PART III: CONSUMER INFORMATION

[Pr]PRO-DESVENLAFAXINE
Desvenlafaxine Extended-Release Tablets

This leaflet is part III of a three-part "Product Monograph" published when PRO-DESVENLAFAXINE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PRO-DESVENLAFAXINE. For further information or advice, please see your doctor or pharmacist.

ABOUT THIS MEDICATION

What the medication is used for:
PRO-DESVENLAFAXINE has been prescribed to you by your doctor to treat your depression. Treatment with these types of medications is most safe and effective when you and your doctor have good communication about how you are feeling.

What it does:
PRO-DESVENLAFAXINE belongs to a class of medicines called serotonin and norepinephrine reuptake inhibitors (SNRIs). It is thought to work by affecting two naturally occurring brain chemicals, serotonin and norepinephrine.

When it should not be used:
Do not use **PRO-DESVENLAFAXINE** if you are:
- allergic (hypersensitive) to desvenlafaxine, venlafaxine or any of the other ingredients in **PRO-DESVENLAFAXINE**.
- taking or have taken, within the last 14 days, another medicine known as monoamine oxidase inhibitor (MAOI) including linezolid, an antibiotic, and methylene blue, a dye used in certain surgeries. Taking an MAOI together with many prescription medicines including **PRO-DESVENLAFAXINE** can cause serious or even life-threatening side effects. Also, you must wait at least 7 days after you stop taking **PRO-DESVENLAFAXINE** before you take any MAOI. (See Other Medicines and Nutritional or Herbal Supplements.)
- taking other drugs that contain venlafaxine or desvenlafaxine.
- taking any prescription or non-prescription medicines, including nutritional or herbal supplements without checking with your doctor first (see Serotonin syndrome or NMS-like reactions).

What the medicinal ingredient is:
Desvenlafaxine succinate.

What the nonmedicinal ingredients are:
The non-medicinal ingredients are: colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, and coating material (which consists of euroxide red iron oxide polyvinyl alcohol, polyethylene glycol, talc, red iron oxide (100 mg) and yellow iron oxide (50 mg), titanium dioxide.

What dosage forms it comes in:
- 50 mg and 100 mg tablets

PRO-DESVENLAFAXINE, 50 mg, and 100 mg are available in:
- HDPE Bottles of 30, 100 and 500 tablets
- Unit Dose Blisters of 100 (10 X 10) tablets

WARNINGS AND PRECAUTIONS

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 aggression, 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 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 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 **PRO-DESVENLAFAXINE** may increase your risk of experiencing sexual problems, which may continue after **PRO-DESVENLAFAXINE** has been discontinued. Tell your doctor if you experience symptoms such as sexual dysfunction, ejaculation disorder (in men), ejaculation failure (in men), libido decrease or anorgasmia (difficulty reaching orgasm).

Not for use in Children
PRO-DESVENLAFAXINE should not be used for children and adolescents under 18 years of age.

Bone Fracture Risk
Taking **PRO-DESVENLAFAXINE** 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.

Other Medicines and Nutritional or Herbal Supplements
- Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- Avoid taking **PRO-DESVENLAFAXINE** with other medicines containing venlafaxine or desvenlafaxine.
- Your health professional will decide if you can take **PRO-DESVENLAFAXINE** with other medicines.

Angle-closure Glaucoma
PRO-DESVENLAFAXINE can cause an acute attack of glaucoma. Having your eyes examined before you take **PRO-DESVENLAFAXINE** 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

Other Medical Problems
Before you use PRO-DESVENLAFAXINE, tell your doctor or pharmacist if you:
- are taking other medicines, herbal or nutritional supplements (see Other Medicines and Nutritional or Herbal Supplements and Serotonin syndrome).
- have a history of high blood pressure.
- have a history of heart problems.
- have a narrowing or blockage of your gastrointestinal tract (your oesophagus, stomach, or small or large intestine).
- have a history of fits (seizures).
- have a history of low sodium levels in your blood.
- have a bleeding disorder or have been told that you have low platelets.
- had a recent bone fracture or were told you have osteoporosis or risk factors for osteoporosis.
- have a history of high cholesterol.
- have a history or family history of mania or bipolar disorder.
- have kidney problems.
- are pregnant or thinking about becoming pregnant, or if you are breast feeding.

If any of these conditions apply to you, please talk with your doctor before taking **PRO-DESVENLAFAXINE.**

INTERACTIONS WITH THIS MEDICATION

Do not use PRO-DESVENLAFAXINE if you are taking or have recently taken monoamine oxidase inhibitors.

Certain laboratory results may be affected by use of **PRO-DESVENLAFAXINE**, 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:

- Monoamine oxidase inhibitors (MAOI) including linezolid, an antibiotic, and methylene blue, a dye used in certain surgeries. Do not take **PRO-DESVENLAFAXINE** with an MAOI or within 14 days of stopping an MAOI. Taking an MAOI together with many prescription medicines, including **PRO-DESVENLAFAXINE**, can cause serious or even life-threatening side effects. Also, you need to wait at least 7 days after you stop taking **PRO-DESVENLAFAXINE** before you take an MAOI.

