

Current and approved Patient Information Leaflet for Cymlafax XR 225

SCHEDULING STATUS: S5

Cymlafax XR 225 mg extended release capsules

Venlafaxine hydrochloride equivalent to venlafaxine

Cymlafax XR 225 is sugar free

Read all of this leaflet carefully before you start taking Cymlafax XR 225

- 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.
- Cymlafax XR 225 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 Cymlafax XR 225 is and what it is used for
2. What you need to know before you take Cymlafax XR 225
3. How to take Cymlafax XR 225
4. Possible side effects
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6. Contents of the pack and other information

1. What Cymlafax XR 225 is and what it is used for

Cymlafax XR 225 is an antidepressant that belongs to a group of medicines called serotonin and norepinephrine reuptake inhibitors (SNRIs). This group of medicines is used to treat depression and other conditions such as anxiety disorders. It is thought that people who are depressed and/or anxious have lower levels of serotonin and noradrenaline in the brain. It is not fully understood how antidepressants work, but they may help by increasing the levels of serotonin and noradrenaline in the brain.

Cymlafax XR 225 is used to treat adults with depression, including depression associated with anxiety

(feeling of worry or nervousness). Cymlafax XR 225 is also used to treat severe and persistent anxiety (known as generalised anxiety disorder), social anxiety disorder also known as social phobia (fear or avoidance of social situations).

Treating depression or anxiety disorders properly is important to help you get better. If it is not treated, your condition may not go away and may become more serious and more difficult to treat.

Cymlafax XR 225 is used to prevent a relapse of an episode of depression or to prevent recurrence and your doctor will periodically re-evaluate you.

2. What you need to know before you take Cymlafax XR 225

Do not take Cymlafax XR 225:

- if you are hypersensitive (allergic) to venlafaxine or to any of the other ingredients of Cymlafax XR 225 (listed in section 6)
- if you are taking monoamine oxidase inhibitors (MAOI's), a medicine also used to treat depression or Parkinson's disease, or have taken it in the last 14 days (also, you must wait at least 7 days after you stop taking Cymlafax XR 225 before you take any MAOI)
- if you are under the age of 18
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with Cymlafax XR 225:

- If you use other medicines that taken together with Cymlafax XR 225 could increase the risk of developing serotonin syndrome (see the section "Other medicines and Cymlafax XR 225").
- 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.
- if you have a history of myocardial infarction or unstable heart disease.
- 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 e.g., warfarin (used to prevent blood clots).
- If you are pregnant as there may be an increased risk of heavy vaginal bleeding shortly after birth (see ‘Pregnancy’ and ‘Do not take Cymlafax XR 225’)
- If you have a history of high cholesterol.
- If you are taking weight loss medicines.
- If you have a history of, or if someone in your family has had, mania or bipolar disorder (feeling over-excited or euphoric).
- If you have a history of aggressive behaviour.
- If you need to have screening tests for phencyclidine and amphetamine.

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 antidepressants, since these medicines all take time to work, usually about two weeks, but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing yourself or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in young adults (less than 25 years old) 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 straight away.

Dry mouth

Cymlafax XR 225 may cause a dry mouth, this may increase the risk of caries and dental hygiene is very important.

Diabetes

Your blood glucose levels may be altered due to Cymlafax XR 225. Therefore, the dosage of your diabetes medicines may need to be adjusted.

Sexual problems

Cymlafax XR 225 (so called SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

Children and adolescents

Do not give Cymlafax XR 225 to children and adolescents under the age of 18 years. Suicide-related behaviours (suicide attempt and suicidal thoughts) and anger (predominantly aggression, oppositional behaviour and anger) were more frequently observed among children and adolescents.

Other medicines and Cymlafax XR 225

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

You should tell your doctor if you are using the following medicines:

- Monoamine Oxidase Inhibitors (MOAI) which are used to treat depression or Parkinson's disease must not be taken with Cymlafax XR 225. Tell your doctor if you have taken these medicines within the last 14 days (MAOIs: see the section What you need to know before you take Cymlafax XR 225).

