Day/Date	Symptoms	How long they lasted	Impact on day

Note to patient: Please complete and share your symptom diary with your healthcare professional. This diary can assist your healthcare professional in monitoring treatment. Only a healthcare professional can diagnose and treat major depressive disorder.

MEDICATION GUIDE

FETZIMA® (fet-ZEE-muh)

(levomilnacipran)

extended-release capsules, for oral use

What is the most important information I should know about FETZIMA?

FETZIMA may cause serious side effects, including:

- **Increased risk of suicidal thoughts and actions**. FETZIMA and other antidepressant medicines may increase suicidal thoughts and actions in some people 24 years and younger, **especially within the first few months of treatment or when the dose is changed. FETZIMA is not for use in children.**
  - **Depression or other mental illnesses are the most important causes of suicidal thoughts or actions.**

  How can I watch for and try to prevent suicidal thoughts and actions?
  - Pay close attention to any changes, especially sudden changes in mood, behavior, thoughts, or feelings, or if you develop suicidal thoughts or actions. This is very important when an antidepressant medicine is started or when the dose is changed.
  - Call your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings or if you develop suicidal thoughts or actions.
  - Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.

  Call your healthcare provider or get emergency medical help right away if you or your family member have any of the following symptoms, especially if they are new, worse, or worry you:
  - attempts to commit suicide
  - acting aggressive, being angry or violent
  - new or worse depression
  - panic attacks
  - new or worse irritability
  - an extreme increase in activity or talking (mania)
  - acting on dangerous impulses
  - thoughts about suicide or dying
  - new or worsening anxiety
  - feeling very agitated or restless
  - trouble sleeping
  - other unusual changes in behavior or mood

What is FETZIMA?

FETZIMA is a prescription medicine used to treat a certain type of depression called Major Depressive Disorder (MDD) in adults.

It is not known if FETZIMA is safe and effective for use in children.

It is not known if FETZIMA is safe and effective for the management of fibromyalgia. FETZIMA is not for use for the management of fibromyalgia.

Do not take FETZIMA if you:

- are allergic to levomilnacipran, milnacipran HCl, or any of the ingredients in FETZIMA. See the end of this *Medication Guide* for a complete list of ingredients in FETZIMA.
- are taking or have taken within the last 14 days, a medicine called a monoamine oxidase inhibitor (MAOI), including

  the antibiotic linezolid or intravenous methylene blue.

Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid or intravenous methylene blue.

Do not start taking an MAOI for at least 7 days after you stop treatment with FETZIMA.

Before taking FETZIMA, tell your healthcare provider about all your medical conditions, including if you:

- have or have a family history of suicide, depression, bipolar disorder, mania, or hypomania
- have high blood pressure
- have or had heart problems, including fast heartbeat, or stroke
- have or had bleeding problems
- have glaucoma (high pressure in the eye)
- have or had problems urinating (hesitation) or emptying your bladder (retention)
- have or had seizures (convulsions)
- have low sodium levels in your blood
- have or had kidney problems
- drink alcohol
- are pregnant or plan to become pregnant. FETZIMA may harm your unborn baby. Taking FETZIMA during your third trimester of pregnancy may cause you to have an increased risk of bleeding after your delivery and may also cause your baby to be at increased risk for withdrawal symptoms, or breathing, temperature control, feeding or other problems at birth. Talk to your healthcare provider about the risks to you and your baby if you take FETZIMA during pregnancy.
  - Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with FETZIMA.
  - There is a pregnancy registry for women who are exposed to FETZIMA during pregnancy. The purpose of the registry is to collect information about the health of women exposed to FETZIMA and their baby. If you become pregnant during treatment with FETZIMA, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or visit online at *https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/*.
- are breastfeeding or plan to breastfeed. It is not known if FETZIMA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with FETZIMA.
  - If you breastfeed during treatment with FETZIMA, call you healthcare provider if your baby develops sleepiness or fussiness, or is not feeding or gaining weight well.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

FETZIMA and other medicines may affect each other causing possible serious side effects.

FETZIMA may affect the way other medicines work and other medicines may affect the way FETZIMA works.

Especially tell your healthcare provider if you take:

- MAOIs
- medicines used to treat migraine headache known as triptans
- tricyclic antidepressants
- fentanyl
- lithium
- tramadol
- tryptophan
- buspirone
- amphetamines
- St. John's Wort
- medicines that can affect blood clotting such as aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs) and warfarin
- diuretics
- medicines used to treat mood, anxiety, psychotic or thought disorders, including selective serotonin reuptake

inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs)

Ask your healthcare provider if you are not sure if you are taking any of these medicines. Your healthcare provider can tell you if it is safe to take FETZIMA with your other medicines.

Do not start or stop any other medicines during treatment with FETZIMA without talking to your healthcare provider first. Stopping FETZIMA suddenly may cause you to have serious side effects. See, **"What are the possible side effects of FETZIMA?"**

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take FETZIMA?

- Take FETZIMA exactly as your healthcare provider tells you to take it. Do not change your dose or stop taking FETZIMA without first talking to your healthcare provider.
- Your healthcare provider may need to change the dose of FETZIMA until it is the right dose for you.
- Take FETZIMA 1 time each day at about the same time each day.
- Take FETZIMA with or without food.
- Swallow FETZIMA capsules whole. Do not open, chew, or crush the FETZIMA capsule.
- If you miss a dose of FETZIMA, take the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and take your next dose at the regular time. Do not take 2 doses of FETZIMA at the same time.
- If you take too much FETZIMA, call your healthcare provider or poison control center at 1-800-222-1222, or go to the nearest hospital emergency room right away.

