

Acumig

1. What this product is and what it is used for

Acumig is a prescripti

- Acumig is not used as a preventive treatment of migraine.
- It is not known if lasmiditan is safe and effective in children.
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2. What you need to know before you use this product

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

- Have liver problems

on medicine used for the acute treatment of migraine attacks with or without aura in adults. 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 lasmiditan will harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if lasmiditan passes into your breastmilk.
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Warnings and precautions

What should I avoid while taking Acumig?

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

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 Acumig 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.

Driving and using machines

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

- You should not drink alcohol or take other medicines that make you drowsy while taking Acumig.
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Acumig contains sodium

Acumig contains sodium. Each film-coated tablet of Acumig 50 mg and 100 mg Film-coated Tablets contains 0.468 mg or 0.936 mg sodium; respectively. This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to use this product.

- Take Acumig exactly as your healthcare provider tells you to take it.
- The recommended dose is 50 mg, 100 mg, or 200 mg taken orally, as needed. No more than one dose should be taken in 24 hours, and Acumig should not be taken unless the patient can wait at least 8 hours between dosing and driving or operating machinery.
- A second dose of lasmiditan has not been shown to be effective for the same migraine attack.
- Your healthcare provider may change your dose. Do not change your dose without first talking to your healthcare provider.

- Take Acumig tablets by mouth with or without food.
- Swallow Acumig tablets whole. Do not split, crush, or chew.
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If you take more Acumig than you should

- Do not take more than one dose in a 24-hour period.
- If you take lasmiditan 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 Acumig tablets may have worse headaches (medication overuse headache). If your headaches get worse, your healthcare provider may decide to stop your treatment with Acumig.
- You should write down when you have headaches and when you take Acumig so you can talk to your healthcare provider about how Acumig is working for you.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Lasmiditan can cause serious side effects including:

See “What is the most important information I should know about lasmiditan?”

- Serotonin syndrome. Serotonin syndrome is a rare but serious problem that can happen in people using lasmiditan, especially if lasmiditan 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 lasmiditan 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 lasmiditan.

The most common side effects of lasmiditan 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 lasmiditan. For more information ask your healthcare provider or pharmacist.

5. How to store this product

Keep this medicine out of the sight and reach of children.

Store below 30°C.

Store in the original package.

Do not use this medicine after the expiry date which is stated on the package after “EXP”. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any signs of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Further information

a. What this product contains

The active substance is lasmiditan hemi succinate.

Each film-coated tablet of Acumig 50 mg Film-coated Tablets contains 57.825 mg lasmiditan hemi succinate equivalents to 50 mg lasmiditan.

Each film-coated tablet of Acumig 100 mg Film-coated Tablets contains 115.65 mg lasmiditan hemi succinate equivalents to 100 mg lasmiditan.

The other ingredients are microcrystalline cellulose, pregelatinized starch, croscarmellose sodium, sodium lauryl sulfate, Syloid, magnesium stearate, Opadry gray (only in Acumig 50 mg Film-coated Tablets) and Opadry purple (only in Acumig 100 mg Film-coated Tablets).

b. What this product looks like and contents of the pack

Acumig 50 mg Film-coated Tablets are light gray-colored oval film-coated tablets, debossed with “LH” on one side and “1” on the other side in aluminum-aluminum blisters. Acumig 100 mg Film-coated Tablets are light purple-colored oval film-coated tablets, debossed with “LH” on one side and “2” on the other side in aluminum-aluminum blisters. Pack sizes: 4 and/or 8 Film-coated Tablets. Not all pack sizes may be marketed.

c. Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder, Batch releaser and Bulk manufacturer

Jazeera Pharmaceutical Industries

Al-Kharj Road

P.O. Box 106229

Riyadh 11666, Saudi Arabia

Tel: + (966-11) 8107023, + (966-11) 2142472

Fax: + (966-11) 2078170

e-mail: SAPV@hikma.com

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can also help provide more information on the safety of this medicine.

- United Arab of Emirates

Pharmacovigilance & Medical Device Section

P.O. Box: 1853

Tel: 800111111

Email: pv@mohap.gov.ae

Drug Department

Ministry of Health & Prevention

Dubai

- Saudi Arabia

The National Pharmacovigilance Centre (NPC)

SFDA Call Center: 19999

E-mail: npc.drug@sfda.gov.sa

Website: <https://ade.sfda.gov.sa>

- Other GCC States

Please contact the relevant competent authority.

d. This leaflet was last revised in:

This leaflet was last revised in 07/2023.