Medication Guide for VIMOVO:
Combination of Naproxen a Nonsteroidal Anti-inflammatory Drug (NSAID)
and Esomeprazole a Proton Pump Inhibitor (PPI)

What is the most important information I should know about medicines called Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?

NSAIDs can cause serious side effects including:

- **Increased risk of a heart attack or stroke that can lead to death.** This risk may happen early in treatment and may increase:
  - with increasing doses of NSAIDs
  - with longer use of NSAIDs

  Do not take NSAIDs right before or after a heart surgery called a "coronary artery bypass graft (CABG)."

  Avoid taking NSAIDs after a recent heart attack, unless your health care provider tells you to. You may have an increased risk of another heart attack if you take NSAIDs after a recent heart attack.
- **Increased risk of bleeding, ulcers, and tears (perforation) of the esophagus (tube leading from the mouth to the stomach), stomach and intestines:**
  - anytime during use
  - without warning symptoms
  - that may cause death

  The risk of getting an ulcer or bleeding increases with:
  - past history of stomach ulcers, or stomach or intestinal bleeding with use of NSAIDs
  - taking medicines called "corticosteroids", "anticoagulants", "SSRIs", or "SNRIs"
  - increasing doses of NSAIDs
  - longer use of NSAIDs
  - smoking
  - drinking alcohol
  - older age
  - poor health
  - advanced liver disease
  - bleeding problems

NSAIDs should only be used:

- exactly as prescribed
- at the lowest dose possible for your treatment
- for the shortest time needed

What are NSAIDs?

NSAIDs are used to treat pain and redness, swelling, and heat (inflammation) from medical conditions such as different types of arthritis, menstrual cramps, and other types of short-term pain.

What is VIMOVO?

VIMOVO contains 2 medicines: naproxen, a non-steroidal anti-inflammatory drug (NSAID) and esomeprazole magnesium, a proton pump inhibitor (PPI). VIMOVO is a prescription medicine used to:

- relieve signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis
- decrease the risk of developing stomach (gastric) ulcers in people who are at risk of developing gastric ulcers with NSAIDs

It is not known if VIMOVO is safe or effective in children under the age of 18.

You should not take a naproxen tablet and an esomeprazole magnesium tablet together instead of taking VIMOVO, because they will not work the same way.

Who should not take NSAIDs?

Do not take NSAIDS or VIMOVO:

- if you have had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAIDs
- right before or after heart bypass surgery
- if you are allergic to any of the ingredients in VIMOVO
- if you are allergic to any other proton pump inhibitor (PPI) medicine

Before taking NSAIDs or VIMOVO, tell your health care provider about all of your medical conditions, including if you:

- have liver or kidney problems
- have high blood pressure
- have asthma
- have low magnesium levels
- have ulcerative colitis or Crohn's disease (inflammatory bowel disease or IBD)
- are pregnant or plan to become pregnant. Talk to your health care provider if you are considering taking NSAIDs during pregnancy. **You should not take NSAIDs after 29 weeks of pregnancy.**
- are breastfeeding or plan to breast feed.

Tell your health care provider about all of the medicines you take, including prescription or over-the-counter medicines, vitamins or herbal supplements. NSAIDs and some other medicines can interact with each other and cause serious side effects. Especially tell your health care provider if you take:

- steroid hormones (corticosteroids)
- St. John's Wort
- Rifampin (Rifater, Rifamate, Rimactane, Rifadin
- medicine for high blood pressure or heart problems
- water pill (diuretic)
- lithium carbonate
- aspirin
- cyclosporine (Gengraf, Neoral, Sandimmune) or tacrolimus (Prograf)
- antidepressant medicine
- blood thinner medicine
- methotrexate
- atazanavir (Reyataz)
- ketoconazole (Nizoral)
- products that contain iron
- digoxin (Lanoxin)
- erlotinib (Tarceva)
- clopidogrel (Plavix)
- mycophenolate mofetil (Cellcept)
- pemetrexed

Do not start taking new medicine without talking to your health care provider first.

What are the possible side effects of NSAIDs and VIMOVO?
NSAIDs can cause serious side effects, including:
See "What is the most important information I should know about medicines called Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?"

- heart attack
- stroke
- new or worse high blood pressure
- heart failure
- liver problems including liver failure
- kidney problems including kidney failure
- bleeding and ulcers in the stomach and intestine
- low red blood cells (anemia)
- life-threatening skin reactions
- life-threatening allergic reactions
- liver problems including liver failure
- asthma attacks in people who have asthma
- **Other side effects of NSAIDs include:** stomach pain, constipation, diarrhea, gas, heartburn, nausea, vomiting and dizziness.
- **Other side effects of VIMOVO include:**
  - Vitamin B-12 deficiency. VIMOVO reduces the amount of acid in your stomach. Stomach acid is needed to absorb vitamin B-12 properly. Talk with your doctor about the possibility of vitamin B-12 deficiency if you have been on VIMOVO for a long time (more than 3 years).
  - Low magnesium levels in your body. Low magnesium can happen in some people who take a PPI medicine for at least 3 months. If low magnesium levels happen, it is usually after a year of treatment. You may or may not have symptoms of low magnesium. Symptoms of low magnesium include:
    - seizures
    - dizziness
    - abnormal or fast heart beat
    - jitteriness
    - jerking movements or shaking
    - muscle weakness
    - spasms of the hands and feet
    - cramps or muscle aches
    - spasm of the voice box

(tremors)

The most common side effects of VIMOVO include:

- inflammation of the lining of the stomach, with or without loss of the protective layer of the stomach (erosive gastritis)
- indigestion
- diarrhea
- stomach ulcers
- upper stomach-area (abdominal) pain
- nausea

Tell your health care provider if you have any side effects that bothers you or that does not go away.

