Navigation

Ξ



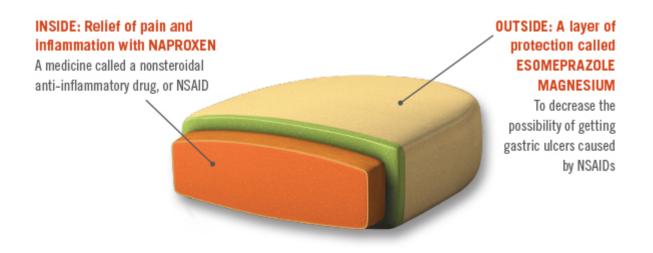


VIMOVO[®] (naproxen and esomeprazole magnesium) Tablets

The Smarter Naproxen Due to Added Gastroprotection

VIMOVO (naproxen and esomeprazole magnesium) delayed-release tablets 375 mg/20 mg and 500 mg/20 mg are a proprietary, single-tablet combination of the nonsteroidal antiinflammatory drug (NSAID) naproxen and immediate-release esomeprazole, a stomach acid –reducing proton pump inhibitor (PPI). Naproxen has proven anti-inflammatory and analgesic properties, and esomeprazole magnesium reduces the stomach acid–secretion that can cause gastric ulceration. With the combination of naproxen and esomeprazole magnesium into a single product, VIMOVO decreases the risk of gastric gastrointestinal (GI) ulcers while reducing pain and inflammation from osteoarthritis (OA), rheumatoid arthritis (RA) and ankylosing spondylitis.

Find authenticated court documents without watermarks at <u>docketalarm.com</u>.



Indications and Usage

VIMOVO is approved to relieve the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis and to decrease the risk of stomach (gastric) ulcers in patients at risk of developing stomach ulcers from treatment with NSAIDs. VIMOVO is not recommended as a starting treatment for relief of acute pain. Controlled studies do not extend beyond 6 months.

Important Safety Information

- Nonsteroidal anti-inflammatory drugs (NSAIDs), including naproxen, a component of VIMOVO, may increase the chance of a heart attack or stroke, which can be fatal. This chance increases with longer use and in people who have heart disease or risk factors for heart disease.
- VIMOVO should not be used before or after a type of heart surgery called coronary artery bypass graft (CABG).
- NSAID-containing medications like VIMOVO may increase the chance of stomach and intestinal problems, such as bleeding or an ulcer. These problems can happen without warning and can lead to death. Older patients may have a greater chance of developing these problems.

VIMOVO is not right for everyone, including patients who have had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAID medicine, patients who are allergic to any of the ingredients in VIMOVO, or women in late stages of pregnancy.

Serious allergic reactions, including skin reactions, can occur without warning and can be lifethreatening; discontinue use of VIMOVO at the first appearance of a skin rash, or if you develop sudden wheezing; swelling of the lips, tongue or throat; fainting; or problems swallowing. VIMOVO should be used at the lowest dose and for the shortest amount of time as directed by your health care provider.

Tell your health care provider right away if you develop signs of active bleeding from any source.

VIMOVO can lead to onset of new hypertension or worsening of existing high blood pressure, either of which may contribute to an increased risk of a heart attack or stroke.

Speak with your health care provider before starting VIMOVO if you

- · Have a history of ulcers or bleeding in the stomach or intestines
- · Have heart problems, high blood pressure, or are taking high blood pressure medications
- · Have kidney or liver problems

Tell your doctor about all of the medicines you take, prescription and non-prescription drugs, including clopidogrel, vitamins and herbal supplements. VIMOVO may affect how other medicines work and other medicines may affect how VIMOVO works.

VIMOVO may increase your risk of getting severe diarrhea. Call your doctor right away if you have watery stool, stomach pain, and fever that does not go away.

Talk to your health care provider about your risk for bone fractures and developing low levels of magnesium if you take VIMOVO for a long period of time.

Talk to your health care provider about your risk for developing low levels of magnesium if you take VIMOVO for a long period of time.

The most common side effects of VIMOVO include: inflammation of the lining of the stomach, indigestion, diarrhea, stomach ulcers, abdominal pain, and nausea.

For more information on VIMOVO, please see the Medication Guide and Full Prescribing Information.

Products:

overview Actimmune® Buphenyl®

DOCKE.

Find authenticated court documents without watermarks at docketalarm.com.

DUEXIS® PENNSAID® RAVICTI® RAYOS® VIMOVO®



375/20+500/20 mg delayed-release tablets

Click here to learn more about VIMOVO (naproxen and esomeprazole magnesium) Tablets including full prescribing information and boxed warning.

Related Links

- Osteoarthritis
- Rheumatoid Arthritis
- Ankylosing Spondylitis
- Patient Resources

Privacy Policy Legal Notice All Rights Reserved ©2015 Horizon Pharma plc HOME PRODUCTS PATIENTS NEWS INVESTORS BUSINESS DEVELOPMENT CONTACT SITEMAP SEARCH



Find authenticated court documents without watermarks at <u>docketalarm.com</u>.