

Medication Guide
VIMOVO (vi-moh-voh)
(naproxen and esomeprazole magnesium)
delayed-release tablets

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

You should take VIMOVO exactly as prescribed, at the lowest dose possible and for the shortest time needed.

VIMOVO may help your acid-related symptoms, but you could still have serious stomach problems. Talk with your healthcare provider.

VIMOVO contains naproxen, a nonsteroidal anti-inflammatory drug (NSAID) and esomeprazole magnesium, a proton pump inhibitor (PPI) medicine.

VIMOVO can 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 VIMOVO right before or after a heart surgery called a “coronary artery bypass graft (CABG).”

Avoid taking VIMOVO 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 NSAIDs 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 called “corticosteroids”, “anticoagulants”, “SSRIs”, or “SNRIs”
- increasing doses of NSAIDs
- longer use of NSAIDs
- smoking
- drinking alcohol
- older age
- poor health
- advanced liver disease
- bleeding problems

Talk to your healthcare provider or pharmacist before using other medicines that contain NSAIDs, including low-dose aspirin, during treatment with VIMOVO. Some NSAIDs are sold in lower doses without a prescription (over-the-counter).

- **A type of kidney problem (acute interstitial nephritis).** Some people who take proton pump inhibitor (PPI) medicines, including VIMOVO, may develop a kidney problem called acute interstitial nephritis that can happen at any time during treatment with VIMOVO. Call your healthcare provider right away if you have a decrease in the amount that you urinate or if you have blood in your urine.
- **Diarrhea caused by an infection (*Clostridium difficile*) in your intestines.** Call your healthcare provider right away if you have watery stools or stomach pain that does not go away. You may or may not have a fever.
- **Bone fractures (hip, wrist, or spine).** Bone fractures in the hip, wrist, or spine may happen in people who take multiple daily doses of PPI medicines and for a long period of time (a year or longer). Tell your healthcare provider if you have a bone fracture, especially in the hip, wrist, or spine.
- **Certain types of lupus erythematosus.** Lupus erythematosus is an autoimmune disorder (the body’s immune cells attack other cells or organs in the body). Some people who take PPI medicines, including VIMOVO, may develop certain types of lupus erythematosus or have worsening of the lupus they already have. Call your healthcare provider right away if you have new or worsening joint pain or a rash on your cheeks or arms that gets worse in the sun.

Talk to your healthcare provider about your risk of these serious side effects.

VIMOVO can have other serious side effects. See “**What are the possible side effects of VIMOVO?**”

What is VIMOVO?

VIMOVO is a prescription medicine used in adults and adolescents, 12 years of age and older who weigh at least 84 pounds (38 kg), who need to take naproxen for relief of symptoms of arthritis and who also need to decrease the risk of developing stomach ulcers caused by naproxen.

The naproxen in VIMOVO is used for the relief of signs and symptoms of:

- osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis in adults
- juvenile idiopathic arthritis (JIA) in adolescents

The esomeprazole magnesium in VIMOVO is used to:

- decrease the risk of developing stomach ulcers in people who are taking naproxen

It is not known if VIMOVO is safe and effective in children less than 12 years of age or who weigh less than 84 pounds (38 kg). You should not take a naproxen tablet and an esomeprazole magnesium tablet together instead of taking VIMOVO, because they will not work the same way.

Studies in people who take VIMOVO have not extended past 6 months.

Do not take VIMOVO:

- if you are allergic to naproxen, esomeprazole magnesium, omeprazole, any other PPI medicine, or any of the ingredients in VIMOVO. See the end of this Medication Guide for a complete list of ingredients in VIMOVO.

- 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.
- if you are taking a medicine that contains rilpivirine (Edurant, Complera, Odefsey) used to treat HIV-1 (Human Immunodeficiency Virus).

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

- have liver, kidney, or heart problems.
- have high blood pressure.
- have asthma.
- have low magnesium levels in your blood.
- have ulcerative colitis or Crohn's disease (inflammatory bowel disease or IBD).
- are pregnant or plan to become pregnant. Talk to your healthcare provider if you are considering taking VIMOVO during pregnancy. **You should not take VIMOVO after 29 weeks of pregnancy.**
- are breastfeeding or plan to breastfeed. The naproxen in VIMOVO can pass into your breast milk. It is not known if VIMOVO will harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take VIMOVO.
- are a female who can become pregnant. VIMOVO may be related to infertility in some women that is reversible when treatment with VIMOVO is stopped.