What should I avoid while taking FETZIMA?

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how FETZIMA affects you. FETZIMA can cause sleepiness or may affect your ability to make decisions, think clearly, or react quickly.
- Avoid drinking alcohol during treatment with FETZIMA.

What are the possible side effects of FETZIMA?

FETZIMA may cause serious side effects, including:

- See **"What is the most important information I should know about FETZIMA?"**
- **Serotonin syndrome.** A potentially life-threatening problem called serotonin syndrome can happen when FETZIMA is taken with certain other medicines. See **"Do not take FETZIMA if you." Call you healthcare provider or go to the nearest hospital emergency room right away** if you have any of the following signs and symptoms of serotonin syndrome:
  - agitation
  - confusion
  - fast heartbeat
  - dizziness
  - flushing
  - tremors, stiff muscles, or muscle twitching
  - seizures
  - seeing or hearing things that are not real (hallucinations)
  - coma
  - blood pressure changes
  - sweating
  - high body temperature (hyperthermia)
  - loss of coordination
  - nausea, vomiting, diarrhea
- **High blood pressure (hypertension).** Your healthcare provider should check your blood pressure before you start and during treatment with FETZIMA. If you have high blood pressure, it should be controlled before you start treatment with FETZIMA.
- **Increased heart rate**. Your healthcare provider should check your heart rate before you start and during treatment with FETZIMA. If you have heart problems or problems with an abnormal heartbeat, your problems should be treated before you start treatment with FETZIMA.
- **Increased risk of bleeding.** Taking FETZIMA with aspirin, non-steroidal anti-inflammatory drugs (NSAIDs), warfarin or blood thinners may add to this risk. Tell your healthcare provider right away about any unusual bleeding or bruising.

- **Eye problems (angle-closure glaucoma).** FETZIMA may cause a type of eye problem called angle-closure glaucoma in people with certain eye problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are. Call your healthcare provider if you have changes in your vision, eye pain, or swelling or redness in or around the eye.
- **Problems with urination.** FETZIMA may cause you to have problems with urination including decreased urine flow and being unable to pass any urine. Tell your healthcare provider if you develop any problems with urine flow during treatment with FETZIMA.
- **Manic episodes.** Manic episodes may happen in people with bipolar disorder who take FETZIMA. Symptoms may include:
  - greatly increased energy
  - racing thoughts
  - unusually grand ideas
  - talking more or faster than usual
  - severe trouble sleeping
  - reckless behavior
  - excessive happiness or irritability
- **Seizures (convulsions).**
- **Discontinuation syndrome.** Suddenly stopping FETZIMA may cause you to have serious side effects. Your healthcare provider may want to decrease your dose slowly. Symptoms may include:
  - changes in your mood
  - irritability and agitation
  - dizziness
  - electric shock sensation (paresthesia)
  - anxiety
  - confusion
  - headache
  - tiredness
  - problems sleeping
  - hypomania
  - ringing in your ears (tinnitus)
  - seizures
- **Low sodium levels in your blood (hyponatremia).** Low sodium levels in your blood that may be serious and may cause death can happen during treatment with FETZIMA. Elderly people and people who take certain medicines may be at greater risk for this. Signs and symptoms may include:
  - headache
  - memory changes
  - weakness and unsteadiness on your feet which can lead to falls
  - difficulty concentrating
  - confusion

  In more severe or more sudden cases, signs and symptoms include:
  - hallucinations (seeing or hearing things that are not real)
  - seizures
  - stopping breathing (respiratory arrest)
  - fainting
  - coma
- **Sexual problems (dysfunction).** Taking FETZIMA may cause sexual problems.

  Symptoms in males may include:
  - delayed ejaculation or inability to have an ejaculation
  - decreased sex drive
  - problems getting or keeping an erection

  Symptoms in females may include:
  - decreased sex drive
  - delayed orgasm or inability to have an orgasm

  Talk to your healthcare provider if you develop any changes in your sexual function or if you have any questions or concerns about sexual problems during treatment with FETZIMA. There may be treatments your healthcare provider can suggest.

The most common side effects of FETZIMA, include:

- nausea
- constipation
- sweating
- increased heart rate
- problems getting or keeping an erection
- delayed ejaculation or inability to have an ejaculation
- vomiting
- fast or irregular heartbeat (palpitations)

These are not all the possible side effects of FETZIMA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store FETZIMA?

- Store FETZIMA at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep FETZIMA and all medicines out of the reach of children.**

General information about the safe and effective use of FETZIMA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use FETZIMA for a condition for which it was not prescribed. Do not give FETZIMA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about FETZIMA that is written for healthcare professionals.

What are the ingredients in FETZIMA?

Active ingredient: levomilnacipran hydrochloride

Inactive ingredients: ethylcellulose, hypromellose, povidone, sugar spheres, talc, titanium dioxide, triethyl citrate, black iron oxide, red iron oxide (80 mg and 120 mg capsules only) shellac glaze, yellow iron oxide (20 mg and 40 mg capsules only)

Distributed by:
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North Chicago, IL 60064

For more information, go to www.FETZIMA.com or call 1-800-678-1605.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: 5/2023
20078875