

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrVENLAFAXINE XR

Venlafaxine Hydrochloride Extended-Release Capsules

Read this carefully before you start taking **VENLAFAXINE XR** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **VENLAFAXINE XR**.

Serious Warnings and Precautions

New or worsened emotional or behaviour problems:

- When you first start taking VENLAFAXINE XR or when your dose is adjusted, you may feel worse instead of better. You may feel new or worsened feelings of agitation, hostility, anxiety, or impulsivity.
- During your treatment with VENLAFAXINE XR, it is important that you and your healthcare professional talk regularly about how you are feeling. They will closely monitor you for signs of new or worsened emotions or behaviours while you are taking VENLAFAXINE XR.
- You may find it helpful to tell a relative or close friend that you are depressed. Ask them to read this leaflet. You might ask them to tell you if they:
 - think your depression is getting worse, or
 - are worried about changes in your behavior.
- If your depression worsens or you experience changes in your behavior, tell your healthcare professional right away. Do not stop taking your medicine as it takes time for VENLAFAXINE XR to work.

Self-harm or Suicide

- Antidepressants, such as VENLAFAXINE XR, can increase the risk of suicidal thoughts or actions.
- If you have thoughts of harming or killing yourself at any time, tell your healthcare professional or go to a hospital right away. Close observation by your healthcare professional is necessary in this situation.

What is VENLAFAXINE XR used for?

VENLAFAXINE XR is used in adults to relieve the symptoms of:

- Major depressive disorder (feeling sad, a change in appetite or weight, difficulty concentrating or sleeping, feeling tired, headaches, unexplained aches and pain)
- Generalized anxiety disorder (anxiety or nervousness)

- Social anxiety disorder, also known as social phobia (avoidance and/or fear of social situations)
- Panic disorder (repeated, unexpected panic attacks)

How does VENLAFAXINE XR work?

VENLAFAXINE XR belongs to a group of medicines called serotonin and norepinephrine reuptake inhibitors (SNRIs). VENLAFAXINE XR is thought to work by increasing the levels of two chemicals in the brain, serotonin and norepinephrine. This helps to relieve your symptoms of major depressive disorder, generalized anxiety disorder, social anxiety disorder and/or panic disorder.

What are the ingredients in VENLAFAXINE XR?

Medicinal ingredients: Venlafaxine Hydrochloride

Non-medicinal ingredients: Ethyl cellulose, hypromellose, sugar spheres & talc.

Capsule shell ingredients: Gelatin, iron oxide black (37.5 mg), iron oxide red, sodium lauryl sulfate and titanium dioxide.

Printing ink ingredients: Black iron oxide NF, potassium hydroxide NF and shellac NF.

Sugar spheres ingredients: Maize starch & sucrose.

VENLAFAXINE XR comes in the following dosage forms:

Extended-Release Capsules: 37.5 mg, 75 mg and 150 mg

Do not use VENLAFAXINE XR if:

- you are allergic to venlafaxine hydrochloride or to any of the non-medicinal ingredients in VENLAFAXINE XR.
- you are taking or have recently taken monoamine oxidase inhibitors (MAOIs) such as phenelzine sulphate and moclobemide, within the last 14 days.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VENLAFAXINE XR. Talk about any health conditions or problems you may have, including if you:

- have ever had any allergic reaction to medications, food, etc;
- have or have a history of:
 - liver problems
 - kidney problems
 - seizures
 - aggression
 - heart problems;

- have or have a family history of QT/QTc prolongation (abnormal electrical activity of the heart);
- have a history or family history of bipolar disorder;
- have a bleeding disorder or have been told that you have low platelets.
- have blood pressure problems;
- are taking any medications, especially:
 - other medicines used to treat depression,
 - medicines used to treat psychiatric disorders,
 - opioids (including those used to treat pain or drug dependence),
 - weight-loss medication,
 - sleeping pills,
 - medicines used to treat anxiety, or
 - medication used to control blood pressure;
- are pregnant or thinking about becoming pregnant, or if you are breast feeding;
- drink alcohol and/or use street drugs;
- had a recent bone fracture or were told you have osteoporosis or risk factors for osteoporosis.

