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**PATIENT INFORMATION LEAFLET****SCHEDULING STATUS:** S5**VENLAFAXINE XR 37,5 BIOTECH hard prolonged-release capsules****VENLAFAXINE XR 75 BIOTECH hard prolonged-release capsules****VENLAFAXINE XR 150 BIOTECH hard prolonged-release capsules**

Venlafaxine

Sugar free.

**Read all of this leaflet carefully before you start taking VENLAFAXINE XR BIOTECH.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or health care provider.
- VENLAFAXINE XR BIOTECH has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**

1. What VENLAFAXINE XR BIOTECH is and what it is used for
2. What you need to know before you take VENLAFAXINE XR BIOTECH
3. How to take VENLAFAXINE XR BIOTECH
4. Possible side effects
5. How to store VENLAFAXINE XR BIOTECH
6. Contents of the pack and other information.

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## 1. What VENLAFAXINE XR BIOTECH is and what it is used for

VENLAFAXINE XR BIOTECH capsules contain venlafaxine as active ingredient in quantities of either 37,5 mg, 75 mg or 150 mg per capsule.

VENLAFAXINE XR BIOTECH is an antidepressant and one of a group of medicines known as serotonin and norepinephrine reuptake inhibitors. Serotonin and norepinephrine are chemical messengers (hormones) in your brain.

People that suffer from depression or anxiety usually have lower levels of serotonin and norepinephrine in the brain. VENLAFAXINE XR BIOTECH may help to increase the levels of serotonin and norepinephrine in your brain.

VENLAFAXINE XR BIOTECH is therefore used in the treatment of depression, including depression with associated anxiety, as well as generalised anxiety (anxiety and uncontrollable worry for several months) and social anxiety disorder (worry about social situations which can cause you severe anxiety and distress).

## 2. What you need to know before you take VENLAFAXINE XR BIOTECH

### Do not take VENLAFAXINE XR BIOTECH:

- If you are hypersensitive (allergic) to venlafaxine or any of the other ingredients of VENLAFAXINE XR BIOTECH.
- If you are also taking a type of medicine known as monoamine oxidase inhibitors (MAOIs) used in the treatment of depression or Parkinson's disease.
- If you have taken MAOIs within the last fourteen days.
- VENLAFAXINE XR BIOTECH must be discontinued for at least 7 days before starting treatment with any MAOI as concomitant use may result in serious or even life-threatening side effects.
- If you are younger than 18 years of age.
- If you are pregnant or breastfeeding your baby.

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## Warnings and precautions

### Take special care with VENLAFAXINE XR BIOTECH

#### Suicide/suicidal thoughts or worsening of depression:

You may sometimes have thoughts of harming or killing yourself if you are suffering from depression and/or have anxiety disorders and such thoughts may be increased when you first start taking VENLAFAXINE XR BIOTECH.

You may experience symptoms such as anxiety, agitation, panic attacks, difficulty sleeping (insomnia), irritability, hostility (aggressiveness), impulsivity, inability to sit still (akathisia), state of extremely energetic, talkative, and confident behaviour commonly exhibited with a flight of creative ideas (hypomania), and abnormal feeling of well-being and excitement (mania).

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital immediately.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

#### Use in children and adolescents under the age of 18 years:

The safety and efficacy of VENLAFAXINE XR BIOTECH in children under 18 years of age have not been established.

#### Serotonin syndrome:

If you are taking VENLAFAXINE XR BIOTECH in combination with particular medicines a potentially life-threatening condition, serotonin syndrome, may result. These medicines include:

- triptans (used in the treatment of migraines);
- SSRIs, SNRIs, lithium, MAOIs (used to treat depression);

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- sibutramine (used in weight loss);
  - St John's wort (*Hypericum perforatum*),
  - medicines used in the treatment of severe pain, such as fentanyl and its analogues, tramadol, tapentadol, pethidine, pentazocine
  - dextromethorphan (in certain cough medicines)
  - tryptophan supplements or antipsychotics and other dopamine antagonists.

You should be carefully monitored if you are starting with any of the above medicine when taking VENLAFAXINE XR BIOTECH, or when the dose is increased.

