

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION**

**Pr VIMOVO®
naproxen/esomeprazole**

Read this carefully before you start taking **VIMOVO** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **VIMOVO**.

Serious Warnings and Precautions

If you have, or previously had, any of the following medical conditions, see your health care provider to discuss treatment options other than VIMOVO:

- Heart Attack or Angina
- Stroke or Mini-stroke
- Loss of Vision
- Current Pregnancy (less than 28 weeks)
- Congestive Heart Failure

What is VIMOVO used for?

VIMOVO treats the signs and symptoms of:

- Osteoarthritis.
- Rheumatoid arthritis.
- Ankylosing spondylitis.

VIMOVO helps to reduce pain, swelling, redness and heat (inflammation).

It is used for people who:

- need to take an anti-inflammatory medicine.
- and are at risk of getting a stomach ulcer (sore) or an ulcer in the small intestine (gut).

How does VIMOVO work?

VIMOVO contains 2 drugs which work together.

- Naproxen belongs to a group of medicines called “nonsteroidal anti-inflammatory drugs” (NSAIDs). It reduces the substances in your body which cause pain and swelling.
- Esomeprazole belongs to a group of medicines called “proton pump inhibitors” (PPIs). It reduces the amount of acid produced by your stomach.
- Naproxen can damage the stomach but esomeprazole helps reduce this damage.
- VIMOVO only treats the symptoms of pain and inflammation of the illness as long as you use it. VIMOVO does not cure the illness.

What are the ingredients in VIMOVO?

Medicinal ingredients: naproxen (enteric-coated, delayed release core) and esomeprazole (as esomeprazole magnesium trihydrate, immediate release coating)

Non-medicinal ingredients: carnauba wax, croscarmellose sodium, glycerol monostearate, hypromellose, iron oxide black, iron oxide yellow, macrogols, magnesium stearate, methacrylic acid-ethyl acrylate copolymer (1:1) dispersion, methyl parahydroxybenzoate, polydextrose, polysorbate, povidone, propylene glycol, propyl parahydroxybenzoate, silica colloidal anhydrous, titanium dioxide and triethyl citrate

VIMOVO comes in the following dosage forms:

VIMOVO is available as modified release tablets of:

- 375 mg naproxen/20 mg esomeprazole.
- 500 mg naproxen/20 mg esomeprazole.

VIMOVO is supplied in bottles of 60 tablets.

Do not use VIMOVO if:

- you have heart bypass surgery (planning to have or recently had).
- you have severe, uncontrolled heart failure.
- you have bleeding in the brain or other bleeding disorders.
- you are pregnant (after 28 weeks of pregnancy).
- you are currently breastfeeding (or planning to breastfeed).
- you are allergic to ASA (Acetylsalicylic Acid), other NSAIDs, naproxen, esomeprazole, substituted benzimidazoles or other ingredients of VIMOVO (see “What are the Ingredients in VIMOVO”).
- you have an active ulcer.
- you have active bleeding from the stomach or gut.
- you have inflammatory bowel disease (Crohn’s Disease or Ulcerative Colitis).
- you have liver disease (active or severe).
- you have kidney disease (severe or worsening).
- you have high potassium in the blood.
- you are taking rilpivirine

Patients who took a drug in the same class as VIMOVO after a type of heart surgery (coronary artery bypass grafting (CABG)) were more likely to have heart attacks, strokes, blood clots in the leg(s) or lung(s), and infections or other complications than those who did NOT take that drug. VIMOVO must not be used after recent CABG.

VIMOVO should NOT be used in patients under 18 years of age.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VIMOVO. Talk about any health conditions or problems you may have, including if you:

- have high blood pressure.
- have high cholesterol.
- have diabetes mellitus or are on a low sugar diet.
- have atherosclerosis.
- have poor blood flow to your extremities, for example, your hands and feet.
- are a smoker or ex-smoker.
- have kidney disease or urine problems.
- had a previous ulcer (sore) or bleeding from the stomach or gut (small or large intestine).
- previously had bleeding in the brain.
- have bleeding problems.
- have a family history of allergy to NSAIDs, such as acetylsalicylic acid (ASA), celecoxib, diclofenac, diflunisal, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, mefenamic acid, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, sulindac, tenoxicam, tiaprofenic acid or tolmetin (NOT a complete list).
- have a family history of asthma, nasal polyps, long-term swelling of the sinus (chronic sinusitis) or hives.
- are planning to get pregnant.
- are due to have a specific blood test (Chromogranin A).

Other warnings you should know about:

This medicine should be used at the lowest dose and for the shortest time suitable for your condition. Talk to your doctor if you have any concerns about your treatment.

