

**SCHEDULING STATUS**

S5

**MYLAN VENLAFAXINE XL 75, capsule****MYLAN VENLAFAXINE XL 150, capsule****Venlafaxine hydrochloride equivalent to venlafaxine**

**This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that  
is to say essentially 'sodium free'**

**Sugar free****Read all of this leaflet carefully before you start taking MYLAN VENLAFAXINE XL**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- MYLAN VENLAFAXINE XL 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 MYLAN VENLAFAXINE XL is and what it is used for.
2. What you need to know before you take/ use MYLAN VENLAFAXINE XL.
3. How to take MYLAN VENLAFAXINE XL.
4. Possible side effects.
5. How to store MYLAN VENLAFAXINE XL.
6. Contents of the pack and other information.



## 1. What MYLAN VENLAFAXINE XL is and what it is used for

### What MYLAN VENLAFAXINE XL is:

MYLAN VENLAFAXINE XL contains the active ingredient called venlafaxine hydrochloride. It belongs to a class of medications for depression and anxiety, called serotonin-noradrenaline reuptake inhibitors (SNRIs). It is thought that people who are depressed may have lower levels of serotonin and noradrenaline in their brain. MYLAN VENLAFAXINE XL may help to relieve the symptoms of depression or anxiety by increasing the levels of these substances in the brain.

### What it is used for;

MYLAN VENLAFAXINE XL is used to treat mental depression including depression associated with anxiety.

## 2. What you need to know before you take MYLAN VENLAFAXINE XL

### Do not take MYLAN VENLAFAXINE XL:

- If you are hypersensitive (allergic) to venlafaxine or any of the other ingredients of MYLAN VENLAFAXINE XL.
- If you are under the age of 18 years.
- If you are pregnant or breastfeeding (*see Pregnancy and breastfeeding and fertility*).
- If you are also taking or have taken any time within the last 14 days any medicines known as monoamine oxidase inhibitors (MAOIs); these are medicines containing moclobemide or selegiline, used to treat depression or Parkinson's disease. Taking a MAOI together with other medicines, including MYLAN VENLAFAXINE XL, can cause serious or even life-threatening side effects. You must also wait at least 7 days after you stop taking MYLAN VENLAFAXINE XL and before you take any MAOIs (*see Other medicines and MYLAN VENLAFAXINE XL*).

## Warnings and precautions

### Take special care with MYLAN VENLAFAXINE XL:

If any of the following conditions apply to you, please talk with your doctor.

- If you use other medicines that when taken together with MYLAN VENLAFAXINE XL, you could have an increased risk of developing serotonin syndrome (see Other medicines and MYLAN VENLAFAXINE XL for information regarding serotonin syndrome).
- If you have eye problems, such as certain kinds of glaucoma (increased pressure in the eye).
- If you have a history of high blood pressure.
- If you have a history of heart problems, such as a previous heart attack.
- If you have a history of fits (seizures).
- If you have a history of low sodium levels in your blood (hyponatraemia).
- 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. If you take aspirin, medicines for pain and swelling (such as diclofenac, ibuprofen and indomethacin), warfarin and other anti-blood clotting medicines, that may increase the risk of bleeding.
- If you have high cholesterol.
- If you have a history of, or if someone in your family has had, mania or bipolar disorder.
- If you have a feeling of over-excitement (mania) or a feeling of mental and physical well-being.
- If you have a history of aggressive behaviour.
- MYLAN VENLAFAXINE XL may cause a sensation of restlessness or an inability to sit or stand still. You should tell your doctor if this happens to you.
- If you have had serious problems with your heart rhythm.



- If you are using weight loss medicines. Using MYLAN VENLAFAXINE XL and weight loss medicines together is not recommended.
- Medicines like MYLAN VENLAFAXINE XL (so called SNRIs) may cause symptoms of sexual dysfunction (see *section 4*).
- Your blood glucose levels may be altered due to MYLAN VENLAFAXINE XL. Therefore, the dosage of your diabetes medicines may need to be adjusted.
- False-positive test results for phencyclidine (PCP) and amphetamine have been reported and may be expected for several days after you have stopped taking MYLAN VENLAFAXINE XL.
- Do not drink alcohol while being treated with MYLAN VENLAFAXINE XL as it can lead to extreme tiredness and unconsciousness. Concomitant use with alcohol and/or certain medicines can make your symptoms of depression and other conditions, such as anxiety disorders worse.

