

## **INDICATIONS AND USAGE**

### **What is VIMOVO® (naproxen and esomeprazole magnesium)?**

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

## **IMPORTANT SAFETY INFORMATION**

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

- VIMOVO can cause an increased risk of a heart attack or stroke that can lead to death. This risk may occur early in treatment and may increase with longer use and with increasing doses of medicine containing NSAIDs.
- VIMOVO can cause an increased risk of bleeding, ulcers, and tears (perforations) of the esophagus, stomach, and intestines. These events can occur at any time during use, without warning symptoms, and may cause death. Elderly patients and patients with a history of ulcer disease or stomach or intestinal bleeding are at greater risk for getting an ulcer or bleeding.
- You should take VIMOVO exactly as prescribed, at the lowest dose possible and for the shortest time needed.

### **VIMOVO can cause serious side effects. Stop taking VIMOVO and call your doctor or go to your emergency department right away if you get:**

- Difficulty breathing, swelling of the face or throat. These could be signs of a serious allergic reaction.
- Chest pain, shortness of breath, weakness in one part or side of your body, or slurring of speech. These could be signs of a serious blood clotting event.
- Upper stomach pain, upset stomach, black, tarry stools, or vomiting of blood. These could be signs of an esophagus, stomach, or intestinal ulcer, bleed, or tear. Note: if you are also taking low-dose aspirin, you are at increased risk for esophagus, stomach, or intestinal bleeding.
- Nausea, more tired or weaker than usual, itching, yellowing of the skin or eyes, right upper abdomen tenderness, and “flu-like” symptoms. These could be signs of a liver problem.
- Shortness of breath, unexplained weight gain, or swelling of the arms, legs, hands, or feet. These could be signs of a serious heart problem.
- Diarrhea that does not improve. This could be a sign of an infection called *Clostridium difficile* infection.
- Any type of rash. This could be a sign of a serious skin reaction.
- New or worsening joint pain or a rash on your cheeks or arms that gets worse in the sun. These could be signs of certain types of lupus erythematosus.
- Decreased volume of urine or blood in urine. These could be signs of a kidney problem.

**These are not all of the possible side effects of VIMOVO. Please talk to your doctor if you experience any symptoms that bother you or that do not go away. If you take too much VIMOVO, call your poison control center at 1-800-222-1222.**

### **Who should not use VIMOVO?**

- **DO NOT USE VIMOVO:**
  - if you are allergic to naproxen, esomeprazole magnesium, omeprazole, any other PPI medicine, or any of the ingredients in VIMOVO. See the Medication Guide for a complete list of ingredients.
  - if you have had an asthma attack, hives, or other allergic reaction after taking aspirin or any other NSAIDs.
  - right before or after a heart bypass surgery called coronary artery bypass graft.
  - If you are taking a medicine that contains rilpivirine (Edurant, Complera, Odefsey) used to treat HIV-1 (Human Immunodeficiency Virus).

### **How should I take VIMOVO?**

Take VIMOVO exactly as your health care provider tells you to take it. Take VIMOVO at least 30 minutes before a meal. Swallow VIMOVO tablets whole with liquid. Do not split, chew, crush, or dissolve the VIMOVO tablet. If you forget to take a 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.

### **What are the possible side effects of VIMOVO?**

The most common side effects of VIMOVO are inflammation of the lining of the stomach and diarrhea.

### **What other medications might interact with VIMOVO?**

Avoid using VIMOVO while taking other naproxen-containing products or other non-aspirin NSAIDs, clopidogrel, St. John's Wort, or rifampin. NSAIDs may be present in over-the-counter medications for treatment of colds, fever, or insomnia; refer to the label of over-the-counter medications you are taking or ask your pharmacist. Do not use VIMOVO and low-dose aspirin until you talk to your health care provider. Tell your health care provider about all of the medicines you take as some medicines can react with VIMOVO and cause serious side effects.

### **What should I tell my health care provider?**

**Before starting VIMOVO**, tell your health care provider if you have a history of ulcer disease or esophagus, stomach, or intestine bleeding, liver or kidney problems, high blood pressure, heart problems, asthma, low magnesium levels, ulcerative colitis or Crohn's disease, or are pregnant, trying to become pregnant, or breast feeding. Talk to your health care provider about the risk of bone fractures or a certain type of stomach growths or developing low magnesium or vitamin B-12 levels if you take VIMOVO for a long period of time. Also tell your health care provider about all of the medicines you take, including prescription or over-the-counter medicines, vitamins, or herbal supplements. Do not start taking new medicines without talking to your health care provider first.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088. You may also contact the Horizon Pharma Medical Information Department toll-free at 1-866-479-6742 or [medicalinformation@horizonpharma.com](mailto:medicalinformation@horizonpharma.com).

The risk information provided here is not comprehensive. To learn more, talk about VIMOVO with your health care provider or pharmacist. The FDA-approved product labeling can be found at [www.VIMOVO.com](http://www.VIMOVO.com) or 1-866-479-6742.