- **Serotonin syndrome:**

A potentially life-threatening condition or Neuroleptic Malignant Syndrome (NMS)-like reactions (see the section "Possible Side Effects") may occur with Cymlafax XR 225 treatment, particularly when taken with other medicines.

Examples of these medicines include:

- Triptans (used for migraine)
- Other medicines to treat depression, for instance SNRIs, SSRIs, tricyclics, or medicines containing lithium

- Medicines containing amphetamines (used to treat attention deficit hyperactivity disorder (ADHD), narcolepsy and obesity)
- Medicines containing sibutramine (used for weight loss)
- Medicines containing tramadol, fentanyl, tapentadol, pethidine, or pentazocine (used to treat severe pain)
- Medicines containing linezolid, an antibiotic (used to treat infections)
- Medicines containing moclobemide, a MAOI (used to treat depression)
- Medicines containing dextromethorphan (used to treat coughing)
- Medicines containing methadone (used to treat opioid drug addiction or severe pain)
- Medicines containing methylene blue (used to treat high levels of methaemoglobin in the blood)
- Products containing St. John's Wort (also called *Hypericum perforatum*, a natural or herbal remedy used to treat mild depression)
- Products containing tryptophan (used for problems such as sleep and depression)
- Antipsychotics (used to treat a disease with symptoms such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, unclear reasoning and becoming withdrawn)

Signs and symptoms of serotonin syndrome may include a combination of the following: restlessness, hallucinations, loss of coordination, 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 (NMS). Signs and symptoms of NMS may include a combination of fever, fast heartbeat, sweating, severe muscle stiffness, confusion, increased muscle enzymes (determined by a blood test).

Tell your doctor immediately or go to the casualty department at your nearest hospital if you experience any of the above symptoms.

You must tell your doctor if you are taking medicines that can affect your heart rhythm such as:

- Anti-dysrhythmics such as quinidine, amiodarone, sotalol or dofetilide (used to treat abnormal heart rhythm)

- Antipsychotics such as thioridazine (See also Serotonin syndrome above)
- Antibiotics such as erythromycin or moxifloxacin (used to treat bacterial infections)
- Antihistamines (used to treat allergy)

The following medicines may also interact with Cymlafax XR 225 and should be used with caution. It is especially important to mention to your doctor or pharmacist if you are taking medicines containing:

- Ketoconazole (an antifungal medicine)
- Cimetidine (an antacid), especially if you are elderly or have liver problems
- Imipramine, bupropion or fluoxetine (antidepressants)
- Ritonavir (an antiretroviral used for HIV/AIDS)
- Haloperidol or risperidone (to treat psychiatric conditions)
- Metoprolol (a beta blocker to treat high blood pressure and heart problems)

Cymlafax XR 225 with food and alcohol

You should not take any alcohol when taking Cymlafax XR 225.

Pregnancy, breastfeeding and fertility

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 healthcare provider for advice before taking Cymlafax XR 225.

Pregnancy

Do not take Cymlafax XR 225 if you are pregnant.

If your baby was exposed to Cymlafax XR 225 late in the third trimester, your baby might have symptoms of not feeding properly when born. If your baby has these symptoms when it is born and you are concerned, contact your doctor and/or midwife who will be able to advise you.

If you take Venlafaxine XR Adco 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. Your doctor or midwife should be aware that you are taking Venlafaxine XR Adco so they can advise you.

Breastfeeding

Cymlafax XR 225 is excreted in breast milk, therefore, mothers who breastfeed their babies should not take Cymlafax XR 225.

Driving and using machines

Cymlafax XR 225 may cause you to feel dizzy and sleepy which may therefore impair your judgement, thinking and motor skills.

It is not always possible to predict to what extent Cymlafax XR 225 may interfere with your daily activities. Do not engage in driving a vehicle or using machines until you are aware of the measure to which Cymlafax XR 225 affects you.

