PART III: CONSUMER INFORMATION

PrVENLAFAXINE XR
Venlafaxine Hydrochloride Extended Release Capsules

This leaflet is part III of a three-part "Product Monograph" published when VENLAFAXINE XR was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about VENLAFAXINE XR. Contact your doctor or pharmacist if you have any questions about the drug.

Please read this information carefully before you start to take your medicine, even if you have taken this drug before. Do not throw away this leaflet until you have finished your medicine as you may need to read it again. For further information or advice, please see your doctor or pharmacist.

ABOUT THIS MEDICATION

What the medication is used for:
VENLAFAXINE XR has been prescribed to you by your doctor to relieve your symptoms of the following conditions:

- Depression (feeling sad, a change in appetite or weight, difficulty concentrating or sleeping, feeling tired, headaches, unexplained aches and pain)

What it does:
VENLAFAXINE XR belongs to a group of medicines called antidepressants. VENLAFAXINE XR is thought to work by affecting two naturally occurring brain chemicals, serotonin and norepinephrine.

When it should not be used:

- Do not use **VENLAFAXINE XR** if you are allergic to it or to any of the components of its formulation (see list of components at the end of this section). Stop taking the drug and contact your doctor immediately if you experience an allergic reaction or any severe or unusual side effects.
- Do not use VENLAFAXINE XR if you are currently taking or have recently taken monoamine oxidase inhibitor antidepressants (e.g. phenelzine sulphate, moclobemide).

What the medicinal ingredient is:
Venlafaxine Hydrochloride.

What the nonmedicinal ingredients are:
Dibutyl Sebecate, Ethyl Cellulose, Povidone and Sugar Spheres. Also contains:

37.5 mg: gelatine, black iron oxide, red iron oxide, titanium dioxide, yellow iron oxide.
75 mg: gelatine, red iron oxide, titanium dioxide, yellow iron oxide.
150 mg: gelatine, red iron oxide, titanium dioxide, yellow iron oxide.

What dosage forms it comes in:
Extended Release Capsules: 37.5 mg, 75 mg and 150 mg.

WARNINGS AND PRECAUTIONS

During treatment with these types of medication it is important that you and your doctor have good ongoing communication about how you are feeling.

VENLAFAXINE XR is not for use in children under 18 years of age.

New or Worsened Emotional or Behavioural Problems
Particularly in the first few weeks or when doses are adjusted, a small number of patients taking drugs of this type may feel worse instead of better. They may experience new or worsened feelings of agitation, hostility, anxiety, impulsivity or thoughts about suicide, self-harm or harm to others. Suicidal thoughts and actions can occur in any age group but may be more likely in patients 18 to 24 years old. Should this happen to you, or to those in your care, consult your doctor immediately. Close observation by a doctor is necessary in this situation. **Do not discontinue your medication on your own.**

You may be more likely to think like this if you have previously had thoughts about harming yourself.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. 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.

Taking VENLAFAXINE XR may increase your risk of breaking a bone if you are elderly or 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.

Before taking VENLAFAXINE XR tell your doctor or pharmacist:

- if you have ever had any allergic reaction to medications, food, etc;
- all your medical conditions, including a history of seizures, liver disease, kidney disease, heart problems or high cholesterol;
- if you have a bleeding disorder or have been told that you have low platelets.
- if you have blood pressure problems;
- any medications (prescription or non-prescription) which you are taking, especially monoamine oxidase (MAO) inhibitors (e.g. phenelzine sulfate, tranylcypromine sulfate, moclobemide or selegeline) or any other antidepressants, weight-loss medication, sleeping pills, antianxiety drugs, or medication to control blood pressure;
- if you are pregnant or thinking about becoming pregnant, or if you are breast feeding;
- your habits of alcohol and/or street drug consumption;
- any natural or herbal products you are taking (e.g., St. John's Wort).
- if you had a recent bone fracture or were told you have osteoporosis or risk factors for osteoporosis.
- if you drive a vehicle or perform hazardous tasks during your

work.
- if you have glaucoma or increased pressure in your eyes.

Discontinuing VENLAFAXINE XR
It is very important that you do NOT stop taking these medications without first consulting your doctor. See SIDE EFFECTS AND WHAT TO DO ABOUT THEM section for more information.

Effects on Pregnancy and Newborns
Post-marketing reports indicate that some newborns whose mothers took an SSRI (selective serotonin reuptake inhibitor) or other newer anti-depressants, such as venlafaxine hydrochloride extended release Capsules, during pregnancy have developed complications at birth requiring prolonged hospitalization, breathing support and tube feeding. Reported symptoms included feeding and/or breathing difficulties, seizures, tense or overly relaxed muscles, jitteriness and constant crying.

