

Medication Guide
PEXEVA[®] (pex-EE-va)
(paroxetine mesylate)

Read the Medication Guide that comes with PEXEVA before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment. Talk with your healthcare provider if there is something you do not understand or want to learn more about.

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

PEXEVA and other antidepressant medicines may cause serious side effects, including:

1. Suicidal thoughts or actions:

- **PEXEVA and other antidepressant medicines may increase suicidal thoughts or actions** in some children, teenagers, or young adults within the **first few months of treatment or when the dose is changed**.
- Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions.
- Watch for these changes and call your healthcare provider right away if you notice:
 - New or sudden changes in mood, behavior, actions, thoughts, or feelings, especially if severe.
 - Pay particular attention to such changes when PEXEVA is started or when the dose is changed.

Keep all follow-up visits with your healthcare provider and call between visits if you are worried about symptoms.

Call your healthcare provider right away if you have any of the following symptoms, or call 911 if an emergency, especially if they are new, worse, or worry you:

- attempts to commit suicide
- acting on dangerous impulses
- acting aggressive or violent
- thoughts about suicide or dying
- new or worse depression
- new or worse anxiety or panic attacks
- feeling agitated, restless, angry or irritable
- trouble sleeping
- an increase in activity or talking more than what is normal for you
- other unusual changes in behavior or mood

Call your healthcare provider right away if you have any of the following symptoms, or call 911 if an emergency. PEXEVA may be associated with these serious side effects:

2. Serotonin Syndrome. This condition can be life-threatening and may include:

- agitation, hallucinations, coma or other changes in mental status
- coordination problems or muscle twitching (overactive reflexes)
- racing heartbeat, high or low blood pressure
- sweating or fever
- nausea, vomiting, or diarrhea

- muscle rigidity

3. Severe allergic reactions:

- trouble breathing
- swelling of the face, tongue, eyes or mouth
- rash, itchy welts (hives) or blisters, alone or with fever or joint pain

4. Abnormal bleeding: PEXEVA and other antidepressant medicines 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's, like ibuprofen or naproxen), or aspirin.

5. Seizures or convulsions

6. Manic episodes:

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

7. Changes in appetite or weight. Children and adolescents should have height and weight monitored during treatment.

8. Low salt (sodium) levels in the blood. Elderly people may be at greater risk for this. Symptoms may include:

- headache
- weakness or feeling unsteady
- confusion, problems concentrating or thinking or memory problems

Do not stop PEXEVA without first talking to your healthcare provider.

Stopping PEXEVA too quickly may cause serious symptoms including:

- anxiety, irritability, high or low mood, feeling restless or changes in sleep habits
- headache, sweating, nausea, dizziness
- electric shock-like sensations, shaking, confusion

What is PEXEVA?

PEXEVA is a prescription medicine used to treat depression. It is important to talk with your healthcare provider about the risks of treating depression and also the risks of not treating it. You should discuss all treatment choices with your healthcare provider. PEXEVA is also used to treat:

- Major Depressive Disorder (MDD)
- Obsessive Compulsive Disorder (OCD)
- Panic Disorder
- Generalized Anxiety Disorder (GAD)

Talk to your healthcare provider if you do not think that your condition is getting better with PEXEVA treatment.

Who should not take PEXEVA?

Do not take PEXEVA if you:

- are allergic to paroxetine mesylate or any of the ingredients in PEXEVA. See the end of this Medication Guide for a complete list of ingredients in PEXEVA.
- take a Monoamine Oxidase Inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI.
 - Do not take an MAOI within 2 weeks of stopping PEXEVA unless directed to do so by your physician.
 - Do not start PEXEVA if you stopped taking an MAOI in the last 2 PEXEVA unless directed to do so by your physician.
 - People who take PEXEVA close in time to an MAOI may have serious or even life-threatening side effects. Get medical help right away if you have any of these symptoms:
 - high fever
 - uncontrolled muscle spasms
 - stiff muscles
 - rapid changes in heart rate or blood pressure
 - confusion
 - loss of consciousness (pass out)
- **take Mellaril[®] (thioridazine). Do not take Mellaril[®] together with PEXEVA because this can cause serious heart rhythm problems or sudden death.**
- **take the antipsychotic medicine pimozide (Orap[®]) because this can cause serious heart problems.**

What should I tell my healthcare provider before taking PEXEVA? Ask if you are not sure.