Medicines such as VIMOVO may be associated with an increased risk of heart attack (myocardial infarction) or stroke. This risk may happen early in treatment.

If you take antibiotics while taking VIMOVO: If you experience symptoms such as severe (bloody or repeated watery) diarrhea, with or without fever, abdominal pain or tenderness, you may have bowel inflammation caused by a bacterial infection (*Clostridium difficile*). If this happens, stop taking the drug combination and call your healthcare professional immediately.

Tell any doctor, dentist, pharmacist or health care professional that you see, that you are taking this medicine. This is especially important if you are planning to have heart surgery.

Do NOT drink alcohol while taking this medication. You would be more likely to get stomach problems.

Fertility may be decreased. The use of VIMOVO is not recommended in women trying to get pregnant.

Tell your doctor or pharmacist about symptoms that may be a sign of a more serious problem in your stomach or intestine such as:

- trouble swallowing.
- unplanned weight loss.
- vomiting blood or food.
- black (blood-stained) stools.

Long-term use of PPIs, like esomeprazole, may interfere with the absorption of Vitamin B12 from the diet. This may cause a shortage of Vitamin B12 in your body. Talk to your doctor about this risk.

Long-term use of PPIs may lead to low blood magnesium in some people. When blood magnesium is lower than normal, it may also lead to low blood calcium and low blood potassium.

Using PPIs for a long time (every day for a year or longer) may increase risks of broken bones of the hip, wrist or spine. Talk to your doctor about this risk.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with VIMOVO (NOT a complete list):

- Acetylsalicylic Acid (ASA) or other NSAIDs (e.g. celecoxib, diclofenac, ibuprofen, indomethacin, ketorolac, meloxicam, naproxen).
- Antacids.
- Antidepressants (Selective Serotonin Reuptake Inhibitors (SSRIs), e.g. citalopram, fluoxetine, paroxetine, sertraline).
- Blood pressure medications (ACE (angiotensin converting enzyme) inhibitors, e.g. enalapril, lisinopril, perindopril, ramipril) or ARBs (angiotensin II receptor blockers, e.g. candesartan, irbesartan, losartan, valsartan).
- Blood thinners (e.g. warfarin, ASA, clopidogrel).
- Corticosteroids (including glucocorticoids e.g. prednisone).
- Cyclosporin.
- Digoxin.
- Diuretics (e.g. furosemide, hydrochlorothiazide).
- Erlotinib (or any other anticancer drug from the same class).
- Lithium.
- Methotrexate.
- Oral contraceptives.
- Oral hypoglycemics (diabetes medications).
- Tacrolimus.

Your health care provider may prescribe low-dose ASA (acetylsalicylic acid) as a blood thinner to reduce your risk of having a heart attack or stroke while you are taking VIMOVO.

Take only the amount of ASA prescribed by your health care provider. The beneficial effects of VIMOVO apply whether you take ASA or not.

Studies with esomeprazole have shown that blood levels of some drugs may be influenced if taken at the same time as drugs used to prevent fungal infections (itraconazole, ketoconazole, voriconazole), anxiety (diazepam), epilepsy (phenytoin), drugs to speed up stomach emptying (cisapride*), poor circulation in the legs (cilostazol*), heart problems (digoxin), treatment for tuberculosis (rifampin), St John's Wort (*Hypericum perforatum*) or a certain type of anticancer drug (erlotinib or any other anticancer drug from the same class). However, none of these interactions have been shown to change the effectiveness of esomeprazole or the other drug.

*not available in Canada

Drugs used to prevent blood clotting (warfarin or coumarin derivatives, clopidogrel) have been reported to interact with esomeprazole. Speak to your doctor or pharmacist if you are taking any of these drugs as monitoring may be required when you start or stop taking VIMOVO. Use of VIMOVO with clopidogrel should be avoided.

Esomeprazole may decrease the effectiveness of some drugs used for HIV treatment. Atazanavir, nelfinavir, and saquinavir should not be used with VIMOVO.

How to take VIMOVO:

Carefully follow your health care provider's directions on how to take VIMOVO.

Do NOT take more of it.

Do NOT take it more often.

Do NOT take it for a longer period of time than your health care provider recommends.

If possible, you should take the lowest dose of this medication for the shortest time period. Taking too much VIMOVO may increase your chances of unwanted and sometimes dangerous side effects, especially if you are elderly, have other diseases or take other medications.

This medication has been prescribed specifically for you. Do NOT give it to anyone else. It may harm them, even if their symptoms seem to be similar to yours.

- VIMOVO should be taken at least 30 minutes before a meal.
- The tablets should be swallowed whole with water.
- Do not chew, split or crush them.