**Narrow-angle glaucoma:**

If you have increased eye ball pressure or are at risk for acute narrow-angle glaucoma VENLAFAXINE XR BIOTECH should be used with caution.

**Blood pressure:**

Regular blood pressure monitoring is advised if you suffer from high blood pressure as VENLAFAXINE XR BIOTECH can cause an increase in your blood pressure.

**Heart disease and risk of irregular heartbeat:**

VENLAFAXINE XR BIOTECH should be used with caution if you have a recent history of heart attack (myocardial infarction) or unstable heart disease as it has not been evaluated in these patients.

**Convulsions:**

If you have a history of convulsions (fits), VENLAFAXINE XR BIOTECH should be used with caution as fits can occur. You should be closely monitored. If you develop seizures the use of VENLAFAXINE XR BIOTECH should be discontinued.

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**Decrease in sodium levels:**

If you are an elderly patient, taking diuretics or are dehydrated, you are at increased risk for developing very low sodium levels (hyponatraemia) or a condition called syndrome of inappropriate antidiuretic hormone (SIADH) secretion with the use of VENLAFAXINE XR BIOTECH.

**Abnormal bleeding:**

If you have a tendency to develop bruises or a tendency to bleed easily (history of bleeding disorders) or if you are taking other medicines that may increase the risk of bleeding VENLAFAXINE XR BIOTECH should be used with caution. You must notify your doctor if you develop a rash, hives, or a related allergic phenomenon. There may be an increased risk of skin and mucous membrane bleeding, including gastrointestinal haemorrhage if you are taking VENLAFAXINE XR BIOTECH.

**Cholesterol monitoring:**

During long-term treatment with VENLAFAXINE XR BIOTECH your blood cholesterol levels should be monitored as there have been reports of increased cholesterol levels.

**Co-administration of weight loss medicine:**

The safety and efficacy of VENLAFAXINE XR BIOTECH therapy in concomitant use with weight loss agents, including phentermine, is not known and therefore not recommended. VENLAFAXINE XR BIOTECH is not indicated for weight loss alone or in combination with other products.

**Mania/hypomania**

If you have a family history of bipolar disease VENLAFAXINE XR BIOTECH should be used

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with caution as you may develop abnormal feelings of well-being and excitement (mania), or a state of extremely energetic, talkative, and confident behaviour commonly exhibited with a flight of creative ideas (hypomania).

**Aggression:**

VENLAFAXINE XR BIOTECH should be used with caution if you have a history of aggression, especially when initiating treatment, with dose changes and discontinuation of treatment.

**Sexual problems**

VENLAFAXINE XR BIOTECH may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

**Restlessness:**

The use of VENLAFAXINE XR BIOTECH has been associated with the development of a condition characterised by restlessness and a need to move often accompanied by an inability to sit or stand still. This generally occurs within the first few weeks of treatment. If you develop these symptoms, increasing the dose may be harmful.

**Dry mouth:**

As VENLAFAXINE XR BIOTECH may cause dry mouth, dental hygiene is very important to prevent an increase in the risk of caries.

**Diabetes:**

If you are a diabetic patient the dose of insulin or and/or oral antidiabetic may need to be adjusted by your doctor when you start taking VENLAFAXINE XR BIOTECH.

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### Laboratory testing

Inform the laboratory technician that you are taking VENLAFAXINE XR BIOTECH if you are going for laboratory testing.

### Other medicines and VENLAFAXINE XR BIOTECH:

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

You should not take medicines known as monoamine oxidase inhibitors (MAOIs), that are used in the treatment of depression or Parkinson's disease, with VENLAFAXINE XR BIOTECH or if you have taken these medicines within the last fourteen days. MAOIs include medicines such as moclobemide and linezolid.

The concomitant use of the following medicines and VENLAFAXINE XR BIOTECH may result in the potentially life-threatening condition, serotonin syndrome:

- MAOIs such as moclobemide (used in treatment of depression)
- linezolid (antibiotic)
- triptans (used in treatment of migraine)
- selective serotonin reuptake inhibitors (e.g. citalopram, fluoxetine, sertraline)
- lithium (used in treatment of depression)
- sibutramine (in weight loss medicine)
- tramadol (used in pain treatment)
- St John's wort (*Hypericum perforatum*), (natural antidepressant)
- serotonin precursors such as tryptophan supplements (used in treatment of sleep problems and depression).