Before starting PEXEVA, tell your healthcare provider if you:

- **are pregnant, may be pregnant, or plan to become pregnant.** There is a possibility that PEXEVA may harm your unborn baby, including an increased risk of birth defects, particularly heart defects. Other risks include a serious condition in which there is not enough oxygen in the baby's blood. Your baby may also have certain other symptoms shortly after birth. Premature births have also been reported in some women who used PEXEVA during pregnancy.
- **are breastfeeding.** PEXEVA passes into your milk. Talk to your healthcare provider about the best way to feed your baby while taking PEXEVA.
- are taking certain drugs such as:
 - triptans used to treat migraine headache
 - other antidepressants (SSRI's, SNRI's, tricyclics, or lithium) or antipsychotics
 - drugs that affect serotonin such as lithium, tramadol, tryptophan, St. John's wort
 - certain drugs used to treat irregular heart beats
 - certain drugs used to treat schizophrenia
 - certain drugs used to treat HIV infection
 - certain drugs that affect the blood such as warfarin, aspirin, and ibuprofen
 - certain drugs used to treat epilepsy
 - atomoxetine
 - cimetidine
 - fentanyl

- metoprolol
- pimozide
- procyclidine
- tamoxifen
- have liver problems
- have kidney problems
- have heart problems
- have or had seizures or convulsions
- have bipolar disorder or mania
- have low sodium levels in your blood
- have a history of a stroke
- have high blood pressure
- have or had bleeding problems
- have glaucoma (high pressure in the eye).

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

PEXEVA and some medicines may interact with each other, may not work as well, or may cause serious side effects.

Your healthcare provider or pharmacist can tell you if it is safe to take PEXEVA with your other medicines. Do not start or stop any medicine while taking PEXEVA without talking to your healthcare provider first.

If you take PEXEVA, you should not take any other medicines that contain paroxetine including: PAXIL[®] and PAXIL CR[®].

How should I take PEXEVA?

- Take PEXEVA exactly as prescribed. Your healthcare provider may need to change the dose of PEXEVA until it is the right dose for you.
- PEXEVA may be taken with or without food.
- If you miss a dose of PEXEVA, 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 PEXEVA at the same time.
- If you take too much PEXEVA, call your healthcare provider or poison control center right away, or get emergency treatment.
- Do not stop taking PEXEVA suddenly without talking to your doctor (unless you have symptoms of a severe allergic reaction). If you need to stop taking PEXEVA, your healthcare provider can tell you how to safely stop taking it.

What should I avoid while taking PEXEVA?

PEXEVA 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 PEXEVA affects you. Do not drink alcohol while using PEXEVA.

What are the possible side effects of PEXEVA?

PEXEVA may cause serious side effects, including all of those described in the section entitled “What is the most important information I should know about PEXEVA?”

Common possible side effects in people who take PEXEVA include:

- Nausea
- Sleepiness
- Weakness
- Dizziness
- Feeling anxious
- Trouble sleeping
- Sexual problems
- Sweating
- Shaking
- Not feeling hungry
- Dry mouth
- Constipation
- Infection
- Yawning

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 PEXEVA. For more information, ask your healthcare provider or pharmacist.

CALL YOUR DOCTOR FOR MEDICAL ADVICE ABOUT SIDE EFFECTS. YOU MAY REPORT SIDE EFFECTS TO THE FDA AT 1-800-FDA-1088.

How should I store PEXEVA?

- Store PEXEVA at room temperature between 59°F and 86°F (15°C to 30°C).
- Keep PEXEVA away from light.
- Keep PEXEVA bottle closed tightly.

Keep PEXEVA and all medicines out of the reach of children.

General information about PEXEVA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use PEXEVA for a condition for which it was not prescribed. Do not give PEXEVA to other people, even if they have the same condition. It may harm them.

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

For more information about PEXEVA call (1-800-455-8070) or go to www.PEXEVA.com.

What are the ingredients in PEXEVA?

Active ingredient: paroxetine mesylate

Inactive ingredients: dibasic calcium phosphate, hydroxypropyl methylcellulose, hydroxypropylcellulose, magnesium stearate, sodium starch glycolate, titanium dioxide, and iron oxide(s)

Manufactured by:

Norwich Pharmaceuticals, Inc. Norwich, NY 13815

Distributed by:

Noven Therapeutics, LLC, 11960 SW 144 St., Miami, FL 33186

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