFAXINE GENERICHEALTH XR.**

### *How long to take VENLAFAXINE GENERICHEALTH 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 VENLAFAXINE GENERICHEALTH XR time to work.

Even when you feel well again, you may need to keep taking VENLAFAXINE GENERICHEALTH XR for several months to make sure the benefits last. Discuss this with your doctor and don't stop taking VENLAFAXINE GENERICHEALTH XR until gaining your doctor's agreement.

### *If you forget to take VENLAFAXINE GENERICHEALTH 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 capsules 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 VENLAFAXINE GENERICHEALTH XR capsules than your doctor has prescribed. If you do take more than you have been prescribed, contact your doctor immediately for advice.

If anyone accidentally swallows any VENLAFAXINE GENERICHEALTH XR capsules, call your nearest Poisons Information Centre for advice (tel: 13 11 26), or go to Accident and Emergency at your nearest hospital. Keep the telephone number for these places handy whilst taking any medications.

If you take too many VENLAFAXINE GENERICHEALTH XR 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 VENLAFAXINE GENERICHEALTH XR**

### *Things you must do*

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

Take VENLAFAXINE GENERICHEALTH XR capsules as your doctor has prescribed.

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

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

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*

VENLAFAXINE GENERICHEALTH XR capsules 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 VENLAFAXINE GENERICHEALTH XR capsules if you have been taking it for some time.**

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

Side effects from stopping treatment with VENLAFAXINE GENERICHEALTH XR may include:

- 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 VENLAFAXINE GENERICHEALTH XR 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

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, passing urine more frequently, or urinary incontinence..

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
- Flow of milk in women who are not breastfeeding
- Bleeding or bruising more easily than normal.

In some people, VENLAFAXINE GENERICHEALTH XR may lead to changes in the way your blood clots.

**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 or tongue, wheezing or difficulty breathing
- 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.

## After using VENLAFAXINE GENERICHEALTH XR

### *Storage*

Keep your VENLAFAXINE GENERICHEALTH XR capsules in their blister pack until it is time to take them. The capsules may not last as well if you take them out of the blister pack.

Keep VENLAFAXINE GENERICHEALTH XR capsules in a cool dry place where the temperature stays below 25 degrees C.

Do not store VENLAFAXINE GENERICHEALTH XR capsules or any other medicine in the bathroom or near a sink. Do not leave VENLAFAXINE GENERICHEALTH XR capsules in the car or on windowsills. Heat and dampness can destroy some medicines.

Keep VENLAFAXINE GENERICHEALTH XR 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 VENLAFAXINE GENERICHEALTH XR looks like*

There are two strengths of VENLAFAXINE GENERICHEALTH XR capsules, containing 75 mg or 150 mg of venlafaxine in an extended release formulation, which allows for once-a-day dosing.

VENLAFAXINE GENERICHEALTH XR 75mg capsules are presented as flesh opaque capsules. VENLAFAXINE GENERICHEALTH XR 150mg capsules are presented as scarlet opaque capsules.

### *Ingredients*

VENLAFAXINE GENERICHEALTH XR capsules contain venlafaxine hydrochloride as the active ingredient.

VENLAFAXINE GENERICHEALTH XR 75 mg and 150 mg capsules contain the following inactive ingredients:

- Hypromellose
- Sodium lauryl sulfate
- Magnesium stearate
- Ammonio methacrylate copolymer
- Basic butylated methacrylate copolymer
- Titanium dioxide (E171)
- Gelatin.

The 75mg capsules also contain red iron oxide (E172). The 150mg capsules also contain Erythrosine (E127) and Indigo carmine (E132)

### **Sponsor**

VENLAFAXINE GENERICHEALTH XR capsules are supplied by:  
Generic Health Pty Limited  
Suite1, 1175 Toorak Road  
Camberwell VIC, 3124, Australia

### **Australian Registration Numbers:**

75 mg blister packs: AUST R 151884

150 mg blister packs: AUST R 151876

This leaflet was prepared July 2009