PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrFETZIMA®

levomilnacipran extended release capsules

Read this carefully before you start taking **FETZIMA** 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 **FETZIMA**.

Serious Warnings and Precautions

New or worsened emotional or behaviour problems:

- When you first start taking FETZIMA 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 FETZIMA, 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 FETZIMA.
- 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 behaviour.
- If your depression worsens or you experience changes in your behaviour, tell your healthcare professional right away. Do not stop taking your medicine as it takes time for FETZIMA to work.

Self-harm or Suicide

- Antidepressants, such as FETZIMA, 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. You will be closely observed by your healthcare professional in this situation.

What is FETZIMA used for?

FETZIMA is used in adults to relieve the symptoms of:

- Depression (feeling sad, change in appetite or weight, difficulty concentrating or sleeping, loss of interest in usual activities, unexplained aches and pains, feeling tired, headaches or suicidal thoughts)

How does FETZIMA work?

FETZIMA belongs to a class of medicines called serotonin and norepinephrine reuptake inhibitors (SNRI). It is thought to work by affecting two naturally occurring brain chemicals, serotonin and norepinephrine.

What are the ingredients in FETZIMA?

Medicinal ingredients: Levomilnacipran (as levomilnacipran hydrochloride)

Non-medicinal ingredients: Ethylcellulose, hypromellose, iron oxide - black, iron oxide - red (80 mg and 120 mg only), iron oxide - yellow (20 mg and 40 mg only), povidone, shellac glaze, sugar spheres, talc, titanium dioxide and triethyl citrate.

FETZIMA comes in the following dosage forms:

Capsules: 20 mg, 40 mg, 80 mg and 120 mg.

Do not use FETZIMA if you:

- are allergic to levomilnacipran, milnacipran or any of the other ingredients in FETZIMA (see **What are the ingredients in FETZIMA?**)
- take a Monoamine Oxidase Inhibitor (MAOI). Ask your healthcare professional if you are not sure you are taking a MAOI, including the antibiotic linezolid and methylene blue.
  - do not take a MAOI within 2 weeks of stopping FETZIMA unless directed to do so by your healthcare professional
  - do not start FETZIMA if you stopped taking a MAOI in the last 2 weeks unless directed to do so by your healthcare professional
- have had the following conditions:
  - recent heart attack or severe heart failure
  - racing heart rate or high blood pressure that cannot be controlled
  - history of stroke

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

- are taking any other medicines
- have had a recent bone fracture or were told you have osteoporosis or risk factors for osteoporosis
- have a history of high blood pressure or abnormally fast heartbeat
- have a history of medical conditions including heart problems, seizures or kidney problems
- have a history of drug abuse. Your healthcare professional may monitor you for signs of misuse or abuse while you take FETZIMA.

- have diabetes and are taking insulin or other medicines to lower your blood sugar. FETZIMA may affect your blood sugar levels. Closely monitor your blood sugar levels while taking it.
- have a history of urinary disorders
- have a bleeding disorder or have been told that you have low platelets in your blood
- have a history of low sodium levels in your blood
- have a condition that causes abnormally high pressure in your eye, such as glaucoma
- have a family history of mania or bipolar disorder
- have a history of sexual problems

Other warnings you should know about:

Do not stop taking FETZIMA without first talking to your healthcare professional. Stopping FETZIMA suddenly may cause symptoms, including:

- anxiety, irritability, high or low mood, feeling restless or sleepy
- headache, sweating, nausea, dizziness
- electric shock-like sensations, tremor, confusion

Your healthcare professional will safely and gradually taper your dose if it is decided that you should stop taking FETZIMA.

FETZIMA can cause serious side effects, including:

- **Serotonin toxicity (also known as serotonin syndrome):** FETZIMA 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 FETZIMA with certain anti-depressants 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.
- **Hypertension** (high blood pressure): If you have high blood pressure, it should be controlled before your start taking FETZIMA.
- **Tachycardia** (abnormally fast heartbeat): If you have heart problems, including an abnormally fast heartbeat, your problems should be treated before you start taking FETZIMA.
- **Problems with urination**: FETZIMA may cause you to have problems with urination including decreased urine flow and being unable to pass any urine. This mostly affects males.

- **Hyponatremia** (low sodium in the blood): FETZIMA may cause low sodium levels in your blood. This condition may be serious and even cause death. Elderly people may be at greater risk for this.
- **Seizures** (fit)
- **Angle-Closure Glaucoma** FETZIMA can cause an acute attack of glaucoma. Having your eyes examined before you take FETZIMA 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.
- **Mania/hypomania:** FETZIMA may cause manic episodes, especially if you have a history of mania or bipolar disorder.

See the **Serious side effects and what to do about them** table below for more information on these and other serious side effects.

Increased risk of bleeding: Taking FETZIMA with acetylsalicylic acid (ASA, or Aspirin), non-steroidal anti-inflammatory drugs (NSAIDs) (e.g. ibuprofen, celecoxib, naproxen), warfarin or other blood thinners may increase your risk of bleeding. This includes:

- Gastrointestinal (GI) bleeding, which can happen anywhere along the GI tract between the mouth and anus. Symptoms of GI bleeding include: blood in vomit, black tarry stools, bright red blood in your stool or coming from the anus
- Bleeding under the skin, or bruising
- Nosebleeds
- Hemorrhages (blood loss inside or outside the body), which can be life-threatening

Tell your healthcare professional **right away** if you have any unusual bleeding or bruising.

