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Vimovo

Generic Name: esomeprazole and naproxen (ee soe MEP ra zole and na PROX en)

Brand Names: Vimovo

What is Vimovo?

Vimovo contains a combination of esomeprazole and naproxen.

Naproxen is a nonsteroidal anti-inflammatory drug (NSAID). It works by reducing substances in the body that cause inflammation, pain, and fever. Esomeprazole is a proton pump inhibitor. It decreases the amount of acid produced in the stomach.

Vimovo is used to treat symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis.

The esomeprazole is included in Vimovo to help reduce the risk of stomach ulcers in people who may be at risk for them while receiving treatment with an NSAID.

Important information

The naproxen in Vimovo can increase your risk of fatal heart attack or stroke, especially if you use it long term or take high doses, or if you have heart disease. Do not use Vimovo just before or after heart bypass surgery (coronary artery bypass graft, or CABG).

Get emergency medical help if you have chest pain, weakness, shortness of breath, slurred speech, or problems with vision or balance while taking Vimovo.

Naproxen may also cause stomach or intestinal bleeding, which can be fatal. These conditions can occur without warning while you are using Vimovo, especially in older adults.

Call your doctor at once if you have symptoms of stomach bleeding such as black, bloody, or tarry stools, or coughing up blood or vomit that looks like coffee grounds.

Taking naproxen during the last 3 months of pregnancy may result in birth defects. Do not take Vimovo during pregnancy unless your doctor has told you to.

Before taking this medicine

The naproxen included in Vimovo may cause stomach or intestinal bleeding, which can be fatal. These conditions can occur without warning while you are using this medicine, especially in older adults.

You should not use Vimovo if you are allergic to esomeprazole (Nexium) or naproxen (Aleve, Naprosyn), or if:

you are allergic to lansoprazole, omeprazole, pantoprazole, rabeprazole, AcipHex, Nexium, Prevacid,

Prilosec, Protonix, and others; or

you have had an asthma attack or severe allergic reaction after taking aspirin or an NSAID.

To make sure Vimovo is safe for you, tell your doctor if you have:

- heart disease, high blood pressure, fluid retention, high cholesterol, diabetes, or if you smoke;
- a history of heart attack, stroke, or blood clot;
- a history of stomach ulcer, stomach bleeding, or intestinal disorder (Crohn's disease, ulcerative colitis);
- · asthma;
- liver or kidney disease; or
- low levels of magnesium in your blood.

Taking a proton pump inhibitor such as esomeprazole may increase your risk of bone fracture in the hip, wrist, or spine. This effect has occurred mostly in people who have taken the medication long term or at high doses, and in those who are age 50 and older. It is not clear whether esomeprazole is the actual cause of an increased risk of fracture.

Taking naproxen during the last 3 months of pregnancy may harm the unborn baby. Tell your doctor if you are pregnant or plan to become pregnant while taking Vimovo.

Naproxen can pass into breast milk and may harm a nursing baby. You should not breast-feed while taking Vimovo.

How should I take Vimovo?

Vimovo is usually taken 2 times each day, at least 30 minutes before a meal. Follow all directions on your prescription label. Do not take this medicine in larger amounts or for longer than recommended. Use the lowest dose that is effective in treating your condition.

Vimovo is usually taken 2 times each day, at least 30 minutes before a meal.

Do not crush, chew, or break a delayed-release tablet. Swallow it whole.

If you use Vimovo long-term, you may need frequent medical tests.

This medicine can cause unusual results with certain medical tests. Tell any doctor who treats you that you are using Vimovo.

If you use Vimovo for longer than 3 years, you could develop a vitamin B-12 deficiency. Talk to your doctor about how to manage this condition if you develop it.

Store Vimovo at room temperature away from moisture, heat, and light.

Read all patient information, medication guides, and instruction sheets provided to you. Ask your doctor or pharmacist if you have any questions.

Vimovo dosing information

Usual Adult Dose of Vimovo for Ankylosing Spondylitis:

Initial dose: Esomeprazole 20 mg-naproxen 500 mg orally twice a day

Duration of therapy: The lowest dose given for the shortest duration (consistent with individual patient treatment goals) should be used.

Comments:

-A lower daily dose of naproxen or another NSAID should be considered for patients that have not been previously treated with an NSAID. This may necessitate using a non-fixed combination product.

General Uses: For the relief of signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric ulcers.

Usual Adult Dose of Vimovo for Osteoarthritis:

Initial dose: Esomeprazole 20 mg-naproxen 500 mg orally twice a day

Duration of therapy: The lowest dose given for the shortest duration (consistent with individual patient treatment goals) should be used.