- Certain medicines which may affect blood clotting and increase bleeding, such as oral anticoagulants (e.g. warfarin, dabigatran), acetylsalicyclic acid (e.g. Aspirin) and other non- steroidal anti-inflammatory drugs (e.g. ibuprofen).

- Medicines containing venlafaxine or other medicines containing desvenlafaxine.

- **Serotonin syndrome or a neuroleptic malignant syndrome (NMS)-like reactions**: Rare, but potentially life-threatening conditions called serotonin syndrome or NMS-like reactions can cause serious changes in how your brain, muscles and digestive system work and can happen when medicines like **PRO-DESVENLAFAXINE** are taken, particularly when taken with certain other medications such as:
  - medicines to treat migraine headaches known as triptans
  - medicines used to treat mood or thought disorders, including tricyclics, lithium, selective serotonin reuptake inhibitors (SSRIs); or serotonin norepinephrine reuptake inhibitors (SNRIs), or dopamine antagonists, including antipsychotics
  - amphetamines
  - sibutramine
  - certain medicines used to treat pain, such as fentanyl (used in anaesthesia or to treat chronic pain), tramadol, tapentadol,

meperidine, methadone, pentazocine
- certain medicines used to treat cough, such as dextromethorphan
- St. John's Wort
- MAOIs (including linezolid, an antibiotic and methylene blue, a dye sometimes injected before surgery to guide the surgeon)
- tryptophan supplements

Before you take **PRO-DESVENLAFAXINE** and any of these medicines together, talk to your healthcare professional about the possibility of serotonin syndrome NMS-like reactions.

Signs and symptoms of serotonin syndrome or NMS may include a combination of the following:
Agitation (excitability, restlessness), hallucinations, confusion, loss of coordination, muscle twitching or stiffness, fast heartbeat, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhea, coma, nausea, vomiting.

Get medical care right away if you think serotonin syndrome is happening to you.

Central Nervous System drugs: caution is advised when **PRO-DESVENLAFAXINE** is taken in combination with other centrally acting drugs or substances, including alcohol and sedative drugs (benzodiazepines, opiates, antipsychotics, phenobarbital, sedative antihistamines). Inform your doctor if you are taking any of these drugs.

You should avoid alcohol while taking **PRO-DESVENLAFAXINE**.

Switching from other antidepressants
Side effects from discontinuing antidepressant medication have occurred when patients switched from other antidepressants, including venlafaxine, to **PRO-DESVENLAFAXINE**. Your doctor may gradually reduce the dose of your initial antidepressant medication to help to reduce these side effects.

PROPER USE OF THIS MEDICATION

Always take **PRO-DESVENLAFAXINE** exactly as your health professional has told you. You should check with your health professional if you have any questions.

PRO-DESVENLAFAXINE is for oral use.

- **PRO-DESVENLAFAXINE** should be taken at approximately the same time each day with or without food. Tablets must be swallowed whole with fluid and not divided, crushed, chewed, or dissolved as it is time released.
- **PRO-DESVENLAFAXINE** is prepared as a matrix tablet that slowly releases the medicine inside your body. You may notice something in your stool that looks like a tablet, but it is an empty matrix. Seeing the empty matrix is not a cause for concern. There is no need to take an extra tablet. The active medication has already been absorbed by the time you see the matrix.

Do not stop taking **PRO-DESVENLAFAXINE** without talking to your doctor.

Usual dose:
The usual dose is 50 mg taken once daily. Your doctor may increase your dose if you need it.

Overdose:

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

Missed dose:
If you miss a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and take only a single dose as usual. Do not take a double dose to make up for a forgotten tablet.

What should you do before stopping PRO-DESVENLAFAXINE?
Do not stop taking or change the dose of **PRO-DESVENLAFAXINE** without first discussing this with your health professional. Your health professional may want to slowly decrease your dose of **PRO-DESVENLAFAXINE** to help avoid side effects. Some patients, who suddenly stop taking **PRO-DESVENLAFAXINE** after more than 1 week of therapy, have felt dizzy, sick (nausea), had a headache or experienced irritability, insomnia, diarrhea, anxiety, abnormal dreams, fatigue, sweating. These symptoms are usually not serious and disappear within a few days, but if you have symptoms that are troublesome you should ask your doctor for advice.

Pregnancy and breast-feeding
The safety of desvenlafaxine during human pregnancy has not been established. Taking **PRO-DESVENLAFAXINE** in mid to late pregnancy may increase the risk for preeclampsia (high blood pressure and protein in the urine) and taking it near delivery may increase the risk of heavy bleeding after giving birth. Desvenlafaxine is excreted in human milk. Tell your doctor immediately if you become pregnant, or if you are trying to become pregnant or are breastfeeding. If you do become pregnant

while taking this drug, do not change your dosage without consulting your doctor.