**Thoughts of suicide and worsening of your depression or anxiety disorder:**

If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or killing yourself. These may be increased when you first start taking MYLAN VENLAFAXINE XL, since MYLAN VENLAFAXINE XL takes time to work, usually about two weeks, but sometimes longer.

**You are more likely to have suicidal thoughts:**

- If you have previously had thoughts about killing yourself or harming yourself.
- If you are a young adult. Information available has shown an increased risk of suicidal behaviour in young adults with psychiatric conditions who were treated with an antidepressant.

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.

### **Children/ and adolescents**

MYLAN VENLAFAXINE XL should not be used for children and adolescents under 18 years because it has not been proven to be an effective medicine in this age group. Also, patients under 18 years may have an increased risk of side effects such as suicidal thoughts and harming themselves when they take MYLAN VENLAFAXINE XL.

### **Other medicines and MYLAN VENLAFAXINE XL**

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

#### **Monoamine oxidase inhibitors (*MAO inhibitors - see section Do not take MYLAN VENLAFAXINE XL*):**

Medicines for depression known as monoamine oxidase inhibitors (such as moclobemide, 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.

Allow at least 7 days after stopping MYLAN VENLAFAXINE XL before starting a MAOI  
Taking this medicine with a MAOI, or within 7 days of taking a MAOI, may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

The appropriate washout period is needed to prevent severe possible side effects.

**Serotonin syndrome:**

A potentially life-threatening condition or neuroleptic malignant syndrome-like reactions (see *section 4*) may occur with MYLAN VENLAFAXINE XL treatment, particularly when taken with other medicines.

Examples of these medicines include:

- Triptans (used for migraine).
- Medicines to treat depression, for instance selective serotonin re-uptake inhibitors, tricyclic antidepressants (used to treat depression or anxiety), or medicines containing lithium.
- Medicines containing sibutramine (used for weight loss).
- Medicines containing e.g. tramadol (a painkiller).
- Medicines containing St. John's Wort (a herbal remedy used to treat mild depression).
- Amphetamines (medicines used for attention deficit hyperactivity disorder, obesity and narcolepsy (a sleep disorder that makes people very drowsy during the day)).
- Medicines containing linezolid, an antibiotic (used to treat infections).
- Medicines containing selegiline (used for Parkinson's disease).
- Opioids (e.g. buprenorphine) used to treat severe pain or opioid use disorder.
- Medicines containing tryptophan (used for problems such as sleep and depression).

The following medicines may also interact with MYLAN VENLAFAXINE XL and should be used with caution. It is especially important to mention to your doctor or pharmacist if you are taking medicines containing:

- Indinavir (used in the treatment of HIV infections).
- Warfarin (for thinning blood to prevent blood clotting).
- Alcohol.
- Haloperidol or risperidone (to treat psychiatric conditions).



- Cimetidine (for antacid treatment) and if you are elderly or have liver or renal problems since cimetidine might increase the effect of MYLAN VENLAFAXINE XL.
- Metoprolol (medicine used to reduce blood pressure).
- Ketoconazole or fluconazole for fungal infections.
- Medicines containing imipramine or desipramine (antidepressants).

### **MYLAN VENLAFAXINE XL with food and drink and alcohol**

- Take MYLAN VENLAFAXINE XL capsules with food.
- Swallow the capsule whole with fluid.
- Do not drink alcohol while being treated with MYLAN VENLAFAXINE XL.

Concomitant use with alcohol can lead to extreme tiredness and unconsciousness and can make your symptoms of depression and other conditions, such as anxiety disorders worse.

### **Pregnancy and breastfeeding and fertility**

If you are already taking MYLAN VENLAFAXINE XL and have just found out you are pregnant, you should talk to your doctor immediately.

You should not take MYLAN VENLAFAXINE XL if you are pregnant or breastfeeding your baby.

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

If you are a woman of childbearing age, you are recommended to use contraception whilst taking MYLAN VENLAFAXINE XL. You should not use MYLAN VENLAFAXINE XL during pregnancy.

If you take MYLAN VENLAFAXINE XL near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders.

### **Driving and using machinery**

It is not always possible to predict to what extent MYLAN VENLAFAXINE XL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MYLAN VENLAFAXINE XL affects them.

