

MEDICATION GUIDE
MOTPOLY XR (mot paa'lee)
(lacosamide) extended-release capsules, for oral use, CV

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

What is the most important information I should know about MOTPOLY XR?

Do not stop taking MOTPOLY XR without first talking to your healthcare provider. Stopping MOTPOLY XR suddenly can cause serious problems. Stopping seizure medicine suddenly in a patient who has epilepsy can cause seizures that will not stop (status epilepticus).

MOTPOLY XR can cause serious side effects, including:

1. **Like other antiepileptic drugs, MOTPOLY XR may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:**

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| • thoughts about suicide or dying | • trouble sleeping (insomnia) |
| • attempt to commit suicide | • new or worse irritability |
| • new or worse depression | • acting aggressive, being angry, or violent |
| • new or worse anxiety | • acting on dangerous impulses |
| • feeling agitated or restless | • an extreme increase in activity and talking (mania) |
| • panic attacks | • other unusual changes in behavior or mood |

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, 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 are worried about symptoms
 - Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes
2. MOTPOLY XR may cause you to feel dizzy, have double vision, feel sleepy, or have problems with coordination and walking. Do not drive, operate heavy machinery, or do other dangerous activities until you know how MOTPOLY XR affects you.
3. MOTPOLY XR may cause you to have an irregular heartbeat or may cause you to faint. In rare cases, cardiac arrest has been reported. Call your healthcare provider right away if you:
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| • have a fast, slow, or pounding heartbeat or feel your heart skip a beat | • feel lightheaded |
| • have shortness of breath | • fainted or if you feel like you are going to faint |
| • have chest pain | |
- If you have fainted or feel like you are going to faint you should lay down with your legs raised.
4. MOTPOLY XR is a federally controlled substance (CV) because it can be abused or lead to drug dependence. Keep your MOTPOLY XR in a safe place to protect it from theft. Never give your MOTPOLY XR to anyone else because it may harm them. Selling or giving away this medicine is against the law.

What is MOTPOLY XR?

MOTPOLY XR is a prescription medicine used:

- to treat partial-onset seizures in adults and in children weighing at least 110 pounds (50 kg).
- with other medicines to treat primary generalized tonic-clonic seizures in adults and children weighing at least 110 pounds (50 kg).

It is not known if MOTPOLY XR is safe and effective for partial-onset seizures and primary generalized tonic-clonic seizures in children weighing less than 50 kg.

What should I tell my healthcare provider before taking MOTPOLY XR?

Before you take MOTPOLY XR, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had depression, mood problems, or suicidal thoughts or behavior
- have heart problems
- have kidney problems
- have liver problems
- have abused prescription medicines, street drugs, or alcohol in the past
- are pregnant or plan to become pregnant. It is not known if MOTPOLY XR can harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking MOTPOLY XR. You and your healthcare provider will decide if you should take MOTPOLY XR while you are pregnant
 - o If you become pregnant while taking MOTPOLY XR, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry. You can enroll in this registry by calling 1-888-233-2334. The purpose of this registry is to collect information about the safety of antiepileptic medicine during pregnancy

- are breastfeeding or plan to breastfeed. MOTPOLY XR passes into breast milk
 - o Breastfeeding during treatment with MOTPOLY XR may cause your baby to have more sleepiness than normal. If this happens, contact your baby's healthcare provider
 - o Talk to your healthcare provider about the best way to feed your baby if you take MOTPOLY XR

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

Taking MOTPOLY XR with certain other medicines may cause side effects or affect how well they work. Do not start or stop other medicines without talking to your healthcare provider. Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist each time you get a new medicine.

How should I take MOTPOLY XR?

- Take MOTPOLY XR exactly as your healthcare provider tells you
- Your healthcare provider will tell you how much MOTPOLY XR to take and when to take it
- Your healthcare provider may change your dose if needed
- Do not stop MOTPOLY XR without first talking to a healthcare provider. Stopping MOTPOLY XR suddenly in a patient who has epilepsy can cause seizures that will not stop (status epilepticus)
- MOTPOLY XR may be taken with or without food
- Swallow MOTPOLY XR whole with liquid. Do not open, chew, or crush the capsules
- If you take too much MOTPOLY XR, call your healthcare provider or local Poison Control Center right away

What should I avoid while taking MOTPOLY XR?

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how MOTPOLY XR affects you
- MOTPOLY XR may cause you to feel dizzy, have double vision, feel sleepy, or have problems with coordination and walking
- You should not drink alcohol while taking MOTPOLY XR. MOTPOLY XR and alcohol can affect each other causing side effects such as sleepiness and dizziness

What are the possible side effects of MOTPOLY XR?

- See **"What is the most important information I should know about MOTPOLY XR?"**

MOTPOLY XR may cause other serious side effects including:

- **A serious allergic reaction that may affect your skin or other parts of your body such as your liver or blood cells.** Call your healthcare provider right away if you have:
 - o a skin rash, hives
 - o fever or swollen glands that do not go away
 - o shortness of breath
 - o tiredness (fatigue)
 - o swelling of the legs
 - o yellowing of the skin or whites of the eyes
 - o dark urine

The most common side effects of MOTPOLY XR include:

- double vision
- headache
- dizziness
- nausea
- sleepiness

These are not all of the possible side effects of MOTPOLY XR. For more information ask your healthcare provider or pharmacist. Tell your healthcare provider about any side effect that bothers you or that does not go away. 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 MOTPOLY XR?

- Store MOTPOLY XR at room temperature between 68°F to 77°F (20°C to 25°C)

Keep MOTPOLY XR and all medicines out of the reach of children.

General Information about the safe and effective use of MOTPOLY XR.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use MOTPOLY XR for a condition for which it was not prescribed. Do not give MOTPOLY XR 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 MOTPOLY XR that is written for health professionals.

What are the ingredients in MOTPOLY XR?

Active ingredient: lacosamide

Capsule inactive ingredients: ethylcellulose, hypromellose, microcrystalline cellulose, povidone, titanium dioxide, triacetin, triethyl citrate, and additional ingredients listed below:

- **100 mg capsules:** red iron oxide
- **150 mg capsules:** red iron oxide, yellow iron oxide
- **200 mg capsules:** black iron oxide, FD&C Blue #1, red iron oxide

Manufactured for: Aucta Pharmaceuticals, Inc., Piscataway NJ 08854