Other warnings you should know about:

During treatment with VENLAFAXINE XR, it is important that you and your healthcare professional talk regularly about how you are feeling.

Do NOT stop taking VENLAFAXINE XR without talking to your healthcare professional first, as it may cause unwanted side effects such as headache, insomnia, numbness, tingling, burning, or prickling, nervousness, anxiety, nausea, sweating, dizziness, jitteriness and weakness.

Activation of Mania: Some patients with bipolar disorder (also known as manic depression) may enter into a manic phase when they start taking VENLAFAXINE XR. Tell your healthcare professional if you experience symptoms of mania such as excessive physical activity, overactive behaviour or thoughts, increased energy, trouble sleeping, racing thoughts, reckless behaviour, excessive happiness or irritability, talking more or faster than usual.

Effects on Sexual Function: Taking medicines like VENLAFAXINE XR may cause symptoms of sexual dysfunction. In some cases these symptoms have continued after stopping VENLAFAXINE XR treatment. Talk to your healthcare professional if you experience symptoms such as a decrease in sexual desire, performance or satisfaction.

Pregnancy: Only take VENLAFAXINE XR during pregnancy if you and your doctor have discussed the risks and have decided that you should. If you take VENLAFAXINE XR near the end of your pregnancy, you may be at a higher risk of heavy vaginal bleeding shortly after birth. If you become pregnant while taking VENLAFAXINE XR, tell your doctor right away.

Effects on newborns: In some cases, babies born to a mother taking VENLAFAXINE XR during pregnancy may require hospitalization, breathing support and tube feeding. Be ready to seek

medical help for your newborn if they:

- have trouble breathing or feeding,
- have muscle stiffness, or floppy muscles (like a rag doll)
- have seizures (fits)
- are shaking (jitteriness)
- are constantly crying

Serotonin toxicity (also known as Serotonin Syndrome): VENLAFAXINE XR can cause serotonin toxicity, a rare but potentially life-threatening condition. It can cause serious changes in how your brain, muscles and digestive system work. You may develop serotonin toxicity if you take VENLAFAXINE XR with certain antidepressants or migraine medications. Serotonin toxicity symptoms include:

- fever, sweating, shivering, diarrhea, nausea, vomiting;
- muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination
- fast heartbeat, changes in blood pressure;
- confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma

Falls and fractures: Taking VENLAFAXINE XR may increase your risk of breaking a bone if you are elderly, have osteoporosis or have other major risk factors for breaking a bone. You should take extra care to avoid falls, especially if you get dizzy or have low blood pressure.

Driving and using machines: Until you know how VENLAFAXINE XR affects you, do not drive or operate a vehicle or potentially dangerous machinery.

Monitoring and tests: Your healthcare professional may do tests, including blood tests, before you take VENLAFAXINE XR and regularly during your treatment. These tests will monitor:

- your blood pressure
- your level of cholesterol (a type of fat) in your blood)

Angle-closure Glaucoma

VENLAFAXINE XR can cause an acute attack of glaucoma. Having your eyes examined before you take VENLAFAXINE XR could help identify if you are at risk of having angle-closure glaucoma. Seek immediate medical attention if you experience:

- eye pain
- changes in vision
- swelling or redness in or around the eye

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

Do not use VENLAFAXINE XR if you are taking or have recently taken

- MAOIs, such as phenelzine, tranylcypromine, moclobemide, selegiline, linezolid, and methylene blue, within the last 14 days.

