

MEDICATION GUIDE

FETZIMA[®] (fet-ZEE-muh) (levomilnacipran) extended-release capsules

Read this Medication Guide before you start taking FETZIMA and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Talk to your healthcare provider about:

- all risks and benefits of treatment with antidepressant medicines
- all treatment choices for depression or other serious mental illness

What is the most important information I should know about depression, antidepressant medicines, other serious mental illnesses, suicidal thoughts or actions and serotonin syndrome?

FETZIMA and other antidepressant medicines may cause serious side effects.

- 1. Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions. Some people may have a particularly high risk of having suicidal thoughts or actions.** These include people who have (or have a family history of) bipolar illness (also called manic-depressive illness).
- 2. Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, or young adults within the first few months of treatment.**

FETZIMA is not approved for use in children. Talk to your child's healthcare provider for more information.

- 3. How can I watch for and try to prevent suicidal thoughts and actions?**
 - Pay close attention to any changes in mood, behavior, thoughts, or feelings, especially sudden changes. 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.
 - 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 right away if you have any of the following symptoms or feelings, especially if they are new, worse, or worry you:

- attempts to commit suicide
- acting on dangerous impulses
- acting aggressive, being angry, or violent

- thoughts about suicide or dying
 - new or worsening depression
 - new or worsening anxiety
 - feeling very agitated or restless
 - panic attacks
 - trouble sleeping
 - new or worsening irritability
 - an extreme increase in activity or talking (mania)
 - other unusual changes in behavior or mood
4. **Serotonin syndrome:** A rare, but potentially life-threatening condition called serotonin syndrome can happen when medicines such as FETZIMA are taken with certain other medicines. Serotonin syndrome can cause serious changes in how your brain, muscles, heart and blood vessels, and digestive system work.
- Symptoms of serotonin syndrome may include:
- agitation, hallucinations, coma or other changes in mental status
 - problems controlling your movements or muscle twitching
 - fast heartbeat
 - high or low blood pressure
 - sweating or fever
 - nausea or vomiting
 - diarrhea
 - muscle stiffness or tightness

What else do I need to know about antidepressant medicines?

- **Antidepressants are medicines used to treat depression and other illnesses.** It is important to discuss all the risks of treating depression and also the risks of not treating it. You should discuss all treatment choices with your healthcare provider, not just antidepressant medications.
- **Antidepressant medicines have other side effects.** Talk to your healthcare provider about the possible side effects of the medicine prescribed for you or your family member.
- **Antidepressant medicines can interact with other medicines.** Know all of the medicines that you or your family member takes. Keep a list of all medicines (including prescription, over-the-counter, vitamins and herbal supplements) to show your healthcare provider. Do not start new medicines without first checking with your healthcare provider.
- **Never stop an antidepressant medicine without first talking to your healthcare provider.** Stopping an antidepressant medicine suddenly can cause other symptoms.

What is FETZIMA?

FETZIMA is a prescription medicine used to treat a certain type of depression called Major Depressive Disorder (MDD). FETZIMA belongs to a class of medicines known as SNRIs (or serotonin-norepinephrine reuptake inhibitors).

Who should not take FETZIMA?

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.
- take a Monoamine Oxidase Inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid or intravenous methylene blue.
- have taken an MAOI within 14 days unless directed by your healthcare provider

What should I tell my healthcare provider before taking FETZIMA?

Before you take FETZIMA, tell your healthcare provider if you:

- have high blood pressure
- have heart problems
- have or had bleeding problems
- have or had urinary retention or problems urinating
- have mania or bipolar disorder (manic depression)
- have or had seizures or convulsions
- have low salt (sodium) levels in your blood
- have kidney problems
- drink alcohol
- are pregnant or plan to become pregnant. It is not known if FETZIMA will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if FETZIMA passes into breast milk. Talk to your healthcare provider if you are or plan to breast feed your baby while taking FETZIMA.

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

Especially tell your healthcare provider if you take:

- medicines used to treat migraine headache (triptans)
- medicines used to treat mood, anxiety, psychotic or thought disorders, including tricyclics, lithium, fentanyl, tryptophan, selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), buspirone, amphetamines, or antipsychotics
- sibutramine
- tramadol
- over-the-counter supplements such as tryptophan or St. John's Wort
- nonsteroidal anti-inflammatory drugs (NSAIDS)
- aspirin
- warfarin (Coumadin®, Jantoven®)
- diuretics

Ask your healthcare provider if you are not sure if you are taking any of these medicines.

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

FETZIMA and some medicines may affect each other, may not work as well, or may cause serious side effects when taken together.

How should I take FETZIMA?

- Take FETZIMA exactly as your healthcare provider tells you to take it.
- Take FETZIMA at about the same time each day.
- Your healthcare provider may need to change the dose of FETZIMA until it is the right dose for you.
- Do not start or stop taking FETZIMA without talking to your healthcare provider first. Stopping FETZIMA suddenly can cause side effects.
- FETZIMA may be taken with or without food.
- Swallow FETZIMA whole. Do not chew, crush, or cut FETZIMA.
- 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 two doses of FETZIMA at the same time.
- If you take too much FETZIMA, call your healthcare provider or your 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?

- FETZIMA can cause sleepiness or may affect your ability to make decisions, think clearly, or react quickly. You should not drive, operate heavy machinery, or do other dangerous activities until you know how FETZIMA affects you.
- You should not drink alcohol while taking FETZIMA. See “**What should I tell my healthcare provider before taking FETZIMA?**”

What are the possible side effects of FETZIMA?

FETZIMA may cause serious side effects, including:

- 1. high blood pressure (hypertension).** Your healthcare provider should evaluate your blood pressure before and while you are taking FETZIMA. If you have high blood pressure, it should be controlled before you start taking FETZIMA.
- 2. increased heart rate (palpitations).** Your healthcare provider should evaluate your heart rate before and while you are taking FETZIMA.
- 3. abnormal bleeding or bruising.** FETZIMA may increase your risk of bleeding or bruising, especially if you take the blood thinner warfarin (Coumadin®, Jantoven®), a non-steroidal anti-inflammatory drug (NSAID), or aspirin.
- 4. visual problems**
 - eye pain
 - changes in vision

- swelling or redness in or around eye

Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.

5. urinary hesitation and retention (difficulty urinating or unable to urinate)

6. hypomania (manic episodes). Symptoms of manic episodes include:

- greatly increased energy
- severe problems sleeping
- racing thoughts
- reckless behavior
- unusually grand ideas
- excessive happiness or irritability
- talking more or faster than usual

7. seizures or convulsions

8. discontinuation symptoms: Do not stop FETZIMA without first talking to your healthcare provider. Stopping FETZIMA suddenly may cause serious symptoms, including:

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

9. low levels of salt (sodium) in your blood. Symptoms of this may include: headache, difficulty concentrating, memory changes, confusion, weakness and unsteadiness on your feet. Symptoms of severe or sudden cases of low salt levels in your blood may include: hallucinations (seeing or hearing things that are not real), fainting, seizures and coma. If not treated, severe low sodium levels could cause death.

The most common side effects of FETZIMA include:

- nausea or vomiting
- constipation
- sweating
- erectile dysfunction

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of FETZIMA. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider 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 condition. It may harm them.

This Medication Guide summarizes the most important information about FETZIMA. If you would like more information, talk with your healthcare provider. You may ask your healthcare provider or pharmacist for information about FETZIMA that is written for healthcare professionals.

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

What are the ingredients in FETZIMA?

Active ingredient: levomilnacipran hydrochloride

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

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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Distributed by:
Allergan USA, Inc.
Irvine, CA 92612

Revised: 01/2017

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