

PATIENT & CAREGIVER EDUCATION

Naproxen and Esomeprazole

This information from Lexicomp® 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

Brand Names: Canada

MYLAN-Naproxen/Esomeprazole MR; Vimovo

Warning

- This drug may raise the chance of heart and blood vessel side effects like heart attack and stroke. If these happen, they can be deadly. The risk of these side effects may be greater if your child has heart disease or risks for heart disease. However, the risk may also be raised in people who do not have heart disease or risks for heart disease. The risk of these health problems can happen as soon as the first weeks of using this drug and may be greater with higher doses or with long-term use. Do not give this drug to your child 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 juvenile arthritis.
- 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.

- It may be given to your child for other reasons. Talk with the doctor.

What do I need to tell the doctor BEFORE my child takes this drug?

- If your child is allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell the doctor about the allergy and what signs your child had.
- If your child has an allergy to aspirin or nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen or naproxen.
- If your child has any of these health problems: Active bleeding or bleeding problems like bleeding in the brain or bleeding ulcers.
- If your child has a stomach or bowel ulcer.
- If your child has any of these health problems: Kidney disease or liver disease.
- If your child is having their fertility checked.
- If your child is taking any other NSAID, a salicylate like aspirin, or pemetrexed.

- If your child is taking any of these drugs: Atazanavir, clopidogrel, methotrexate, nelfinavir, rifampin, rilpivirine, St. John's wort, or warfarin.

If your child is pregnant:

- Talk to the doctor if your child is pregnant, plans to become pregnant, or gets pregnant while taking this drug. This drug may cause harm to an unborn baby if taken at 20 weeks or later in pregnancy. If your child is between 20 to 30 weeks of pregnancy, only give this drug if the doctor has told you to. Do not give this drug to your child if she is more than 30 weeks pregnant.

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

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

What are some things I need to know or do while my child takes this drug?

- Tell all of your child's health care providers that your child is taking this drug. This includes your child's doctors, nurses, pharmacists, and dentists.
- Have blood work checked if your child is on this drug for a long time. Talk with your child's doctor.
- This drug may affect certain lab tests. Tell all of your child's health care providers and lab workers that your child takes this drug.
- High blood pressure has happened with drugs like this one. Have your child's blood pressure checked as you have been told by the doctor.
- Alcohol may interact with this drug. Be sure your child does not drink alcohol.
- If your child smokes, talk with the doctor.
- Do not give your child more of this drug than what the doctor told you to give. Giving more of this drug than you are told may raise the chance of severe side effects.
- Do not have your child use longer than you have been told by your child's doctor.
- If your child has asthma, talk with the doctor. Your

child may be more sensitive to this drug.

- Your child may bleed more easily. Make sure your child is careful and avoids injury. Be sure your child has a soft toothbrush.
- If your child is taking aspirin to help prevent a heart attack, talk with the doctor.
- Give calcium and vitamin D as you were told by your child's doctor.
- 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.
- This drug may raise the chance of hip, spine, and wrist fractures in people with weak bones (osteoporosis). The chance may be higher if this drug is taken in high doses or for longer than a year.

- Use care if your child has 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 child's doctor about your child's 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. Your child may need to have blood work checked as the doctor has told you.
- Rarely, long-term treatment (for instance longer than 3 years) with drugs like this one has caused low vitamin B-12 levels. Call your child's doctor right away if your child has 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.
- 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.

If your child is or may be sexually active:

- 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.

If your child is breast-feeding a baby:

- Tell the doctor if your child is breast-feeding a baby. You will need to talk about any risks to the baby.

What are some side effects that I need to call my child's 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 child's doctor or get medical help right away if your child has 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 the doctor right away if your child has 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 chance of a severe form of diarrhea called C diff-associated diarrhea (CDAD). Call your child's doctor right away if your child has stomach pain or cramps, very loose or watery stools, or bloody stools. Do not try to treat diarrhea without first checking with your child's doctor.
- 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 your child has signs like red, swollen, blistered, or peeling skin; red or irritated eyes; sores in the 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 child's doctor if your child has lupus. Call your child's doctor right away if your child has 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.

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 child's doctor or get medical help if any of these side effects or any other side effects bother your child 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 child's doctor. Call your child's doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best given?

Give this drug as ordered by your child's doctor. Read all information given to you. Follow all instructions closely.

- Give this drug at least 30 minutes before meals.
- Have your child swallow whole with some water or other drink.
- Do not let your child chew, break, or crush.
- Keep giving this drug to your child as you have been told by your child's doctor or other health care provider, even if your child feels well.

What do I do if my child misses a dose?

- Give a missed dose as soon as you think about it.
- If it is close to the time for your child's next dose, skip the missed dose and go back to your child's normal time.
- Do not give 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 child's symptoms or health problems do not get better or if they become worse, call your child's doctor.
- Do not share your child's drug with others and do not

give anyone else's drug to your child.

- 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.
- 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.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits

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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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