PATIENT & CAREGIVER EDUCATION

Naproxen and Esomeprazole

This information from UpToDate® Lexidrug™ explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Vimovo [DSC]

Brand Names: Canada

APO-Naproxen-Esomeprazole; MYLAN-Naproxen/Esomeprazole MR; Vimovo

Warning

- This drug may raise the risk of heart and blood vessel problems like heart attack and stroke. These effects can be deadly. The risk may be greater if you have heart disease or risks for heart disease. However, it can also be raised even if you do not have heart disease or risks for heart disease. The risk can happen within the first weeks of using this drug and may be greater with higher doses or long-term use. Do not use this drug right before or after bypass heart surgery.
- This drug may raise the chance of severe and sometimes deadly stomach or bowel problems like ulcers or bleeding. The risk is greater in older people, and in people who have had stomach or bowel ulcers or bleeding before. These problems may occur without warning signs.

What is this drug used for?

- It is used to treat some types of arthritis.
- It is used to treat ankylosing spondylitis.
- It is used to treat or prevent nonsteroidal anti-inflammatory drugs (NSAID)-associated gastric ulcers in

patients with a history of ulcers. Examples of NSAIDs include ibuprofen and naproxen.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have an allergy to aspirin or nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen or naproxen.
- If you have ever had asthma caused by a salicylate drug like aspirin or a drug like this one like NSAIDs.
- If you have any of these health problems: Active bleeding, bleeding in the brain or GI (gastrointestinal) tract, other bleeding problems, heart failure (weak heart), kidney or liver problems, or a stomach or bowel ulcer.
- If you have had a recent heart attack.
- If you are taking any other NSAID, a salicylate drug like aspirin, or pemetrexed.
- If you are taking any of these drugs: Atazanavir, clopidogrel, methotrexate, nelfinavir, rifampin, rilpivirine, St. John's wort, or warfarin.
- If you are having trouble getting pregnant or you are

having your fertility checked.

- If you are pregnant, plan to become pregnant, or get pregnant while taking this drug. This drug may cause harm to an unborn baby if taken at 20 weeks or later in pregnancy. If you are between 20 to 30 weeks of pregnancy, only take this drug if your doctor has told you to. Do not take this drug if you are more than 30 weeks pregnant.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Have your blood work checked if you are on this drug for a long time. Talk with your doctor.

- This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.
- High blood pressure has happened with drugs like this one. Have your blood pressure checked as you have been told by your doctor.
- Talk with your doctor before you drink alcohol.
- If you smoke, talk with your doctor.
- Do not take more than what your doctor told you to take. Taking more than you are told may raise your chance of severe side effects.
- Do not take this drug for longer than you were told by your doctor.
- If you have asthma, talk with your doctor. You may be more sensitive to this drug.
- You may bleed more easily. Be careful and avoid injury. Use a soft toothbrush and an electric razor.
- If you are taking aspirin to help prevent a heart attack, talk with your doctor.
- Take calcium and vitamin D as you were told by your doctor.
- This drug may raise the chance of hip, spine, and wrist fractures in people with weak bones (osteoporosis). The

chance may be higher if you take this drug in high doses or for longer than a year, or if you are older than 50 years old.

- Use care if you have risks for soft, brittle bones (osteoporosis). Some of these risks include drinking alcohol, smoking, taking steroids, taking drugs to treat seizures, or having family members with osteoporosis. Talk with your doctor about your risks of osteoporosis.
- Rarely, low magnesium levels have happened in people taking drugs like this one for at least 3 months. Most of the time, this happened after 1 year of treatment. Low magnesium levels may lead to other electrolyte problems. You may need to have your blood work checked as your doctor has told you.
- The chance of heart failure is raised with the use of drugs like this one. In people who already have heart failure, the chance of heart attack, having to go to the hospital for heart failure, and death is raised. Talk with the doctor.
- The chance of heart attack and heart-related death is raised in people taking drugs like this one after a recent heart attack. People taking drugs like this one after a first heart attack were also more likely to die in the year after the heart attack compared with people not taking drugs like this one. Talk with the doctor.

- The risk of stomach growths called fundic gland polyps may be higher in people who take this drug for more than 1 year. If you have questions, talk with the doctor.
- NSAIDs like this drug may affect egg release (ovulation). This may affect being able to get pregnant. This goes back to normal when this drug is stopped. Talk with the doctor.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of electrolyte problems like mood changes; confusion; muscle pain, cramps, or spasms; weakness; shakiness; change in balance; an abnormal heartbeat;

seizures; loss of appetite; or severe upset stomach or throwing up.

- Signs of kidney problems like unable to pass urine, change in how much urine is passed, blood in the urine, or a big weight gain.
- Signs of bleeding like throwing up or coughing up blood; vomit that looks like coffee grounds; blood in the urine; black, red, or tarry stools; bleeding from the gums; abnormal vaginal bleeding; bruises without a cause or that get bigger; or bleeding you cannot stop.
- Signs of high potassium levels like a heartbeat that does not feel normal; feeling confused; feeling weak, lightheaded, or dizzy; feeling like passing out; numbness or tingling; or shortness of breath.
- Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Chest pain or pressure or a fast heartbeat.
- Weakness on 1 side of the body, trouble speaking or thinking, change in balance, drooping on one side of the face, or blurred eyesight.
- Shortness of breath, a big weight gain, or swelling in the arms or legs.
- Feeling very tired or weak.

- Bone pain.
- Ringing in ears.
- Change in eyesight.
- Depression.
- Feeling confused.
- Flu-like signs.
- Liver problems have happened with drugs like this one. Sometimes, this has been deadly. Call your doctor right away if you have signs of liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- This drug may raise the risk of diarrhea caused by a certain bowel infection (C diff). Call your doctor right away if you have stomach cramps, fever, long-lasting diarrhea, very loose or watery stools, or bloody stools. Check with your doctor before treating diarrhea.
- Severe skin reactions may happen with this drug. These include Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and other serious reactions. Sometimes, body organs may also be affected. These reactions can be deadly. Get medical help right away if you have signs like red, swollen, blistered, or peeling skin; red or irritated eyes; sores in your mouth, throat,

nose, eyes, genitals, or any areas of skin; fever; chills; body aches; shortness of breath; or swollen glands.

- Lupus has happened with this drug, as well as lupus that has gotten worse in people who already have it. Tell your doctor if you have lupus. Call your doctor right away if you have signs of lupus like a rash on the cheeks or other body parts, change in skin color, sunburn easy, muscle or joint pain, chest pain or shortness of breath, or swelling in the arms or legs.
- Rarely, long-term treatment (for instance longer than 3 years) with drugs like this one has caused low vitamin B-12 levels. Call your doctor right away if you have signs of low vitamin B-12 levels like shortness of breath, dizziness, abnormal heartbeat, muscle weakness, pale skin, tiredness, mood changes, or numbness or tingling in the arms or legs.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Constipation, diarrhea, stomach pain, upset stomach, or throwing up.
- Heartburn.

- Gas.
- Dizziness.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1- 800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- Take this drug at least 30 minutes before meals.
- Swallow whole with some water or other drink.
- Do not chew, break, crush, or dissolve.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store tablets in the original container at room temperature. Keep the cap tightly closed.
- Store in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- This drug comes with an extra patient fact sheet called a Medication Guide. Read it with care. Read it again each time this drug is refilled. If you have any questions about

this drug, please talk with the doctor, pharmacist, or other health care provider.

- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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