Postmarketing reports indicate that some newborns whose mothers took an SNRI (Serotonin Norepinephrine Reuptake Inhibitor), SSRI (Selective Serotonin Reuptake Inhibitor) or other newer antidepressants, during pregnancy have developed complications at birth requiring prolonged hospitalization, breathing support and tube feeding. Reported symptoms include: feeding and/or breathing difficulties, seizures, tense or overly relaxed muscles, jitteriness and constant crying. These symptoms are consistent with either a direct adverse effect of the medication 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.

Driving and using machines
Do not drive or operate any tools or machines until you know how **PRO-DESVENLAFAXINE** affects you. Do not drive or operate any tools or machines if **PRO-DESVENLAFAXINE** affects you in a way that prevents you from safely performing these operations.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medications, **PRO-DESVENLAFAXINE** 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 can 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 need 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 seek emergency medical attention immediately.

Frequency of Side Effects
Very common (in more than 1 in 10 patients): Nausea, Dry mouth, Dizziness, Trouble sleeping, Sweating, Headache, Drowsiness

Common (in more than 1 in 100 patients, but in less than 1 in 10 patients): Heart pounding, Heart racing, Ringing in the ears, Vertigo, Dilated pupils, Vision blurred, Vomiting, Diarrhea, Weakness, Chills, Feeling Jittery, Irritability, Weight Decreased, Weight Increased, Blood Pressure Increased, Musculoskeletal Stiffness, Shaking, Disturbance in Attention, Tingling sensations, Taste changes, No orgasms, Anxiety, Nervousness, Interest in sex decreased, Abnormal dreams, Ejaculation delayed (in men), Erectile dysfunction (in men), Yawning, Rash, Hot flush, Decreased appetite, Constipation, Tiredness, Drug withdrawal syndrome, Liver function tests abnormal

Uncommon (in more than 1 in 1000 patients, but in less than 1 in 100 patients): Hypersensitivity, Blood cholesterol increased, Blood prolactin increased, Blood triglyceride increased, Fainting, Depersonalization, Nose bleeds, Drop in blood pressure when standing, Coldness in hands and feet, Loss of hair, orgasm abnormal, Movement disorders, Difficulty emptying your bladder, Urinary hesitation, protein in the urine, Ejaculation disorder (in men), Ejaculation failure (in men), Sexual dysfunction.

Rare (in more than 1 in 10,000 patients, but in less than 1 in 1000 patients): Seizures, Sodium levels decreased, Swelling beneath the skin (e.g. throat, face, hands), Mania, Hypomania, Convulsions Hallucinations, Muscle contractions, Sensitivity to light.

Other Side effect Information
These are not all the possible side effects of **PRO-DESVENLAFAXINE**. Call your health professional right away if the side effects become serious, if you notice any side effects not listed in this leaflet, or if there is any other side effect that concerns you.

Discontinuation Symptoms
Contact your doctor before stopping or reducing your dosage of **PRO-DESVENLAFAXINE**. Symptoms such as visual impairment, high blood pressure, dizziness, nausea, headache, irritability, trouble sleeping, diarrhea, anxiety, abnormal dreams, tiredness, and sweating have been reported after stopping treatment with **PRO-DESVENLAFAXINE**. Tell your doctor immediately if you have any of these or other symptoms. Your doctor may adjust the dosage of **PRO-DESVENLAFAXINE** to alleviate the symptoms.

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	High Blood Pressure on 3 occasions		√	
Common	Increased Blood Pressure		√	
Common	Increased Cholesterol		√	
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			√
Unknown	Low Platelets: Bruising or unusual bleeding from the skin or other areas		√	
Rare	**Mania / Hypomania:** elevated or irritable mood, decreased need for sleep, racing thoughts		√	

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	
Rare	**Seizures:** loss of consciousness with uncontrollable shaking; "fit"			√
Rare	**Severe Increased Blood Pressure**: headache, stronger and possibly faster heartbeat, chest pain, dizziness, excessive tiredness, and blurred vision			√
Rare	Uncontrollable movements of the body or face		√	
Rare	**Glaucoma:** swelling or redness in or around the eye, eye pain, and changes in vision			√
See Warnings and Precautions	**Low sodium level in blood:** tiredness, weakness, confusion combined with achy, stiff or uncoordinated muscles		√	

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**	
See Warnings and Precautions	New or worsened emotional or behavioural problems		√	
See Warnings and Precautions	**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			√

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

HOW TO STORE IT

Do not use **PRO-DESVENLAFAXINE** after the expiration date (EXP), which is stated on the package. The expiration date refers to the last day of that month.

Medicines should not be disposed of in wastewater or in household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- 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.

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.

MORE INFORMATION

If you want more information about PRO-DESVENLAFAXINE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html). Or by contacting Pro Doc Ltée : http://www.prodoc.qc.ca, medinfo@prodoc.qc.ca or 1800-361-8559.

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