The following may interact with VENLAFAXINE XR:

- other antidepressants, such as other SNRIs, selective serotonin reuptake inhibitors and certain tricyclics
- other drugs that affect serotonin such as, amphetamines, opioids, lithium, linezolid, sibutramine, tryptophan, triptans used to treat migraines
- medicines used to treat pain, such as fentanyl (used in anaesthesia or to treat chronic pain), tramadol, tapentadol, meperidine, methadone, pentazocine
- medicines used to treat cough, such as dextromethorphan
- medicines used to treat bipolar depression, such as lithium
- medicines used to treat high blood pressure such as metoprolol
- medicines used to treat heartburn and ulcers such as cimetidine
- medicines called triptans which are used to treat migraines, such as almotriptan, sumatriptan, rizatriptan, naratriptan, and zolmitriptan
- medicines that affect how your heart beats such as quinidine, procainamide, disopyramide, amiodarone, sotalol, ibutilide, dronedarone, flecainide, and propafenone
- medicines used to manage psychosis (antipsychotics) such as chlorpromazine, pimozide, haloperidol, droperidol, ziprasidone, risperidone and clozapine medicines to treat bacterial and fungal infections such as erythromycin, clarithromycin, telithromycin, tacrolimus, moxifloxacin, levofloxacin, and ciprofloxacin, ketoconazole, fluconazole, and voriconazole
- medicines used to treat malaria such as quinine, and chloroquine
- medicines used to treat nausea and vomiting such as domperidone, dolasetron, and ondansetron
- medicines used in cancer therapy such as vandetanib, sunitinib, nilotinib, lapatinib, and vorinostat
- medicines used to treat asthma such as salmeterol, and formoterol
- medicines that affect your electrolyte levels such as diuretics (“water pills”), laxatives and enemas, amphotericin B, and high dose corticosteroids (drugs that reduce inflammation)
- medicines that can affect how your blood clots such as warfarin, acetylsalicylic acid (Aspirin), and non-steroidal anti-inflammatory drugs (NSAIDs)
- herbal medicines such as St. John’s Wort
- alcohol, it is recommended to avoid drinking alcohol while taking VENLAFAXINE XR

How to take VENLAFAXINE XR:

- It is very important that you take VENLAFAXINE XR exactly as your healthcare professional has instructed.
- Do not change your dose without talking to your healthcare professional.

- Your healthcare professional will tell you when to stop taking VENLAFAXINE XR. Always follow your healthcare professional's instructions on how to lower your dose carefully and safely to avoid experiencing withdrawal symptoms.
- Continue to take VENLAFAXINE XR even if you do not feel better, as it may take several weeks for your medicine to start working.
- Take with food either in the morning or the evening.
- Swallow the capsules whole with water. Do not divide, crush, chew or place the capsules in water.

REMEMBER: This medicine has been prescribed only for you. Do not give it to anybody else. If you have any further questions, please ask your doctor or pharmacist.

Usual dose:

Major depressive disorder: The usual dose is 75 mg once daily. Your healthcare professional may decide to start you on a lower dose of 37.5 mg once daily. Based on how you respond and your tolerability, your healthcare professional may increase your dose. The maximum daily dose is 225 mg / day.

Generalized anxiety disorder: The usual starting dose is 37.5 mg once daily for 4 to 7 days. The usual maintenance dose is 75 mg once daily. Based on how you respond and your tolerability, your healthcare professional may increase your dose. The maximum daily dose is 225 mg / day.

Social anxiety disorder: The usual dose is 75 mg once daily. Your healthcare professional may decide to start you on a lower dose of 37.5 mg once daily. Based on how you respond and your tolerability, your healthcare professional may increase your dose. The maximum daily dose is 225 mg / day.

Panic disorder: The usual starting dose is 37.5 mg once daily for 7 days. The usual maintenance dose is 75 mg once daily. Based on how you respond and your tolerability, your healthcare professional may increase your dose. The maximum daily dose is 225 mg / day.

If you have liver or kidney problems, your healthcare professional may prescribe a lower dose.

Overdose:

If you think you, or a person you are caring for, have taken too much VENLAFAXINE XR, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you missed a dose of this medication, you do not need to make up the missed dose. Skip the missed dose and continue with your next scheduled dose. Do not take two doses at the same time.

