

Medication Guide
REYVOW™ (RAY-vow)
(lasmiditan)

tablets, for oral use, [symbol pending DEA decision]

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

- **Do not** drive or operate machinery for at least 8 hours after you take REYVOW, even if you feel well enough.
- **You should not** take REYVOW if you cannot wait at least 8 hours between taking REYVOW and driving or operating machinery.

What is REYVOW?

REYVOW is a prescription medicine used for the acute treatment of migraine attacks with or without aura in adults.

- REYVOW is not used as a preventive treatment of migraine.
- It is not known if REYVOW is safe and effective in children.
- [There is a pending DEA decision for control of REYVOW (lasmiditan) under the Controlled Substances Act. A statement for patients about abuse and dependence risks cannot be completed at this time.]

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

- have liver problems
- have high blood pressure
- have a low heart rate
- are allergic to lasmiditan
- are pregnant or plan to become pregnant. It is not known if REYVOW will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if REYVOW passes into your breastmilk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider will decide if you can take REYVOW with your other medicines.

Especially, tell your healthcare provider if you take:

- propranolol or other medicines that can lower your heart rate
- any medicines that can increase your blood pressure
- any medicines that make you sleepy
- anti-depressant medicines called:
 - selective serotonin reuptake inhibitors (SSRIs)
 - serotonin norepinephrine reuptake inhibitors (SNRIs)
 - tricyclic anti-depressants (TCAs)
 - monoamine oxidase inhibitors (MAOIs)

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure.

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

How should I take REYVOW?

- Take REYVOW exactly as your healthcare provider tells you to take it.
- Your healthcare provider may change your dose. Do not change your dose without first talking to your healthcare provider.
- Take REYVOW tablets by mouth with or without food.
- Do not take more than one dose in a 24-hour period.
 - If you take REYVOW 50 mg, 100 mg, or 200 mg, and your headache goes away but comes back, you should not take a second dose within 24 hours.
- Some people who take too many REYVOW tablets may have worse headaches (medication overuse headache). If your headaches get worse, your healthcare provider may decide to stop your treatment with REYVOW.
- You should write down when you have headaches and when you take REYVOW so you can talk to your healthcare provider about how REYVOW is working for you.

What should I avoid while taking REYVOW?

- **Do not** drive or operate machinery for at least 8 hours after taking REYVOW.
- You should not drink alcohol or take other medicines that make you drowsy while taking REYVOW.

What are the possible side effects of REYVOW?

REYVOW can cause serious side effects including:

- **See “What is the most important information I should know about REYVOW?”**
 - **serotonin syndrome.** Serotonin syndrome is a rare but serious problem that can happen in people using REYVOW, especially if REYVOW is used with anti-depressant medicines called SSRIs or SNRIs. Call your healthcare provider right away if you have any of the following symptoms of serotonin syndrome:
 - mental changes such as seeing things that are not there (hallucinations), agitation, or coma
 - fast heartbeat
 - changes in blood pressure

- high body temperature
- tight muscles
- trouble walking
- nausea, vomiting, or diarrhea
- **medication overuse headache.** Some people who take medicines like REYVOW for the acute treatment of migraine attacks for 10 or more days each month may have worse headaches (medication overuse headache). If your headaches get worse, your healthcare provider may decide to stop your treatment with REYVOW.

The most common side effects of REYVOW include:

- dizziness
- numbness
- tingling
- sleepiness
- feeling tired

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

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

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

You may also report side effects to Lilly at 1-800-LillyRx (1-800-545-5979).

How should I store REYVOW?

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

General information about the safe and effective use of REYVOW.

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

You can ask your pharmacist or healthcare provider for information about REYVOW that is written for health professionals.

What are the ingredients in REYVOW?

Active ingredient: lasmiditan hemisuccinate

Inactive ingredients: croscarmellose sodium, magnesium stearate, microcrystalline cellulose, pregelatinized starch, sodium lauryl sulfate.

Color mixture ingredients: black ferric oxide, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide. 100 mg tablets also contain red ferric oxide.

REYVOW is a trademark of Eli Lilly and Company.

Marketed by: Lilly USA, LLC, Indianapolis, IN 46285, USA
www.REYVOW.com

Copyright © YYYY, Eli Lilly and Company. All rights reserved.

For more information go to www.REYVOW.com or call 1-800-LillyRx (1-800-545-5979).

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

Issued: 10/2019

3.0-REY-0000-MG-YYYYMMDD