Do not drink alcohol while on VENLAFAXINE XR BIOTECH treatment.

VENLAFAXINE XR BIOTECH may lower the blood levels of the following medicine:

- indinavir.

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VENLAFAXINE XR BIOTECH may increase the blood levels of:

- imipramine (used to treat depression)
- haloperidol or risperidone (used to treat psychiatric conditions)
- metoprolol (used to treat high blood pressure and heart problems).

The concomitant use of VENLAFAXINE XR BIOTECH with the following medicine can change the rhythm of your heart and should be avoided:

- class Ia and III antidysrhythmics (e.g. quinidine, amiodarone, sotalol, dofetilide)
- certain antipsychotics (e.g. thioridazine)
- certain antibiotics (e.g. erythromycin)
- certain antihistamines
- certain quinolone antibiotics (e.g. moxifloxacin).

The following medicines may increase the blood levels of VENLAFAXINE XR BIOTECH:

- antifungal medicine called ketoconazole, voriconazole, posaconazole, ketoconazole, itraconazole
- antiviral medicine called atazanavir; clarithromycin, indinavir, nelfinavir; ritonavir, saquinavir
- antibiotic called telithromycin.

**VENLAFAXINE XR BIOTECH with food, drink and alcohol:**

VENLAFAXINE XR BIOTECH should be taken with food.

You should avoid alcohol while you are taking VENLAFAXINE XR BIOTECH.

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**Pregnancy and breastfeeding:**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking VENLAFAXINE XR BIOTECH.

You should not take VENLAFAXINE XR BIOTECH if you are pregnant or breastfeeding your baby.

**Driving and using machines:**

VENLAFAXINE XR BIOTECH may cause dizziness, drowsiness, blurred vision, hallucinations or other central nervous system side effects, which affect concentration. If you experience such symptoms, do not drive a vehicle, use machines, or do other activities that your attention.

**3. How to take VENLAFAXINE XR BIOTECH**

Do not share medicines prescribed for you with any other person.

Always take VENLAFAXINE XR BIOTECH exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is 75 mg, given once daily. If after several weeks further clinical improvement is required, your doctor may increase your dose to 150 mg, given once daily. If needed, the dose can be further increased up to 225 mg given once daily. Dose increments should be made at intervals of approximately 2 weeks or more, but not less than 4 days.

The dose for depressed patients may be further increased, if needed, up to 375 mg, given once daily.

You should take VENLAFAXINE XR BIOTECH with food. Each capsule should be swallowed whole with fluid. Do not divide, crush, chew or place capsule in water.

VENLAFAXINE XR BIOTECH should be taken at approximately the same time either in the morning or in the evening.

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If you have impaired kidney or liver function you should take lower doses VENLAFAXINE XR BIOTECH as prescribed by your doctor.

Your doctor will tell you how long your treatment with VENLAFAXINE XR BIOTECH will last.

If you have the impression that the effect of VENLAFAXINE XR BIOTECH is too strong or too weak, tell your doctor or pharmacist.

### **If you take more VENLAFAXINE XR BIOTECH than you should**

In the event of over dosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.

Overdose with VENLAFAXINE XR BIOTECH was primarily reported in combination with alcohol and/or other medicines.


Symptoms of overdose include fast or slow heart rate, low blood pressure, low blood sugar, spinning sensation, changes in levels of consciousness, dilated pupils, fits and vomiting.

### **If you forget to take VENLAFAXINE XR BIOTECH:**

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for forgotten individual doses.

### **If you stop taking VENLAFAXINE XR BIOTECH:**

You should not suddenly stop taking VENLAFAXINE XR BIOTECH as withdrawal symptoms are well-known to occur. Symptoms of withdrawal include extremely energetic, talkative and confident behaviour commonly exhibited with a flight of creative ideas (hypomania), anxiety, agitation, nervousness, confusion, difficulty sleeping (insomnia) or other sleep disturbances, fatigue, drowsiness (somnolence), sensation of pins and needles (paraesthesia), dizziness, fits (convulsions), dizziness (vertigo), headache, flu-like symptoms, ringing in ears (tinnitus), impaired coordination and balance, shivering (tremor), sweating, dry mouth, weight loss (anorexia), diarrhoea, nausea and vomiting.