MYLAN VENLAFAXINE XL may cause effects such as impairment of judgement, thinking and motor skills. Do not drive or operate machinery if you are unsure of the effect that the medicine will have on your abilities. It may affect your co-ordination or concentration.

### **MYLAN VENLAFAXINE XL contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium free'.

### **3. How to take MYLAN VENLAFAXINE XL**

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

Always take MYLAN VENLAFAXINE XL exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose of MYLAN VENLAFAXINE XL is:

- One capsule of 75 mg once daily, which may be increased to 150 mg once daily, with food. Your doctor will assess your condition and prescribe the right dose for you.
- Take MYLAN VENLAFAXINE XL at approximately the same time every day in the morning or at night.
- Swallow the capsule whole with fluid.
- Do not divide, crush, chew or place the capsule in water.
- Your doctor will tell you how long your treatment with MYLAN VENLAFAXINE XL will last.

- You may have to take MYLAN VENLAFAXINE XL for at least a few weeks or longer before you will begin to feel better. Also, you will need to keep taking MYLAN VENLAFAXINE XL for at least a few months, even after you feel better, to help prevent your depression from returning.
- Do not suddenly stop taking MYLAN VENLAFAXINE XL as you may experience withdrawal reactions.
- If you want to stop taking MYLAN VENLAFAXINE XL, talk to your doctor first so that he can advise you on how to stop gradually.
- If you have the impression that the effect of MYLAN VENLAFAXINE XL is too strong or too weak, talk to your doctor or pharmacist.

#### **If you take more MYLAN VENLAFAXINE XL than you should**

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

Overdose can be life-threatening, especially with concomitant use of alcohol and/or certain medicines (see *Other medicines and MYLAN VENLAFAXINE XL*).

The symptoms of a possible overdose may include a rapid heartbeat, changes in level of alertness (ranging from sleepiness to coma), blurred vision, seizures or fits, and vomiting.

#### **If you forget to take a dose of MYLAN VENLAFAXINE XL**

- If you missed a dose, take it as soon as possible.
- However, if you do not remember the missed dose until the next day, skip the missed dose and go back to your regular dosing schedule.
- Do not take more than the amount of MYLAN VENLAFAXINE XL that has been prescribed for you in one day.

## If you stop taking MYLAN VENLAFAXINE XL

- Your doctor might recommend that you stop treatment gradually to minimise these effects.
- Do not stop taking your capsules or change the dose without the advice of your doctor even if you feel better.
- If your doctor thinks that you no longer need MYLAN VENLAFAXINE XL, he/she will ask you to reduce your dose slowly before stopping treatment altogether. This should help reduce the chance of withdrawal symptoms.
- If MYLAN VENLAFAXINE XL is stopped suddenly or the dose reduced too quickly, some patients may experience symptoms such as overactive behaviour, anxiety, agitation, nervousness, confusion, sleeplessness, tiredness, drowsiness, tingling or electric shock sensations on the skin, dizziness, seizures, feeling of falling or spinning, headache, flu-like symptoms, tinnitus (ringing in the ears), poor coordination and balance, tremor, sweating, dry mouth, loss of appetite, diarrhoea, feeling or being sick.
- These symptoms are generally mild and disappear within a few days.
- Your doctor will advise you on how you should gradually discontinue MYLAN VENLAFAXINE XL treatment.
- If you experience any of these or other symptoms which are troublesome, return to your doctor for further advice.
- After you stop using MYLAN VENLAFAXINE XL, your body may need time to adjust.
- The length of time this takes depends on the amount of MYLAN VENLAFAXINE XL you were using and how long you used it.

### 4. Possible side effects

MYLAN VENLAFAXINE XL can have side effects.



Not all side effects reported for MYLAN VENLAFAXINE XL are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking MYLAN VENLAFAXINE XL, please consult your healthcare provider for advice.