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

Especially tell your healthcare provider if you take:

- | | |
|--|--|
| • steroid hormones (corticosteroids) | • antidepressant medicine |
| • St. John's Wort | • medicine used to reduce the risk of blood clots, such as warfarin (Coumadin, Jantoven) |
| • rifampin (Rifater, Rifamate, Rimactane, Rifadin) | • methotrexate (Otrexup, Rasuvo, Trexall, Xatmep) |
| • medicine for high blood pressure or heart problems | • digoxin (Lanoxin) |
| • a water pill (diuretic) | • clopidogrel (Plavix) |
| • aspirin | |

How should I take VIMOVO?

- Take VIMOVO exactly as prescribed by your healthcare provider.
- Take 1 VIMOVO tablet 2 times each day.
- Take VIMOVO at least 30 minutes before a meal.
- Swallow VIMOVO tablets whole with liquid. Do not split, chew, crush or dissolve VIMOVO.
- You may use antacids while taking VIMOVO.
- If you forget to take your dose of VIMOVO, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose. Take the next dose on time. Do not take 2 doses at one time to make up for a missed dose.
- If you take too much VIMOVO, call your healthcare provider or your poison control center at 1-800-222-1222 right away or go to the nearest emergency room.

What are the possible side effects of VIMOVO?

VIMOVO can cause serious side effects, including:

See **"What is the most important information I should know about VIMOVO?"**

- liver problems, including liver failure.
- new or worsening high blood pressure.
- heart failure.
- kidney problems, including kidney failure.
- life-threatening allergic reactions.
- asthma attacks in people who have asthma.
- life-threatening skin reactions.
- low red blood cells (anemia).
- hiding (masking) symptoms of an infection, such as swelling and fever.
- **Low vitamin B-12 levels** in your body can happen in people who have taken VIMOVO for a long time (more than 3 years). Tell your healthcare provider if you have symptoms of low vitamin B-12 levels, including shortness of breath, lightheadedness, irregular heartbeat, muscle weakness, pale skin, feeling tired, mood changes, and tingling or numbness in the arms or legs.
- **Low magnesium levels** in your body can happen in people who have taken VIMOVO for at least 3 months. Tell your healthcare provider if you have symptoms of low magnesium levels, including seizures, dizziness, irregular heartbeat, jitteriness, muscle aches or weakness, and spasms of hands, feet or voice.
- **Stomach growths (fundic gland polyps)** People who take PPI medicines for a long time have an increased risk of developing a certain type of stomach growths called fundic gland polyps, especially after taking PPI medicines for more than 1 year.

The most common side effects of VIMOVO include: inflammation of the lining of the stomach and diarrhea

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 VIMOVO 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 your 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

If you take too much VIMOVO, call your healthcare provider or get medical help right away.

These are not all the possible side effects of VIMOVO. 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 VIMOVO?

- Store VIMOVO at room temperature between 68°F to 77°F (20°C to 25°C).
- Store VIMOVO in the original container.
- Keep the bottle of VIMOVO tightly closed to protect from moisture.

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

What are the ingredients in VIMOVO?

Active ingredients: naproxen and esomeprazole magnesium

Inactive ingredients: carnauba wax, colloidal silicon dioxide, croscarmellose sodium, iron oxide yellow, glyceryl monostearate, hypromellose, iron oxide black, magnesium stearate, methacrylic acid copolymer dispersion, methylparaben, polysorbate 80, polydextrose, polyethylene glycol, povidone, propylene glycol, propylparaben, titanium dioxide, and triethyl citrate

General information about the safe and effective use of VIMOVO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use VIMOVO for a condition for which it was not prescribed. Do not give VIMOVO to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about VIMOVO that is written for health professionals.

Distributed by: Horizon Pharma USA Inc., Lake Forest, IL 60045

For more information, go to www.VIMOVO.com or call 1-866-479-6742.

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

Revised: 06/2018