Cymlafax XR 225 contains the colourant Carmoisine (E122)

Carmoisine (E122) may cause allergic reactions.

3. How to take Cymlafax XR 225

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

Always take Cymlafax XR 225 exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual recommended starting dose for Cymlafax XR 225 for treatment of depression, generalised anxiety disorder and social anxiety disorder is 75 mg per day. The dose can be raised by your doctor gradually, and if needed, even up to a maximum dose of 375 mg daily for depression. The maximum dose for generalised anxiety disorder, social anxiety disorder and panic disorder is 225 mg/day.

Swallow the capsule whole with fluid. Do not divide, crush, chew or place capsule in water.

Take Cymlafax XR 225 once daily at the same time either in the morning or in the evening.

Cymlafax XR 225 should be taken with food.

If you have liver or kidney problems, talk to your doctor, since your dose of Cymlafax XR 225 may need to be different.

Your doctor will frequently assess if you need to be on long-term therapy with Cymlafax XR 225.

Your doctor will tell you how long your treatment with Cymlafax XR 225 will last. Do not stop treatment early because you feel better. If you have the impression that the effect of Cymlafax XR 225 is too strong or too weak, tell your doctor or pharmacist.

If you take more Cymlafax XR 225 than you should

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

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 Cymlafax XR 225

Do not take a double dose to make up for forgotten individual doses.

If you stop taking Cymlafax XR 225

Do not stop taking your treatment or reduce the dose without the advice of your doctor even if you feel better. If your doctor thinks that you no longer need Cymlafax XR 225, he/she may ask you to reduce your dose slowly before stopping treatment altogether. Side effects are known to occur when people stop using Cymlafax XR 225, especially when it is stopped suddenly, or the dose is reduced too quickly. Some patients may experience symptoms such as tiredness, dizziness, light-headedness, headache, sleeplessness, nightmares, dry mouth, loss of appetite, nausea, diarrhoea, nervousness, agitation, confusion, ringing in the ears, tingling or rarely electric shock sensations, weakness, sweating, seizures, or flu-like symptoms.

Your doctor will advise you on how you should gradually discontinue Cymlafax XR 225 treatment. If you

experience any of these or other symptoms that are troublesome, ask your doctor for further advice.

4. Possible side effects

Cymlafax XR 225 can have side effects.

Not all side effects reported for Cymlafax XR 225 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Cymlafax XR 225, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking Cymlafax XR 225 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 Cymlafax XR 225. 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:

- Heart problems, such as fast or irregular heart rate, increased blood pressure.
- Chest tightness, wheezing, trouble swallowing or breathing.
- Severe skin rash, itching or hives (elevated patches of red or pale skin that often itch).
- Signs and symptoms of serotonin syndrome which may include restlessness, hallucinations, loss of coordination, 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 (NMS). Signs and symptoms of NMS may include a combination of fever, fast heartbeat, sweating, severe muscle stiffness, confusion, increased muscle enzymes (determined by a blood test).

- Signs of infection, such as high temperature, chills, shivering, headaches, sweating, flu-like symptoms.

This may be the result of a blood disorder which leads to an increased risk of infection.

- Severe rash, which may lead to severe blistering and peeling of the skin.
- Unexplained muscle pain, tenderness or weakness. This may be a sign of rhabdomyolysis.
- Thoughts of harming or killing yourself.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- decreased appetite
- difficulty sleeping
- abnormal dreams, nervousness
- decreased libido, abnormal ejaculation/orgasm (males)
- dizziness, drowsiness, shaking
- paraesthesia (abnormal sensation, typically tingling or pricking)
- altered taste
- blurred vision, dilated pupils, vision loss, inability of the eye to automatically change focus from distant to near objects
- hot flushes
- yawning
- nausea, dry mouth, constipation, vomiting, stomach pain
- an abnormally high level of muscle tone or tension, back pain
- inability to pass urine; difficulties passing urine
- impotence
- tiredness, lack of energy, pain
- weight gain, weight loss
- increased cholesterol

