

Medication Guide
Mefenamic (me-fe-NAM-ik) Acid Capsules USP

Mefenamic acid capsules are prescription medicine that contains mefenamic acid (a nonsteroidal anti-inflammatory drug [NSAID]).

What is the most important information I should know about mefenamic acid capsules, and medicines called nonsteroidal anti-inflammatory drugs (NSAIDs)?

Mefenamic acid capsules may cause serious side effects, including:

- **Increased risk of a heart attack or stroke that can lead to death.** This risk may happen early in treatment and may increase:
 - with increasing doses of NSAIDs
 - with longer use of NSAIDs

Do not take mefenamic acid capsules right before or after a heart surgery called a “coronary artery bypass graft (CABG)”. Avoid taking mefenamic acid capsules after a recent heart attack unless your healthcare provider tells you to. You may have an increased risk of another heart attack if you take mefenamic acid capsules after a recent heart attack.

- **Increased risk of bleeding, ulcers and tears (perforation) of the esophagus (tube leading from the mouth to the stomach), stomach and intestines:**
 - anytime during use
 - without warning symptoms
 - that may cause death

The risk of getting an ulcer or bleeding increases with:

- past history of stomach ulcers, or stomach or intestinal bleeding with use of NSAIDs
- taking medicines in the drug classes of corticosteroids, antiplatelets (such as aspirin), anticoagulants, selective serotonin reuptake inhibitors (SSRIs), and serotonin norepinephrine reuptake inhibitors (SNRIs)
- increasing doses of NSAIDs
- longer use of NSAIDs
- smoking
- drinking alcohol
- older age
- poor health
- advanced liver disease
- bleeding problems

Mefenamic acid capsules should only be used:

- exactly as prescribed
- at the lowest dose possible for your treatment
- for the shortest time needed

What are mefenamic acid capsules?

Mefenamic acid capsules are prescription medicine used:

- for the management of mild to moderate pain in adults and children 14 years of age and older, when your treatment will not be longer than 1 week (7 days).
- for the treatment of menstrual cramps.

It is not known if mefenamic acid capsules are safe and effective for the management of mild to moderate pain in children less than 14 years of age.

Who should not take mefenamic acid capsules?

Do not take mefenamic acid capsules:

- if you are allergic to mefenamic acid or to any of the ingredients in mefenamic acid capsules. See the end of this Medication Guide for a complete of ingredients in mefenamic acid capsules.
- if you have had an asthma attack, hives, or other allergic reaction after taking aspirin or any other NSAIDs.
- right before or after heart bypass surgery.

Before taking mefenamic acid capsules, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems
- have bleeding problems
- have or have had ulcers
- have liver or kidney problems
- have high blood pressure
- have asthma
- are pregnant or plan to become pregnant. Taking mefenamic acid capsules at about 20 weeks of pregnancy or later may harm your unborn baby.
 - If you need to take mefenamic acid capsules for more than 2 days when you are between 20 and 30 weeks of pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. **You should not take mefenamic acid capsules after about 30 weeks of pregnancy.**
 - Mefenamic acid capsules may cause fertility problems in females, which may affect your ability to become pregnant. Talk to your healthcare provider if this is a concern for you.
- are breastfeeding or plan to breastfeed. Mefenamic acid can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with mefenamic acid capsules.

Tell your healthcare provider about all of the medicines you take, including prescription or over-the-counter medicines, vitamins, or herbal supplements. Mefenamic acid capsules and some other medicines can interact with each other and cause serious side effects. **Do not start taking any new medicine without talking to your healthcare provider first.**

How should I take mefenamic acid capsules?

- Take mefenamic acid capsules exactly as your healthcare provider tells you to take it.
- If you take too much mefenamic acid capsules, call your healthcare provider or Poison Help Line at 1-800-222-1222, or go to the nearest hospital emergency room right away.

What are the possible side effects of mefenamic acid capsules?

Mefenamic acid capsules may cause serious side effects, including:

See “What is the most important information I should know about mefenamic acid capsules, and medicines called nonsteroidal anti-inflammatory drugs (NSAIDs)?”

- liver problems including liver failure
- new or worse high blood pressure
- heart failure
- kidney problem including kidney failure
- increase in blood potassium level (hyperkalemia)
- life-threatening allergic reactions
- asthma attacks in people who have asthma
- serious skin reactions, including life-threatening skin reactions
- low red blood cells (anemia)

Other side effects of mefenamic acid capsules include: stomach pain, constipation, diarrhea, indigestion, gas, heartburn, nausea, vomiting, dizziness, swelling, increased liver enzyme levels, headaches, itching, rashes, and ringing in the ear.

Get emergency help right away if you get any of the following symptoms:

- shortness of breath or trouble breathing
- chest pain
- weakness in one part or side of your body
- slurred speech
- swelling of the face or throat

Stop taking mefenamic acid capsules and call your healthcare provider right away if you get any of the following symptoms:

- nausea
- more tired or weaker than usual
- diarrhea
- itching
- your skin or eyes look yellow
- indigestion or stomach pain
- flu-like symptoms
- vomit blood
- there is blood in the bowel movement or it is black and sticky like tar
- unusual weight gain
- skin rash or blisters with fever
- swelling of the arms, legs, hands, and feet

These are not all of the possible side effects of mefenamic acid capsules.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or Lupin Pharmaceuticals, Inc at 1-800-399-2561.

Other information about NSAIDs

- Aspirin is an NSAID medicine but it does not increase the chance of a heart attack. Aspirin can cause bleeding in the brain, stomach, and intestines. Aspirin can also cause ulcers in the stomach and intestines.
- Some NSAIDs are sold in lower doses without a prescription (over-the-counter). Talk to your healthcare provider before using over-the-counter NSAID.

How should I store mefenamic acid capsules?

- Store mefenamic acid capsules at room temperature at 25°C (77°F).

Keep mefenamic acid capsules and all medicines out of the reach of children.

General information about the safe and effective use of mefenamic acid capsules.

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

What are the ingredients in mefenamic acid capsules?

Active ingredient: mefenamic acid

Inactive ingredient: lactose monohydrate and magnesium stearate. The capsule shell contains gelatin, sodium lauryl sulfate, titanium dioxide, D&C yellow No. 10, FD&C yellow No. 6 and FD&C red No. 3.



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