In most cases, the SSRI or other newer anti-depressant was taken during the third trimester of pregnancy. These symptoms are consistent with either a direct adverse effect of the antidepressant on the baby, or possibly a discontinuation syndrome caused by sudden withdrawal from the drug. These symptoms normally resolve over time. However, if your baby experiences any of these symptoms, contact your doctor as soon as you can.

If you are pregnant and taking an SSRI, or other newer anti-depressant, you should discuss the risks and benefits of the various treatment options with your doctor. It is very important that you do NOT stop taking these medications without first consulting your doctor. See SIDE EFFECTS AND WHAT TO DO ABOUT THEM section for more information.

INTERACTIONS WITH THIS MEDICATION

Do not use VENLAFAXINE XR if you are taking or have recently taken monoamine oxidase inhibitors.

You should avoid taking St. John's Wort if you are taking VENLAFAXINE XR.

Certain laboratory results may be affected by use of VENLAFAXINE XR, discuss with your doctor if you receive any unusual lab reports.

You should tell your doctor if you are taking or have recently taken any medications (prescription, non-prescription or natural/herbal), especially:
- other antidepressants, such as SSRIs and certain tricyclics
- other drugs that affect serotonin such as, lithium, linezolid, sibutramine, tryptophan, triptans used to treat migraines
- certain medicines used to treat pain, such as fentanyl (used in anaesthesia or to treat chronic paint), tramadol, tapentadol, meperidine, methadone, pentazocine
- certain medicines used to treat cough, such as dextromethorphan
- certain medicines used to treat schizophrenia
- certain medicines used to treat bipolar depression, such as lithium
- metoprolol or other medications used to treat high blood pressure and angina
- certain medicines which may affect blood clotting and increase bleeding, such as oral anti-coagulants (e.g. warfarin, dabigatran) acetylsalicylic acid and other non-steroidal anti-inflammatory drugs (e.g. ibuprofen)
- certain medicines used to treat epilepsy
- cimetidine
- In general, drinking alcoholic beverages should be kept to a minimum or avoided completely while taking VENLAFAXINE XR.
- Ketoconazole

PROPER USE OF THIS MEDICATION

Usual dose:
- It is very important that you take VENLAFAXINE XR exactly as your doctor has instructed.
- Never increase or decrease the amount of VENLAFAXINE XR you, or those in your care if you are a caregiver or guardian, are taking unless your doctor tells you to and do not stop taking this medication without consulting your doctor.
- As with all antidepressants improvement with VENLAFAXINE XR is gradual. You may not have noticeable effect in the first few days of treatment. Some symptoms may begin to improve within about 2 weeks but significant improvement can take several weeks.
- VENLAFAXINE XR should be taken once a day with food, as prescribed; do not divide, crush or chew the capsules.

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.

Overdose:

In case of overdose, contact your doctor, the nearest hospital emergency department or your local poison control centre, even though you may not feel sick.

Missed Dose:
If you happen to miss a dose, do not try to make up for it by doubling up on the dose next time. Just take your next regularly scheduled dose and try not to miss any more.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medications, VENLAFAXINE XR can cause some side effects. You may not experience any of them. For most patients these side effects are likely to be minor and temporary. However, some may be serious. Some of these side effects may be dose related. Consult your doctor if you experience these or other side effects, as the dose may have to be adjusted.

If you experience an allergic reaction (including red skin, hives, itching, swelling of the lips, face, tongue, throat, trouble breathing, wheezing, shortness of breath, skin rashes, blisters of the skin, sores or pain in the mouth or eyes) or any severe or

unusual side effects, stop taking the drug and contact your doctor immediately.

Some side effects of VENLAFAXINE XR are:
- headache
- nausea
- dry mouth
- constipation
- loss of appetite
- vomiting
- sleepiness
- dizziness
- insomnia
- sexual problems
- weakness
- sweating
- nervousness
- abnormal vision
- abnormal dreams

Particularly in the first few weeks or when doses are adjusted, a small number of patients taking drugs of this type may feel worse instead of better; for example, they may experience unusual feelings of agitation, hostility or anxiety, or have impulsive or disturbing thoughts such as thoughts of self-harm or harm to others. Should this happen to you, or to those in your care if you are a caregiver or guardian, consult your doctor immediately; do not discontinue your medication on your own.

VENLAFAXINE XR does not usually affect people's normal activities. However, some people feel sleepy while taking it, in which case they should not drive or operate machinery.

Although psychiatric disorders may be associated with decreases in sexual desire, performance and satisfaction, treatment with this medication may also affect sexual functioning.

