

Drug : **VIMOVO TAB**

What is this medicine?

ESOMEPRAZOLE; NAPROXEN (es oh ME pray zol; na PROX en) is two medicines together. Naproxen is a non-steroidal anti-inflammatory drug (NSAID). It is used to treat the pain of arthritis. Esomeprazole is a proton pump inhibitor (PPI). It is used to prevent stomach problems from the naproxen.

This medicine may be used for other purposes; ask your health care provider or pharmacist if you have questions.

What should I tell my health care provider before I take this medicine?

They need to know if you have any of these conditions: -asthma -cigarette smoker -drink more than 3 alcohol containing beverages a day -heart disease or circulation problems such as heart failure or leg edema (fluid retention) -high blood pressure - kidney disease -liver disease -low levels of magnesium in the blood -lupus -stomach bleeding or ulcers -an unusual or allergic reaction to naproxen, aspirin, other NSAIDs, esomeprazole or other proton pump inhibitors, other medicines, foods, dyes, or preservatives -pregnant or trying to get pregnant -breast-feeding

How should I use this medicine?

Take this medicine by mouth with a glass of water. Follow the directions on the prescription label. Do not crush, chew, split, or dissolve. Take this medicine on an empty stomach at least 30 minutes before a meal. Take your medicine at regular intervals. Do not take it more often than directed. Long term, continuous use may increase the risk of heart attack or stroke. A special MedGuide will be given to you by the pharmacist with each prescription and refill. Be sure to read this information carefully each time. Talk to your pediatrician regarding the use of this medicine in children. Special care may be needed.

Overdosage: If you think you have taken too much of this medicine contact a poison control center or emergency room at once.

NOTE: This medicine is only for you. Do not share this medicine with others.

What if I miss a dose?

If you miss a dose, take it as soon as you can. If it is almost time for your next dose, take only that dose. Do not take double or extra doses.

Where should I keep my medicine?

Keep out of the reach of children. Store at room temperature between 15 and 30 degrees C (59 and 86 degrees F). Protect from light and moisture. Throw away any unused medicine after the expiration date.

NOTE: This sheet is a summary. It may not cover all possible information. If you have questions about this medicine, talk to your doctor, pharmacist, or health care provider.

What should I watch for while using this medicine?

Tell your doctor or health care professional if your pain does not get better. Talk to your doctor before taking another medicine for pain. Do not treat yourself. You may need blood work done while you are taking this medicine. This medicine does not prevent heart attack or stroke. In fact, this medicine may increase the chance of a heart attack or stroke. The chance may increase with longer use of this medicine and in people who have heart disease. If you take aspirin to prevent heart attack or stroke, talk with your doctor or health care professional. Do not take other medicines that contain aspirin, ibuprofen, or naproxen with this medicine. Side effects such as stomach upset, nausea, or ulcers may be more likely to occur. Many medicines available without a prescription should not be taken with this medicine. This medicine can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Do not smoke cigarettes or drink alcohol. These increase irritation to your stomach and can make it more susceptible to damage from this medicine. Ulcers and bleeding can happen without warning symptoms and can cause death. You may get drowsy or dizzy. Do not drive, use machinery, or do anything that needs mental alertness until you know how this medicine affects you. Do not stand or sit up quickly, especially if you are an older patient. This reduces the risk of dizzy or fainting spells. This medicine can cause you to bleed more easily. Try to avoid damage to your

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teeth and gums when you brush or floss your teeth.

What side effects may I notice from receiving this medicine?

Side effects that you should report to your doctor or health care professional as soon as possible: -allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue -black or bloody stools, blood in the urine or vomit -blurred vision -bone, muscle or joint pain -chest pain -dark yellow or brown urine -difficulty breathing or wheezing -dizziness -fast, irregular heartbeat -feeling faint or lightheaded -fever or sore throat -muscle spasms -nausea or vomiting -palpitations -rash on cheeks or arms that gets worse in the sun -seizures -slurred speech or weakness on one side of the body -stomach pain -tremors -unexplained weight gain or swelling -unusual bleeding or bruising -unusually weak or tired -yellowing of eyes or skin -vomiting Side effects that usually do not require medical attention (report to your doctor or health care professional if they continue or are bothersome): -constipation -diarrhea -dry mouth -headache -heartburn -nausea

This list may not describe all possible side effects. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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