What are possible side effects from using VENLAFAXINE XR?

These are not all the possible side effects you may have when taking VENLAFAXINE XR. If you experience any side effects not listed here, tell your healthcare professional.

Some side effects of VENLAFAXINE XR are:

- headache
- nausea
- dry mouth
- constipation
- loss of appetite
- vomiting
- sleepiness
- dizziness
- insomnia
- weakness
- sweating
- nervousness
- abnormal vision
- abnormal dreams
- tremors (shaking)
- diarrhea
- discomfort or pain in the upper abdomen
- weight loss
- prickling of the skin
- rash

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Increase in Blood Pressure: headache, stronger and possibly faster heartbeat, chest pain, dizziness, excessive tiredness, and blurred vision. Sometimes, the increase in blood pressure could be severe enough to require urgent medical attention		✓	
Tachycardia (abnormally fast heartbeat): dizziness, light		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
headedness, shortness of breath, racing heart			
UNCOMMON			
Akathisia (a type of movement disorder): feeling restless and unable to sit or stand still		✓	
Allergic Reaction: difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat			✓
Gastrointestinal Bleeding (bleeding in the stomach or bowels): black, tarry stool, blood in the stool, vomiting blood			✓
Hallucinations (seeing or hearing things that are not there)		✓	
Hyponatremia (low sodium in the blood): lethargy, confusion, muscular twitching, achy, stiff or uncoordinated muscles, seizure, coma		✓	
Low Platelets: Bruising or unusual bleeding from the skin or other areas		✓	
Mania: elevated or irritable mood, decreased need for sleep, racing thoughts		✓	
Uncontrollable movements of the body or face		✓	
Urinary retention (inability to urinate or empty or loss of control of the bladder): pain		✓	
Self-harm or Suicide: thoughts or actions about hurting or killing yourself		✓	
Sexual problems: milky discharge from breasts in		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
women, abnormal ejaculation or impotence in men, decreases in sexual desire, performance and satisfaction			
RARE			
Angle-closure Glaucoma: blurred vision, halos around lights, eye pain and redness, nausea and vomiting, severe headache			✓
Heart rhythm problems: dizziness, increased heart rate, palpitations, fainting or seizures			✓
Liver Disorder: yellowing of the skin or eyes, dark urine and pale stools, abdominal pain, nausea, vomiting, loss of appetite		✓	
New or worsened emotional or behavioural problems: agitation, anger, aggression, anxiety, suicidal or violent thoughts		✓	
Seizures (fit): uncontrollable shaking with or without loss of consciousness			✓
Serotonin toxicity: mental changes such as agitation, hallucinations, confusion, or other changes in mental status; coordination problems, uncontrolled muscle spasms, or muscle twitching (overactive reflexes); restlessness, shaking, shivering, racing or fast heartbeat, high or low blood pressure, sweating or fever, nausea, vomiting, or diarrhea, muscle rigidity (stiff muscles), tremor, loss of muscle control			✓
Symptoms after discontinuation	✓		

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
or dose reduction: loss of appetite or weight, anxiety, restlessness, aggression, confusion, convulsions, coordination problems, diarrhea, dizziness, dry mouth, fatigue, headache, rapid mood swings, nausea, nightmares, tingling of the skin, sleep disturbances, sweating, ringing in the ears or vomiting			
Syndrome of inappropriate antidiuretic hormone secretion (SIADH): concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits (seizures) which may be due to inappropriate secretion of ADH (antidiuretic hormone)			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
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Storage:

- Store at room temperature (15°C to 30°C).

- Keep all medicines out of the sight and reach of children.
- If your doctor tells you to stop taking VENLAFAXINE XR please return any leftover medicine to your pharmacist.

If you want more information about VENLAFAXINE XR:

- Talk to your healthcare professional
 - Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.sivem.com, or by calling 1-855-788-3153.

This leaflet was prepared by Sivem Pharmaceuticals ULC.

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