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, wheezing and chest tightness.
- Severe rash or itching or hives (elevated patches of red or pale skin that often itch);
- Fainting.
- Feeling nervous or anxious, dizziness, throbbing sensations, sudden reddening of the skin and/or a warm feeling.
- Signs and symptoms of serotonin syndrome which may include a combination of the following:
  - restlessness, hallucinations, loss of co-ordination, fast heartbeat, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea, vomiting;
  - in its most severe form, serotonin syndrome can resemble neuroleptic malignant syndrome. The signs and symptoms of neuroleptic malignant syndrome may include a combination of fever, fast heartbeat, sweating, severe muscle stiffness, confusion, increased muscle enzymes (determined by a blood test).
- Thinking of or planning suicide; suicidal behaviours;

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MYLAN VENLAFAXINE XL. 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:**

- Coughing, shortness of breath and a high temperature black (tarry) stools or blood in stools;
- yellow skin or eyes, itchiness or dark urine, which may be symptoms of inflammation of the liver (hepatitis);
- heart problems, such as fast or irregular heart rate;
- eye problems, such as blurred vision, dilated pupils;
- nerve problems, such as pins and needles, movement disorder, seizures or fits psychiatric problems, such as hyperactivity and feeling unusually overexcited), withdrawal effects if you stop taking MYLAN VENLAFAXINE XL (*see section If you stop taking MYLAN VENLAFAXINE XL*).

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

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

The following side effects have been reported frequently:

- Weight loss, changes in cholesterol levels;
- abnormal dreams, sleeplessness, nervousness, feeling separated (or detached), from yourself and reality, tremor, sedation, headache;
- abnormal sensitivity to sunlight on the skin;
- pain in chest;
- increase in blood pressure, flushing;
- yawning;
- nausea, vomiting, constipation, decreased appetite, dry mouth, increased appetite
- severe abdominal pain (which could indicate a serious problem in the gut, liver or pancreas);
- sweating;



- inability to control urination;
- abnormal ejaculation/orgasm (males); lack of orgasm, impotence;
- lack of strength, chills, fatigue.

The following side effects have been reported less frequently:

- Reduced number of platelets in your blood, leading to an increased risk of bruising or bleeding; blood disorders which may lead to an increased risk of infection; slight changes in blood levels of liver enzymes; decrease in blood sodium levels;
- increased breast milk production;
- disorientation and confusion;
- weight gain;
- agitation, hallucinations, lack of feeling or emotion, sensation of restlessness or an inability to sit or stand still, grinding of the teeth; involuntary movement of the muscles;
- eye disorders (glaucoma);
- ringing in the ears;
- feeling dizzy (particularly when standing up too quickly);
- diarrhoea;
- inflammation of the pancreas;
- altered taste sensation;
- neck pain, back pain, pain in joints;
- weakness;
- inability to urinate and increase in frequency in urination;
- menstrual irregularities such as increased bleeding or increased irregular bleeding.

The following side effects have been reported but the frequency is unknown:

- Forgetfulness;



- anxiety;
- depression;
- abnormal thinking;
- aggression;
- migraine;
- twitching;
- pain in muscles;
- anorexia;
- inflammation with: pain in the throat, runny nose, bronchitis indigestion, bringing up winds, bloated feeling.

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

### **Reporting of side effects**

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of MYLAN VENLAFAXINE XL.

### **5. How to store MYLAN VENLAFAXINE XL**

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from light.
- Do not remove blisters from carton until required for use.



- Do not use after the expiry date stated on the label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Do not store in a bathroom.

## 6. Contents of the pack and other information

### What MYLAN VENLAFAXINE XL contains:

The active substance is:

- MYLAN VENLAFAXINE XL 75: Venlafaxine hydrochloride equivalent to 75 mg venlafaxine per capsule
- MYLAN VENLAFAXINE XL 150: Venlafaxine hydrochloride equivalent to 150 mg venlafaxine per capsule

The other ingredients are:

Hypromellose (Methocel K100M), Eudragit RS 100, sodium lauryl sulphate, magnesium stearate, Eudragit E 12,5, hard gelatin capsule.

### What MYLAN VENLAFAXINE XL looks like and contents of the pack:

#### What MYLAN VENLAFAXINE XL looks like:

MYLAN VENLAFAXINE XL 75:

A flesh opaque- flesh opaque size O hard gelatin capsule containing two (37,5 mg) tablets.

MYLAN VENLAFAXINE XL 150:

A scarlet opaque-scarlet opaque size 00 hard gelatin capsule containing two (75 mg) tablets.

#### Contents of the pack:

Blister strips with white opaque PVC/PE/PVDC/Aluminium foil will be placed into an outer carton of printed cardboard along with a printed package insert.

Each unit carton will contain a total of 30 capsules.

**Holder of Certificate of Registration and Manufacturer**

Viartis South Africa (Pty) Ltd

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**Access to the corresponding Professional Information**

Can be obtained on the SAHPRA website.