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On discontinuing treatment your doctor will taper down your dose over at least a two-week period.

#### 4. Possible side effects

VENLAFAXINE XR BIOTECH can have side effects.

Not all side effects reported for VENLAFAXINE XR BIOTECH are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking VENLAFAXINE XR BIOTECH, please consult your health care provider for advice.

**If any of the following happens, stop taking VENLAFAXINE XR BIOTECH and tell your doctor immediately or go to the casualty department at your nearest hospital:**

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to VENLAFAXINE XR BIOTECH. You may need urgent medical attention or hospitalisation.

**Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:**

*The following side effects were experienced frequently:*

- fast heart rate (tachycardia), rapid, strong or irregular heartbeat (palpitations)
- urinary retention/hesitation, abnormally frequent urination (pollakiuria)

*The following side effects were experienced less frequently:*

- heart rhythm disorders or other heart conditions

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- respiratory disorders: inability to breathe and get enough oxygen into your bloodstream (interstitial lung disease) or pulmonary eosinophilia (respiratory disorder characterised by the accumulation of white blood cells in the lungs).

These are all serious side effects. You may need urgent medical attention.

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

*The following side effects were experienced frequently:*

- decreased appetite
- difficulty to sleep (insomnia), feeling confused, thoughts and feelings that seem unreal or not to belong to oneself (depersonalisation), abnormal dreams, nervousness, low sex drive (libido), feeling agitated, inability to achieve orgasm (anorgasmia)
- headache, dizziness, sleepiness (sedation), feeling of restlessness (akathisia), shivering (tremor), sensation of pins and needles (paraesthesia), taste disorder (dysgeusia)
- visual impairment, including blurred vision, dilated pupils (mydriasis), accommodation disorder, visual disturbance
- ringing in ears (tinnitus)
- high blood pressure, hot flushes
- yawning
- nausea (feeling sick), dry mouth, constipation, diarrhoea, vomiting (being sick)
- sweating (including night sweats)
- abnormally high level of muscle tone or tension (hypertonia)
- menstrual disorders associated with increased bleeding or increased irregular bleeding (e.g. menorrhagia, metrorrhagia), erectile dysfunction and ejaculation disorders
- unusual weakness or tiredness (fatigue), lack of energy (asthenia), chills
- increased or decreased body mass, increased blood cholesterol.

*The following side effects were experienced less frequently:*

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- blood disorders (agranulocytosis, aplastic anaemia, pancytopenia neutropenia and thrombocytopenia)
  - excessive water intake (known as syndrome of inappropriate antidiuretic hormone secretion), milky discharge from breasts (when not pregnant or breastfeeding)
  - very low sodium levels (hyponatraemia)
  - abnormal feeling of well-being and excitement (mania), confident behavior commonly exhibited with a flight of creative ideas (hypomania), hallucinations (hearing and seeing things that do not exist), abnormal orgasm (female), talkative and excessive grinding of the teeth and/or excessive clenching of the jaw (bruxism), a feeling that one's surroundings are not real (derealisation), lack of feeling, emotion, interest, and concern (apathy), restlessness, illusions (delirium)
  - fainting (syncope), twitching of a muscle or a group of muscles (myoclonus), balance disorders, abnormal coordination, abnormality or impairment of voluntary movement (dyskinesia), fever, muscular rigidity, altered mental status (neuroleptic malignant syndrome), serotonin syndrome (characterised by high body temperature, agitation, increased reflexes, tremor, sweating, dilated pupils and diarrhoea), seizures, muscle contractions (dystonia), involuntary, repetitive body movements (tardive dyskinesia)
  - increased pressure in the eye (glaucoma)
  - feeling dizzy when standing up from a lying or sitting position (orthostatic hypotension), low blood pressure (hypotension)
  - blood in your stools, inflammation of your pancreas (pancreatitis)
  - abnormal liver function tests, jaundice (hepatitis)
  - hair loss (temporary), bruising (ecchymosis), sensitivity of skin when exposed to sunlight, Stevens-Johnson syndrome (serious skin disorder), toxic epidermal necrolysis (life-threatening skin condition, characterised by skin peeling), erythema multiforme (serious skin condition of unknown cause)

- breakdown of muscle tissue (rhabdomyolysis)
- involuntary leakage of urine (urinary incontinence)
- bleeding gums (mucosal haemorrhage)
- abnormal results in blood tests.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### **Reporting of side effects:**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of VENLAFAXINE XR BIOTECH.