Less frequent side effects:

- over activity, racing thoughts and decreased need for sleep (mania)
- feeling over-excited (hypomania)
- hallucinations
- derealisation (feeling that one's surroundings are not real), apathy (lack of interest)
- abnormal orgasm
- involuntary muscle jerks or twitches; fits
- feeling dizzy (particularly when standing up too quickly)
- sensitivity to sunlight; bruising

Frequency unknown:

- sensation of whirling and loss of balance
- blood disorders such as granulocytes in the blood, deficiency of all types of blood cell caused by failure of bone marrow development, red cells, white cells, and platelets deficiency (pancytopaenia), platelets deficiency in the blood (thrombocytopaenia) (will be determined by a blood test)
- excessive water retention (known as SIADH)
- abnormal breast milk production
- decrease in blood sodium levels
- increased appetite
- confusion, feeling separated (or detached) from yourself
- agitation
- grinding of teeth (especially during sleep)
- headache
- a sensation of restlessness or an inability to sit or stand still
- involuntary movements of the muscles
- balance disorder
- muscular spasm and abnormal posture
- angle-closure glaucoma
- ringing in the ears
- low blood pressure

- inflammation of the lungs
- coughing, wheezing and shortness of breath which may be accompanied by a high temperature
- sore throat, runny nose, sneezing
- vomiting blood, black tarry stools (faeces) or blood in stools which can be signs of bleeding in the gastrointestinal tract
- severe abdominal or back pains, feeling sick and vomiting which could indicate inflammation of the pancreas
- diarrhoea
- severe weight loss (anorexia)
- indigestion, burping, wind (flatulence)
- increased liver function tests (determined by a blood test)
- itchiness, yellow skin or eyes, dark urine, or flu-like symptoms, which are symptoms of inflammation of the liver (hepatitis)
- excessive sweating (including night sweats)
- hives, hair loss, swelling of the legs and arms
- bulging, rash-like lesion that is red, pink, purple, or brown
- muscle pain
- increased frequency in urination
- involuntary leakage of urine
- menstrual irregularities such as increased bleeding or increased irregular bleeding
- chills
- unexpected bleeding, e.g. bleeding gums, blood in the urine or in vomit, or the appearance of unexpected bruises or broken blood vessels (broken veins)
- extended bleeding - if you cut or injure yourself, it may take slightly longer than usual for bleeding to stop
- heavy vaginal bleeding shortly after birth (postpartum haemorrhage)

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction 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 Cymlafax XR 225.

5. How to store Cymlafax XR 225

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C. Store in original packaging until required for use.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Cymlafax XR 225 contains

The active substance is venlafaxine hydrochloride equivalent to 225 mg venlafaxine free base.

The other ingredients are:

Capsule contents (mini tablets):

Core: microcrystalline cellulose, colloidal silicon dioxide, magnesium stearate, povidone, talc.

Film coating: copovidone, ethyl cellulose.

Capsule shell: Carmoisine (E122), gelatine, titanium dioxide (E171), purified water.

Capsule printing ink: butyl alcohol, dehydrated alcohol (E1510), isopropyl alcohol, propylene glycol (E1520), shellac (E904), concentrated ammonia solution (E527), Indigo Carmine (E132) lake.

What Cymlafax XR 225 looks like and contents of the pack

Cymlafax XR 225 is a pink opaque / pink opaque, size ”00” hard gelatine capsule having thick and thin radial circular bands on the body in blue ink and thick and thin radial circular band on the cap in blue ink filled with mini tablets.

Cymlafax XR 225 extended release capsules are packed in:

- Aluminium/aluminium foil blister strips

- Aluminium foil and white opaque PVC-Aclar film blister strips
- Aluminium foil and white opaque PVC-PVdC film blister strips

Pack sizes: 10 or 14 capsules per blister strip in a pack of 10, 14, 28, 30 or 100 capsules in an outer carton along with professional information and/or patient information leaflet.

Not all pack sizes may be marketed.

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