

PART III: CONSUMER INFORMATION

 **VIMOVO**[®]
(naproxen/esomeprazole)

Read this information each time you refill your prescription in case new information has been added.

This leaflet is a summary designed specifically for you to read. It will NOT tell you everything about VIMOVO. See your health care provider and pharmacist regularly and ask them questions about your health and any medications you take.

ABOUT THIS MEDICATION

WHAT THE MEDICATION IS USED FOR:

Your health care provider has prescribed VIMOVO for you for one or more of the following medical conditions:

- For the treatment of the signs and symptoms of osteoarthritis, rheumatoid arthritis or ankylosing spondylitis in patients at risk of developing stomach ulcers caused by medications for pain or inflammation.

WHAT IT DOES:

VIMOVO contains two different drugs, naproxen and esomeprazole. Each of these works in a different way.

- Naproxen as a nonsteroidal anti-inflammatory drug (NSAID) can reduce the substances produced by your body which cause pain and swelling.
- Esomeprazole belongs to a group of medicines called “proton pump inhibitors”. It works by reducing the amount of acid your stomach produces.

Naproxen can cause damage to your stomach while esomeprazole can help to reduce this damage. Your health care provider has prescribed VIMOVO for you to reduce your inflammation or pain, and reduce the risk of damage by naproxen to your stomach.

Naproxen, the NSAID component of VIMOVO, does NOT cure your illness or prevent it from getting worse. VIMOVO DOES help to reduce the pain and swelling caused by your condition, while protecting your stomach. VIMOVO can only relieve pain and reduce swelling as long as you continue to take it.

WHEN IT SHOULD NOT BE USED:

DO NOT TAKE VIMOVO if you have any of the following medical conditions:

- Heart bypass surgery (planning to have or recently had)
- Severe, uncontrolled heart failure
- Bleeding in the brain or other bleeding disorders
- Current pregnancy (after 28 weeks of pregnancy)
- Currently breastfeeding (or planning to breastfeed)
- Allergy to ASA (Acetylsalicylic Acid), other NSAIDs (Nonsteroidal Anti-Inflammatory Drugs), naproxen, esomeprazole or other ingredients of VIMOVO (see What the Nonmedicinal Ingredients Are)
- Ulcer (active)
- Bleeding from the stomach or gut (active)
- Inflammatory bowel disease (Crohn’s Disease or Ulcerative Colitis)
- Liver disease (active or severe)
- Kidney disease (severe or worsening)
- High potassium in the blood

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 should NOT be used in patients under 18 years of age since safety and effectiveness have NOT been established.

WHAT THE MEDICINAL INGREDIENTS ARE:

Naproxen (enteric-coated, delayed release core) and esomeprazole (as esomeprazole magnesium trihydrate, immediate release coating)

WHAT THE NONMEDICINAL INGREDIENTS ARE:

VIMOVO contains the following nonmedicinal ingredients (listed in alphabetical order): 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.

WHAT DOSAGE FORMS IT COMES IN:

VIMOVO is available as modified release tablets of either 375 mg naproxen/20 mg esomeprazole or 500 mg naproxen/20 mg esomeprazole.

VIMOVO is supplied in bottles of 60 tablets.

WARNINGS AND PRECAUTIONS

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**

Before taking this medication, tell your health care provider if you have any of the following:

- High blood pressure
- High cholesterol
- Diabetes mellitus or on a low sugar diet
- Atherosclerosis
- Poor circulation to your extremities
- Smoker or ex-smoker
- Kidney disease or urine problems
- Previous ulcer or bleeding from the stomach or gut
- Previous bleeding in the brain
- Bleeding problems
- 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, rofecoxib, sulindac, tenoxicam, tiaprofenic acid, tolmetin, or valdecoxib (NOT a complete list)
- Family history of asthma, nasal polyps, long-term swelling of the sinus (chronic sinusitis) or hives

Also, before taking this medication, tell your health care provider if you are planning to get pregnant or if you are allergic to naproxen, esomeprazole or any other ingredients or components of the container.

While taking this medication:

- tell any other doctor, dentist, pharmacist or other health care professional that you see, that you are taking this medication, especially if you are planning to have heart surgery;
- do NOT drink alcoholic beverages while taking this medication because you would be more likely to develop stomach problems;
- fertility may be decreased. The use of VIMOVO is not recommended in women trying to get pregnant. In women who have difficulty conceiving, stopping VIMOVO should be considered;
- 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, or black (blood-stained) stools.