Usual dose:

Medical Condition	Recommended (and Maximum) Dose per day
Osteoarthritis or Rheumatoid Arthritis or Ankylosing Spondylitis	375/20 mg twice a day or 500/20 mg twice a day

Overdose:

If you think you have taken too much VIMOVO, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of VIMOVO, take the dose as soon as possible. Then go back to your regular schedule. If you remember your missed dose close to the time of your next dose, do not take the missed dose. Do not double dose. Just take the next dose on time.

What are possible side effects from using VIMOVO?

VIMOVO may cause some side effects, especially if you use it for a long time or take large doses. When these side effects occur, you may need to see a health care provider. These are not all the possible side effects you may feel when taking VIMOVO. If you experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

VIMOVO may cause you to become drowsy or tired. Be careful about driving or doing activities that require you to be alert. If you become drowsy, dizzy or light-headed after taking VIMOVO, do NOT drive or use machines.

VIMOVO may cause you to become more sensitive to sunlight. Sunlight or sunlamps may cause sunburn, skin blisters, skin rash, redness, itching or discolouration, or vision changes. If you have a reaction from the sun, check with your health care provider.

Tell your doctor right away if you have any of these symptoms:

- New or worsening joint pain.
- Rash on your cheeks or arms that gets worse in the sun.

Stomach upset is a common problem with NSAIDs, such as naproxen. The esomeprazole in VIMOVO helps to reduce this side effect. However, side effects, usually mild, have been

reported with esomeprazole use. These side effects may not be caused by esomeprazole in your case, but only a doctor can assess this. If these become bothersome (or last more than 1-2 days), discuss with your doctor.

Common:

- Nausea.
- Stomach upset.
- Diarrhea.
- Headache.

Uncommon:

- Dry mouth.
- Dizziness.
- Insomnia.
- Feeling of burning/prickliness/numbing.
- Swelling of extremities.
- Feeling sleepy.
- Feeling like you or your surroundings are moving (vertigo).

Rare:

- Taste disorders.
- Nervousness.
- Hair loss.
- Increased sweating.

Stopping VIMOVO after taking it for a long time may cause your stomach to increase acid production. This may cause stomach symptoms. Carefully follow your doctor’s instructions when stopping VIMOVO.

Serious side effects of NSAIDs and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Bloody or black tarry stools			X
Shortness of breath, wheezing, any trouble breathing or chest tightness			X
Skin rash, hives, swelling or itching			X
Blurred vision, or any visual disturbance			X

Any change in the amount or colour of your urine (red or brown)			X
Chills, fever, muscle aches or pains, or other flu-like symptoms, especially if they occur before or together with a skin rash; these symptoms may be the first signs of a serious allergic reaction to the medication			X
Any pain or difficulty experienced while urinating		X	
Swelling of the feet, lower legs; weight gain		X	
Vomiting or persistent indigestion, nausea, stomach pain or diarrhea		X	
Yellow discolouration of the skin or eyes, with or without itchy skin			X
Malaise, fatigue, loss of appetite		X	
Headaches, stiff neck		X	
Mental confusion, depression		X	
Dizziness, lightheadedness		X	
Hearing problems		X	

Serious side effects of esomeprazole and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE (≥ 1 in 10 000 patients but < 1 in 1000 patients)			
inflammation in the mouth		X	
severe allergic reaction (such as swelling or anaphylactic reaction/shock)			X
muscle pain		X	
blood disorders (reduced number of cells in the blood, low blood sodium) [†]		X	
gastrointestinal fungal infection		X	

photosensitivity		X	
VERY RARE (< 1 in 10 000 patients)			
severe skin disorders (blisters, ulcers and/or lesions)			X
aggression		X	
hallucinations		X	
severely impaired liver function		X	
decreased consciousness		X	
inflammation of the kidney		X	
muscular weakness		X	
development of breasts in males		X	
low blood magnesium ⁰ (which may result in low blood calcium and/or low blood potassium)		X	
Inflammation in the gut (leading to diarrhea)		X	

⁰These would only be seen if a blood test was taken

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect;
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

VIMOVO tablets should be kept in their original container. Keep bottles tightly closed to protect from moisture.

Store at room temperature (15-30°C). Do not keep VIMOVO in the bathroom medicine cabinet or other warm, moist places.

Do NOT keep expired medicine or medicine no longer needed. Return to your pharmacist.

Keep out of sight and reach of children.

If you want more information about VIMOVO:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; the AstraZeneca Canada Inc. website: www.astrazeneca.ca, or by calling AstraZeneca Canada Inc. at:
Customer Inquiries – 1 (800) 668-6000
Renseignements – 1 (800) 461-3787.

NOTE: This PATIENT MEDICATION INFORMATION leaflet provides you with the most current information at the time of printing.

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