

VIMOVO MODIFIED-RELEASE TABLETS

Naproxen /esomeprazole (500mg/20mg)

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What Vimovo is used for

Vimovo is used to treat the following inflammatory problems:

- Osteoarthritis (degenerative joint disease).
- Rheumatoid Arthritis (systemic inflammatory disorder that affects joints).
- Ankylosing Spondylitis (chronic inflammatory disease of the skeleton).

Vimovo helps to reduce pain, swelling, redness and heat (inflammation). You will be given this medicine if you need to be treated with an anti-inflammatory medicine and you are at risk of getting a stomach ulcer or an ulcer in your small intestine (gut). This medicine has been shown to reduce the risk of ulcers occurring when compared to taking naproxen on its own.

How Vimovo works

Vimovo contains two different medicines called naproxen and esomeprazole. Each of these medicines works in a different way.

Naproxen belongs to a group of medicines called “Non-Steroidal Anti-Inflammatory Drugs” (NSAIDs). It works by reducing inflammation.

Esomeprazole belongs to a group of medicines called “proton pump inhibitors”. It works by reducing the amount of acid your stomach produces. Esomeprazole helps to reduce the risk of ulcers and stomach problems developing

in patients who need to take naproxen to reduce inflammation.

Before you use Vimovo

- When you must not use it

Do not take Vimovo if

- You are allergic (hypersensitive) to naproxen, esomeprazole, or any of the other ingredients of Vimovo (listed under ‘Ingredients’ section).
 - You are allergic to other proton pump inhibitor medicines.
 - You are taking a medicine called “atazanavir” or “nelfinavir” (used to treat HIV).
 - If aspirin, naproxen or other NSAIDs such as ibuprofen, diclofenac or Cox II Inhibitors have caused you to have asthma (wheeziness) or an allergic reaction such as itchiness or skin rash (urticaria), or if you have had a history of angioedema (swelling), rhinitis (inflammation of the mucus membrane) or nasal polyps.
 - You are in the last 3 months of pregnancy.
 - You have **severe** problems with your liver, kidney or heart .
 - You have active stomach ulceration.
 - You have stomach and intestinal bleeding, or other bleeding disorder.
- Do not take Vimovo if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Vimovo.

You must not take Vimovo and talk to your doctor straight away, if any of the following happen to you before or while you are taking Vimovo as this medicine may hide the symptoms of other disease:

- You lose a lot of weight for no reason and have problems swallowing.
- You start to vomit food or blood.
- You pass black stools (blood-stained faeces).

Pregnancy and breast-feeding:

Do not take Vimovo if you are in the last 3 months of pregnancy.

Talk to your doctor before taking this medicine if you are planning to get pregnant or if you are in the first or

second trimester of pregnancy. Your doctor will decide whether you can take Vimovo.

Do not breast-feed if you are taking Vimovo. This is because small amounts may pass into the mothers’ milk. If you are planning to breast-feed you should not take Vimovo.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant, might become pregnant or are breast-feeding.

- Before you start to use it

Take special care with Vimovo

Check with your doctor or pharmacist before taking this medicine if:

- You have inflammation of your intestines (Crohn’s disease or ulcerative colitis).
- You have any other problems with your liver or kidneys or if you are elderly.
- You are taking other certain medicines such as corticosteroids taken by mouth, warfarin, clopidogrel, Serotonin Selective Reuptake Inhibitors (SSRIs), aspirin or NSAIDs including COX II inhibitors (see section Taking other medicines)
- You have ulceration, bleeding or perforation of your stomach or intestinal.
- You have the following conditions:
 - inducible porphyries
 - systemic lupus erythematosus and mixed connective tissue disease
- You have suspected gastric cancer and have alarm symptoms such as unintentional weight loss, recurrent vomiting, dysphagia (difficulty in swallowing)
- You are suffering from dyspepsia (discomfort at the epigastric region due to digestion problem).
- You have stomach or intestinal infection.
- You have vitamin B12 deficiency (proton pump inhibitors may cause vitamin B12 deficiency).
- You have vision problem.
- You have fever or other inflammation. Vimovo may cause severe skin reactions, e.g. exfoliative dermatitis,

toxic epidermal necrolysis, Steven-Johnson Syndrome. Symptoms may include skin rash, blisters and peel off. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

- You are due to have a specific blood test (Chromogranin A).

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking this medicine.

Medicines such as Naproxen (which is a component of Vimovo) and other NSAIDs may be associated with an increase in the risk of you having a heart attack (myocardial infarction) or stroke. This risk may happen early in treatment. Any risk is more likely with high doses and long lasting treatment. Do not exceed the recommended dose or length of treatment. Oh

Also, check with your doctor before taking this medicine if you have any heart problems, previous stroke or think you might be at risk of these problems. You may be at risk of getting these problems if:

- You have high blood pressure.
- You have problems with your blood circulation or with your blood clotting.
- You have diabetes.
- You have high cholesterol.
- You are a smoker.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription, including herbal medicines. This is because Vimovo can affect the way some other medicines work. Also some other medicines can affect the way Vimovo works.

Do not take this medicine and tell your doctor or pharmacist if you are taking a medicine called “atazanavir” or “nelfinavir” (used to treat HIV).