Increased risk of breaking a bone: Taking FETZIMA 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: Before doing any tasks that require special attention, wait until you know how you respond to FETZIMA.

Children and adolescents: FETZIMA is not to be used in children and adolescents under 18 years of age.

Pregnancy:

- Tell your healthcare professional **right away** if you become pregnant while taking FETZIMA. It is very important that you do **not** stop taking FETZIMA without first consulting with your healthcare professional.
- If you are pregnant, your healthcare professional will decide if FETZIMA is right for you. They will also discuss with you the risk of complications after birth if you take it during pregnancy.
- If you take FETZIMA near the end of your pregnancy, you may be at higher risk of heavy vaginal bleeding shortly after birth.

- If you have been prescribed FETZIMA during pregnancy, be ready to seek immediate 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

Breastfeeding: It is not known if FETZIMA can pass into your breastmilk and harm your baby. Talk to your healthcare professional about ways to feed your baby while taking FETZIMA.

Check-ups and testing: Your healthcare professional may do tests, including blood tests, before you take FETZIMA and regularly during your treatment. These tests will monitor:

- your blood pressure
- your heart rate
- your level of cholesterol (a type of fat) in your blood
- your blood sugar levels

Your healthcare professional will also closely monitor you while you are taking FETZIMA for any changes in your behaviour or emotions or thoughts of suicide.

Depending on your test results, your healthcare professional may adjust your dose or discontinue your treatment with FETZIMA.

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 take FETZIMA if you:

- are taking or have recently taken (in the last 14 days) any monoamine oxidase inhibitors (MAOIs) such as phenelzine, tranylcypromine, moclobemide, linezolid, methylene blue, isocarboxazid, isoniazid as you may have serious side effects

Taking FETZIMA with any of these medicines may cause serious drug interactions. Ask your healthcare professional if you are unsure.

The following may interact with FETZIMA:

- other antidepressants
- other medicines that affect serotonin such as lithium, linezolid, sibutramine, tryptophan, triptans, St. John's Wort
- certain medicines that may affect blood clotting and increase bleeding, such as oral blood thinners (e.g., warfarin, dabigatran), acetylsalicylic acid (ASA, or Aspirin) and other NSAIDs (e.g., ibuprofen, celecoxib, naproxen)

- 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
- Ketoconazole, a medicine used to treat fungal infections
- Medicines used to treat high blood pressure such as clonidine, methyldopa, diuretics (also known as “water pills”)

As with other drugs that affect the brain, use of alcohol is not recommended when taking FETZIMA.

How to take FETZIMA:

- FETZIMA should be taken once a day, with or without food. The capsules should be swallowed whole. Do not open, chew or crush the capsule.

Usual dose:

- Take FETZIMA exactly as your healthcare professional tells you
- Never change your dose without first consulting your healthcare professional
- Do not stop taking FETZIMA without first talking to your healthcare professional

Overdose:

If you think you, or a person you are caring for, have taken too much FETZIMA, 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 of FETZIMA by a few hours, take the dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and take the next dose at your usual time. Do not take two doses at one time.

What are possible side effects from using FETZIMA?

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

Side effects may include:

- Nausea
- Sexual problems
- Excessive sweating
- Constipation

- Gas
- Trouble sleeping
- Vomiting
- Dry mouth
- Abdominal pain
- Sore throat or runny nose
- Hot flashes
- Loss of appetite
- Dry eyes
- Feeling thirsty
- Headache
- Tingling sensation in hands or feet
- Teeth grinding
- Weight loss
- Nosebleeds

FETZIMA can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

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			
Hypertension (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or heart palpitations		✓	
Problems with urination: decreased urine flow or inability to pass any urine		✓	
Rash alone		✓	
Tachycardia (abnormally fast heartbeat)		✓	
UNCOMMON			
Hives		✓	
Mania/Hypomania: elevated or irritated mood, decreased need for sleep, racing thoughts		✓	
RARE			

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**	
Angle-Closure Glaucoma: Eye pain, changes in vision, and swelling or redness in or around the eye			✓
Seizures (fit): loss of consciousness with uncontrollable shaking			✓
UNKNOWN FREQUENCY			
Allergic reactions: red skin, hives, itching, swelling of the lips, face, tongue or throat, trouble breathing, wheezing, shortness of breath, skin rashes, blisters of the skin, sores or pain in the mouth or eyes.			✓
Hyponatremia (low sodium in the blood): symptoms of tiredness, weakness, confusion, combined with achy, stiff or uncoordinated muscles, seizure, coma		✓	
New or worsened emotional or behavioural problems: • feeling very agitated or restless • acting aggressive • being angry or violent • feeling anxious • acting on dangerous impulses • thoughts of harming others		✓	
Self-harm and suicide: Have thoughts of harming or killing yourself			✓
Serotonin toxicity: a reaction which may cause feelings or agitation or restlessness, flushing, muscle twitching, involuntary eye movements, heavy sweating, high body temperature (>38 °C), or rigid muscles			✓
Thrombocytopenia (low blood platelets): Bruising or unusual bleeding from the skin or other areas		✓	

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.

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.

Storage:

Store at 15° to 30°C.

Keep out of reach and sight of children.

If you want more information about FETZIMA:

- 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.abbvie.ca, or by calling AbbVie Corporation at 1-888-704-8271.

This leaflet was prepared by AbbVie Corporation.

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