Get emergency help right away if you get any of the following symptoms:

- shortness of breath or trouble breathing
- chest pain
- weakness in one part or side of your body
- slurred speech
- swelling of the face or throat

Stop taking your NSAID and call your health care provider right away if you get any of the following symptoms:

- nausea
- more tired or weaker than usual
- diarrhea
- itching
- your skin or eyes look yellow
- indigestion or stomach pain
- flu-like symptoms
- vomit blood
- there is blood in your bowel movement or it is black and sticky like tar
- unusual weight gain
- skin rash or blisters with fever
- swelling of the arms, legs, hands, and feet

If you take too much of your NSAID, call your health care provider or get medical help right away.

These are not all the possible side effects of NSAIDs. Your health care provider may do certain tests from time to time to check you for side effects of VIMOVO. For more information, ask your health care provider or pharmacist about NSAIDs or VIMOVO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Other information about NSAIDs

- Aspirin is an NSAID but it does not increase the chance of a heart attack. Aspirin can cause bleeding in the brain, stomach, and intestines. Aspirin can also cause ulcers in the stomach and intestines.
- Some NSAIDs are sold in lower doses without a prescription (over-the-counter). Talk to your pharmacist or health care provider before using over-the-counter NSAIDs for more than 10 days.

What other important information should I know about VIMOVO?

VIMOVO may help your acid-related symptoms, but you could still have serious stomach problems. Talk with your health care provider.

VIMOVO can cause other serious side effects, including:

- A type of kidney problem (acute interstitial nephritis). Some people who take PPI medicines, including VIMOVO may develop a kidney problem called acute interstitial nephritis that can happen at any time during treatment with VIMOVO. Call your health care provider if you have a decrease in the amount that you urinate or if you have blood in your urine.
- Diarrhea. VIMOVO may increase your risk of getting severe diarrhea. This diarrhea may be caused by an infection *(Clostridium difficile)* in your intestines. Call your health care provider right away if you have watery stool, stomach pain, and fever that does not go away.
- Bone fractures. People who take multiple daily doses of PPI medicines for a long period of time (a year or longer) may have an increased risk of fractures of the hip, wrist, or spine. You should take VIMOVO exactly as prescribed, at the lowest dose possible for your treatment and for the shortest time needed. Talk to your health care provider about your risk of bone fracture if you take VIMOVO.
- Certain types of lupus erythematosus. Lupus erythematosus is an autoimmune disorder (the body's immune cells attack other cells or organs in the body). Some people who take PPI medicines, including VIMOVO, may develop certain types of lupus erythematosus or have worsening of the lupus they already have. Call your doctor right away if you have new or worsening joint pain or a rash on your cheeks or arms that gets worse in the sun.

How should I take VIMOVO?

- Take VIMOVO exactly as your health care provider tells you to take it.

- Your health care provider may tell you to take Vitamin D and Calcium supplements during treatment with VIMOVO.
- Your health care provider will tell you how many VIMOVO to take and when to take them.
- Do not change your dose or stop VIMOVO without first talking to your health care provider.
- Take VIMOVO at least 30 minutes before a meal.
- Swallow VIMOVO tablets whole with liquid. Do not split, chew, crush or dissolve the VIMOVO tablet. Tell your health care provider if you cannot swallow the tablet whole. You may need a different medicine.
- You may use antacids while taking VIMOVO.
- If you forget to take a dose of VIMOVO, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose. Take the next dose on time. Do not take 2 doses at one time to make up for a missed dose.

How should I store VIMIVO?

- Store VIMOVO at room temperature between 68ºF to 77ºF (20ºC to 25ºC)
- Keep VIMOVO in the original container and keep the bottle tightly closed
- Keep VIMOVO dry

Keep VIMOVO and all medicines out of the reach of children.

What are the ingredients in VIMOVO?

Active ingredients: naproxen and esomeprazole magnesium

Inactive ingredients: carnauba wax, colloidal silicon dioxide, croscarmellose sodium, iron oxide yellow, glyceryl monostearate, hypromellose, iron oxide black, magnesium stearate, methacrylic acid copolymer dispersion, methylparaben, polysorbate 80, polydextrose, polyethylene glycol, povidone, propylene glycol, propylparaben, titanium dioxide, and triethyl citrate

General information about the safe and effective use of NSAIDs, specifically VIMOVO

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use VIMOVO for a condition for which it was not prescribed. Do not give NSAIDs to other people, even if they have the same symptoms that you have. It may harm them.

If you would like more information about NSAIDs, talk with your health care provider. You can ask your pharmacist or health care provider for information about NSAIDs that is written for health care professionals.

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For more information, go to www.VIMOVO.com or call 1-866-479-6742.

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