Comments:

-A lower daily dose of naproxen or another NSAID should be considered for patients that have not been previously treated with an NSAID. This may necessitate using a non-fixed combination product

Usual Adult Dose of Vimovo for Rheumatoid Arthritis:

Initial dose: Esomeprazole 20 mg-naproxen 500 mg orally twice a day

Duration of therapy: The lowest dose given for the shortest duration (consistent with individual patient treatment goals) should be used.

Comments:

-A lower daily dose of naproxen or another NSAID should be considered for patients that have not been previously treated with an NSAID. This may necessitate using a non-fixed combination product.

What happens if I miss a dose?

Take the missed dose as soon as you remember. Skip the missed dose if it is almost time for your next scheduled dose. Do not take extra medicine to make up the missed dose.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

Overdose symptoms may include vomiting, stomach pain, severe weakness, confusion, sweating, fast heart rate, dizziness, bloody or tarry stools, and weak or shallow breathing.

What should I avoid while taking Vimovo?

This medicine can cause diarrhea, which may be a sign of a new infection. If you have diarrhea that is watery or bloody, stop taking Vimovo and call your doctor. Do not use anti-diarrhea medicine unless your doctor tells you to.

Avoid drinking alcohol. It may increase your risk of stomach bleeding.

Avoid taking aspirin while you are taking Vimovo.

Ask a doctor or pharmacist before using any cold, allergy, or pain medication. Many medicines available over the counter contain aspirin or other medicines similar to naproxen. Taking certain products together can cause you to get too much of this type of medication. Check the label to see if a medicine contains aspirin, ibuprofen, ketoprofen, or naproxen.

Vimovo side effects

Get emergency medical help if you have **signs of an allergic reaction to Vimovo:** sneezing, runny or stuffy nose; wheezing or trouble breathing; hives; swelling of your face, lips, tongue, or throat.

Get emergency medical help if you have **signs of a heart attack or stroke**: chest pain spreading to your jaw or shoulder, sudden numbness or weakness on one side of the body, slurred speech, feeling short of breath.

Stop using Vimovo and call your doctor at once if you have:

- diarrhea that is watery or bloody;
- shortness of breath (even with mild exertion);
- swelling or rapid weight gain;
- the first sign of any skin rash, no matter how mild;
- signs of stomach bleeding bloody or tarry stools, coughing up blood or vomit that looks like coffee grounds;
- liver problems nausea, upper stomach pain, itching, tired feeling, flu-like symptoms, loss of appetite, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes);
- kidney problems little or no urinating, painful or difficult urination, swelling in your feet or ankles, feeling tired or short of breath;
- low red blood cells (anemia) pale skin, feeling light-headed or short of breath, rapid heart rate, trouble concentrating; or

 severe skin reaction - fever, sore throat, swelling in your face or tongue, burning in your eyes, skin pain, followed by a red or purple skin rash that spreads (especially in the face or upper body) and causes blistering and peeling.

Common Vimovo side effects may include:

- stomach pain, nausea, vomiting, heartburn;
- · constipation, diarrhea, gas; or
- dizziness.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

See also: Side effects (in more detail)

What other drugs will affect Vimovo?

Ask your doctor before using naproxen if you take an antidepressant such as citalopram, escitalopram, fluoxetine (Prozac), fluoxamine, paroxetine, sertraline (Zoloft), trazodone, or vilazodone. Taking any of these medicines with an NSAID may cause you to bruise or bleed easily.

Ask a doctor or pharmacist if it is safe for you to use naproxen if you are also using any of the following drugs:

- atazanavir:
- clopidogrel;
- · cholestyramine;
- erlotinib;
- ketoconazole;
- lithium;
- methotrexate;
- mycophenolate mofetil;
- probenecid;
- rifampin;
- St. John's wort;
- a blood thinner (warfarin, Coumadin, Jantoven);

- heart or blood pressure medication, including a diuretic or "water pill";
- medicine or supplements that contain iron;
- medicine to prevent organ transplant rejection (cyclosporine, tacrolimus); or
- steroid medicine (such as prednisone).

This list is not complete. Other drugs may interact with esomeprazole and naproxen that are contained in Vimovo, including prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible interactions are listed in this medication guide.

Where can I get more information?

Your pharmacist can provide more information about Vimovo.

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Vimovo only for the indication prescribed.

Disclaimer: Every effort has been made to ensure that the information provided is accurate, up-to-date, and complete, but no guarantee is made to that effect. Multum's drug information is an informational resource designed to assist licensed healthcare practitioners in caring for their patients and/or to serve consumers viewing this service as a supplement to, and not a substitute for, the expertise, skill, knowledge and judgment of healthcare practitioners. The information contained herein is not intended to cover all possible uses, directions, precautions, warnings, drug interactions, allergic reactions, or adverse effects. If you have guestions about the drugs you are taking, check with your doctor, nurse or pharmacist.

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