VENLAFAXINE XR may increase blood pressure in some people. You should have your blood pressure measured prior to starting VENLAFAXINE XR and during treatment. High blood pressure should be controlled before starting VENLAFAXINE XR. Blood pressure changes may sometimes be sudden and without warning. Consult your doctor if you have symptoms that may indicate a sudden rise in your blood pressure, such as headache (particularly in the back of head/neck when waking up); stronger, possibly more rapid, or irregular heart beat; chest pain; dizziness; excessive tiredness; or blurred vision.

VENLAFAXINE XR may raise cholesterol levels in some patients. Blood cholesterol tests may be required by your doctor during treatment with VENLAFAXINE XR.

Discontinuation Symptoms
Contact your doctor before stopping or reducing your dosage of VENLAFAXINE XR. Symptoms such as anorexia (loss of appetite, loss of weight), anxiety, agitation (restlessness), aggression, confusion, convulsions, coordination problems, diarrhea, dizziness, dry mouth, fatigue, headache, hypomania (rapid mood swings), insomnia, nausea, nervousness, nightmares, paresthesia (sensation of tingling, burning or crawling of the skin), electric shock sensations, sleep disturbances, somnolence (drowsiness), sweating, tinnitus (ringing in the ears), vertigo (sensation that the world is spinning), vomiting and other symptoms have been reported after stopping treatment, reducing the dosage of VENLAFAXINE XR, or when a dose is missed. These symptoms usually disappear without needing treatment. Tell your doctor immediately if you have these or any other symptoms. Your doctor may adjust the dosage of VENLAFAXINE XR to alleviate the symptoms.

Effects on Newborns
Some newborns whose mothers took an SSRI (Selective Serotonin Reuptake Inhibitor) or other newer anti-depressant, such as VENLAFAXINE XR, during pregnancy have shown such symptoms as breathing and feeding difficulties, jitteriness and constant crying. If your baby experiences any of these symptoms, contact your doctor as soon as you can. See WARNINGS AND PRECAUTIONS section for more information.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk with your doctor or pharmacist right away		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Common	Increased blood pressure that persists [see also Severe Hypertension below]		✓	
Common	Fast heartbeat		✓	
Uncommon	Allergic reactions [red skin, hives, itching, swelling of the lips, face, tongue, throat, trouble breathing, wheezing, shortness of breath, skin rashes, blisters of the skin, sores or pain in the mouth or eyes]			✓
Uncommon	Low sodium level in blood [symptoms of tiredness, weakness, confusion combined with achy, stiff or uncoordinated muscles]		✓	
Unknown	Low Platelets: Bruising or unusual bleeding from the skin or other areas		✓	
Uncommon	Mania/hypomania [elevated or irritable mood, decreased need for sleep, racing thoughts]		✓	
Uncommon	Akathisia [feeling restless and unable to sit or stand still]		✓	
Uncommon	Hallucinations [strange visions or		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom/effect		**Talk with your doctor or pharmacist right away**		**Stop taking drug and seek immediate emergency medical attention**
		Only if severe	**In all cases**	
	sounds]			
Uncommon	Uncontrollable movements of the body or face		✓	
Uncommon	Inability to urinate		✓	
Uncommon	Gastrointestinal bleeding [vomiting blood or passing blood in stools]			✓
Rare	Seizures [loss of consciousness with uncontrollable shaking "fit"]			✓
Rare	Serotonin syndrome [a combination of most or all of the following; confusion, restlessness, sweating, shaking, shivering, high fever, sudden jerking of the muscles, hallucinations, fast heartbeat]			✓
Rare	Liver disorder [symptoms include nausea, vomiting, loss of appetite combined with itching, yellowing of the skin or eyes, dark urine]		✓	
Rare	Glaucoma: Increased pressure in the eyes eye pain and blurred vision		✓	
See Warnings and Precautions	New or worsened emotional or behavioural problems		✓	
See Side Effects and What to Do About Them	Severe Hypertension [symptoms include headache, stronger and possibly faster heartbeat, chest pain, dizziness, excessive tiredness, blurred vision]			✓

This is not a complete list of side effects. For any unexpected effects while taking VENLAFAXINE XR, contact your doctor or pharmacist.

HOW TO STORE IT

- Store VENLAFAXINE XR between 15°C and 30°C, in a dry place.
- Keep container tightly closed.
- Keep all medicines out of the sight and reach of children.
- If your doctor tells you to stop taking VENLAFAXINE XR please return any left over medicine to your pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, ON K1A 0K9

  Postage paid labels, Canada Vigilance Reporting Form and the adverse reactions reporting guidelines are available on the MedEffect™ Canada Website at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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