INTERACTIONS WITH THIS MEDICATION

Talk to your health care provider and pharmacist if you are taking any other medication (prescription or non-prescription) such as any of the following (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.

Drugs used for blood clotting (warfarin or coumarin derivatives) 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.

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

*not available in Canada

PROPER USE OF THIS MEDICATION

USUAL DOSE (18 years and older):

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

Take VIMOVO only as directed by your health care provider. **Do NOT take more of it, do NOT take it more often and do NOT take it for a longer period of time than your health care provider recommended. 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 is NOT recommended for use in patients under 18 years of age since safety and effectiveness have NOT been established.

Administration

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.

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.

OVERDOSE:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

VIMOVO may cause some side effects, especially when used for a long time or in large doses. When these side effects occur, you may require medical attention. Report all symptoms or side effects to your health care provider.

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

VIMOVO may cause you to become more sensitive to sunlight. Any exposure to 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.

Check with your health care provider IMMEDIATELY if you develop 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 this medication.

SERIOUS SIDE EFFECTS OF NSAIDs, AND WHAT TO DO ABOUT THEM

Symptom	STOP taking VIMOVO and get emergency medical attention IMMEDIATELY	STOP taking VIMOVO and talk to your physician or pharmacist
Bloody or black tarry stools	√	
Shortness of breath, wheezing, any trouble breathing or chest tightness	√	
Skin rash, hives, swelling or itching	√	
Blurred vision, or any visual disturbance	√	
Any change in the amount or colour of your urine (red or brown)	√	
Any pain or difficulty experienced while urinating		√
Swelling of the feet, lower legs; weight gain		√
Vomiting or persistent indigestion, nausea, stomach pain or diarrhea		√
Yellow discolouration of the skin or eyes, with or without itchy skin		√
Malaise, fatigue, loss of appetite		√

SERIOUS SIDE EFFECTS OF NSAIDs, AND WHAT TO DO ABOUT THEM

Symptom	STOP taking VIMOVO and get emergency medical attention IMMEDIATELY	STOP taking VIMOVO and talk to your physician or pharmacist
Headaches, stiff neck		√
Mental confusion, depression		√
Dizziness, lightheadedness		√
Hearing problems		√

Stomach upset is one of the common problems with NSAIDs, such as naproxen. The esomeprazole in VIMOVO helps to reduce this side effect from happening. 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 exceed 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, vertigo

Rare: taste disorders, nervousness, hair loss, increased sweating

Treatment in combination with antibiotics:
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 call your doctor or pharmacist immediately and stop taking the drug combination.

SERIOUS SIDE EFFECTS OF ESOMEPRAZOLE, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	STOP taking VIMOVO and call your physician or pharmacist	Talk with your physician or pharmacist in all cases
Rare (frequency of greater than or equal to 1 in 10 000 patients but less than 1 in 1000 patients)		
inflammation in the mouth		√
severe allergic reaction (such as swelling or anaphylactic reaction/shock)	√	√
muscle pain		√

SERIOUS SIDE EFFECTS OF ESOMEPRAZOLE, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	STOP taking VIMOVO and call your physician or pharmacist	Talk with your physician or pharmacist in all cases
blood disorders (reduced number of cells in the blood, low blood sodium) ⁰		√
gastrointestinal fungal infection		√
photosensitivity		√
Very Rare (frequency of less than 1 in 10 000 patients)		
severe skin disorders (blisters, ulcers and/or lesions)	√	√
aggression		√
hallucinations		√
severely impaired liver function		√
decreased consciousness		√
inflammation of the kidney		√
muscular weakness		√
development of breasts in males		√
low blood magnesium ⁰		√
Inflammation in the gut (leading to diarrhea)		√

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

This is NOT a complete list of side effects. If you develop any other symptoms while taking VIMOVO, see your health care provider.

HOW TO STORE IT

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 outdated medicine or medicine no longer needed. Any outdated or unused medicine should be returned to your pharmacist.

Keep out of reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

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

The Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at:

www.astrazeneca.ca

or by contacting the sponsor, AstraZeneca Canada Inc. at:
Customer Inquiries – 1 (800) 668-6000,
Renseignements – 1 (800) 461-3787.

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