## **5. How to store VENLAFAXINE XR BIOTECH**

- Store at or below 25 °C. Protect from moisture.
- Keep blister strips in outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

## **6. Contents of the pack and other information**

### **What VENLAFAXINE XR BIOTECH contains:**

The active substance is venlafaxine.

Other ingredients are:

*Extended-release mini film coated tablets:* microcrystalline cellulose, povidone, talc, colloidal silicon dioxide, magnesium stearate, ethyl cellulose, copovidone.

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*Capsule shell (VENLAFAXINE XR 37,5 BIOTECH):* gelatine, iron oxide black (E172), iron oxide red (E172), iron oxide yellow (E172), titanium dioxide (E171), red ink (butyl alcohol, dehydrated alcohol, isopropyl alcohol, propylene glycol, shellac, strong ammonia solution, iron oxide red (E172)).

*Capsule shell (VENLAFAXINE XR 75 BIOTECH):* gelatine, iron oxide black (E172), iron oxide red (E172), titanium dioxide (E171), red ink (butyl alcohol, dehydrated alcohol, isopropyl alcohol, propylene glycol, shellac, strong ammonia solution, iron oxide red (E172)).

*Capsule shell (VENLAFAXINE XR 150 BIOTECH):* gelatine, FD&C Blue 1 (E133), FD&C Red 40 (E129), FD&C Yellow 6 (E110), titanium dioxide (E171), white ink (butyl alcohol, dehydrated alcohol, isopropyl alcohol, povidone, propylene glycol, shellac, sodium hydroxide, titanium dioxide (E171)).

#### **What VENLAFAXINE XR BIOTECH looks like and contents of the pack:**

VENLAFAXINE XR BIOTECH are hard gelatine capsules, filled with extended-release mini film coated tablets.

Each extended-release mini film coated tablet contains venlafaxine hydrochloride equivalent to 12,5 mg venlafaxine.

VENLAFAXINE XR 37,5 BIOTECH: Each hard prolonged-release capsule contains venlafaxine hydrochloride equivalent to 37,5 mg venlafaxine.

VENLAFAXINE XR 37,5 BIOTECH capsules are filled with 3 extended-release mini film coated tablets (3 x 12,5 mg venlafaxine).

VENLAFAXINE XR 75 BIOTECH: Each hard prolonged-release capsule contains venlafaxine hydrochloride equivalent to 75 mg venlafaxine.

VENLAFAXINE XR 75 BIOTECH capsules are filled with 6 extended-release mini film coated tablets (6 x 12,5 mg venlafaxine).

VENLAFAXINE XR 150 BIOTECH: Each hard prolonged-release capsule contains

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venlafaxine hydrochloride equivalent to 150 mg venlafaxine.

VENLAFAXINE XR 150 BIOTECH capsules are filled with 12 extended- release mini film coated tablets (12 x 12,5 mg venlafaxine).

PVC/PVdC//aluminium (white opaque//silver) blister strips containing 10 capsules per blister strip, packed in an outer carton.

PVC/Aclar//aluminium (white opaque//silver) blister strips containing 10 capsules per blister strip, packed in an outer carton.

Pack sizes: 30 (3 blister strips x 10 capsules) and 100 (10 blister strips x 10 capsules).

**Holder of Certificate of Registration:**

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**This leaflet was last revised in**

30 September 2024

**Registration number**

**VENLAFAXINE XR 37,5 BIOTECH:** 51/1.2/0638

**VENLAFAXINE XR 75 BIOTECH:** 51/1.2/0639

**VENLAFAXINE XR 150 BIOTECH:** 51/1.2/0640

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