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Aspirin/acetylsalicylic acid to prevent blood clots.
- Other NSAID medicines (including COX II Inhibitors).
- Certain drugs such as ketoconazole, itraconazole or voriconazole used to treat infections caused by a fungus.
- Cholestyramine (used to reduce cholesterol)
- Clarithromycin (used to treat infection)
- Diazepam (used to treat anxiety, to relax your muscles or used in epilepsy).
- Hydantoins such as phenytoin (used to treat epilepsy).
- Lithium (used to treat some types of depression)
- Methotrexate (used to treat rheumatoid arthritis, psoriasis and cancer).
- Probenecid (for gout)
- “Serotonin Selective Reuptake Inhibitors” (SSRIs) (used to treat anxiety and depression).
- Sulphonylureas (oral medicines used to control your blood sugar in diabetes).
- Medicines used to treat high blood pressure called diuretics (such as furosemide or hydrochlorothiazide), ACE Inhibitors, angiotensin II receptor antagonists (such as losartan) and beta-blockers (such as propranolol).
- Corticosteroid medicines (used as anti-inflammatory medicines).
- Anticoagulants (use to thin your blood). Your doctor may need to monitor you when you start or stop taking Vimovo.
- Cilostazol (used for pain in legs due to poor blood flow)
- Cyclosporin/tacrolimus (used to prevent the immune system from attacking transplant organs)
- Digoxin (for heart problems)
- St John’s wort (used to treat depression)
- Erlotinib (an anticancer drug)
- Clopidogrel (used to prevent blood clotting)

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Vimovo.

How to use Vimovo

- How much to use

Take one tablet twice a day.

Always take Vimovo exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- When to use it

Do not take Vimovo with food. This may reduce the effect of Vimovo. Take your tablets at least 30 minutes before you have a meal.

- How long to use it

If you are taking this medicine for a long time, your doctor will want to monitor you (particularly if you are taking it for more than a year).

- If you forget to use it

If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose.

Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

- If you use too much (overdose)

If you take more Vimovo than you should, talk to your doctor or pharmacist straight away.

While you are using it

- Things you must do

Swallow your tablets whole with a drink of water.

Take your tablets at least 30 minutes before you have a meal.

- Things you must not do

Do not chew, split or crush the tablets. It is important that you take your tablets whole for your medicine to work properly.

- Things to be careful of

Driving and using machines

You may feel dizzy while taking Vimovo. If this happens, do not drive or use any tools or machines.

Side effects

Like all medicines, Vimovo can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Stop taking Vimovo and see a doctor immediately if you notice any of the following serious side effects – you may need urgent medical treatment:

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
- Reddening of your skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals.
- Yellowing skin or the whites of your eyes, having dark urine and tiredness which can be symptoms of liver problems.
- Heart attack or stroke. Signs include confusion, chest pain spreading to your neck and shoulders and down your left arm, confusion or muscle weakness or numbness which may only be on one side of your body.
- You pass black sticky bowel motions (stools) or have bloody diarrhoea.
- You vomit any blood or dark particles that look like coffee grounds.
- Rash (especially in areas exposed to the sun), possibly with pain in the joints (Subacute Cutaneous Lupus Erythematosus, SCLE).
- Fever, extreme tiredness, pus/blood in urine.
- Involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate.
- Fracture in the hip, wrist or spine
- Watery stool, stomach pain and fever that do not go away.
- Anemic (pale skin, weakness, tiredness or lightheadedness), shortness of breath, a smooth tongue, nerve problems (numbness or tingling, muscle weakness and problems walking), vision loss and mental problems (depression, memory loss or behavioral changes).

Other possible side effects include: Common (affects less than 1 in 10 people)

- Headache
- Feeling tired
- Feeling thirsty
- Feeling depressed

- Feeling breathless
- Increased sweating
- Itchy skin and skin rashes
- Spinning feeling (vertigo)
- Red or purple marks, bruising or spots on your skin
- Feeling sick (nausea) or being sick (vomiting)
- A fluttering feeling in your heart (palpitations)
- Disturbed sleep or trouble sleeping (insomnia)
- Hearing problems such as ringing in your ears
- Dizziness, feeling drowsy or feeling light-headed
- Swelling of your hands, feet and ankles (oedema)
- An inflammation inside the mouth, a sore mouth or mouth ulcers
- Eyesight problems such as blurred vision, conjunctivitis or eye pain
- Effects on your stomach or gut: diarrhoea, stomach pain, heartburn, indigestion, constipation, burping or wind (flatulence)
- Fundic Gland Polyps (benign polyps in the stomach)

Uncommon, rare or very rare (affects 1 to 10 users in 1,000 or less)

- Fever
- Fainting
- Dry mouth
- Aggression
- Hearing loss
- Asthma attack
- Fits or seizures
- Period problems
- Weight changes
- Hair loss (alopecia)
- Lumpy rash (hives)
- Joint pain (arthralgia)
- Enlarged breasts in men
- Sore or swollen tongue
- Twitching or muscle tremor
- Appetite problems, or taste changes
- Muscle weakness or pain (myalgia)
- Your blood may take longer to clot
- Problems for women in getting pregnant
- Fever, redness or other signs of infection
- An irregular, slow or very fast heartbeat.

- Tingling feelings such as “pins and needles”
- Difficulty with your memory or concentration
- Feeling agitated, confused, anxious or nervous
- Generally feeling unwell, weak and lacking energy
- Swollen or painful parts of your body because you have gained water
- High or low blood pressure. You may feel faint or dizzy
- Skin rash or blistering, or your skin becoming more sensitive on exposure to sunlight
- Seeing, feeling or hearing things that are not there (hallucinations)
- Changes in your blood test results, such as to see how your liver is working. Your doctor can explain more
- An infection called “thrush” which can affect the gut and is caused by a fungus.
- Blood in your urine or other kidney problems (interstitial nephritis). You may have back pain.
- Difficulty breathing, which may get slowly worse. This may be signs of pneumonia or swelling of your lungs developing
- Low levels of salt (sodium) in your blood. This may cause weakness, being sick (vomiting) and cramps
- Symptoms of meningitis such as fever, feeling or being sick, a stiff neck, headache, sensitivity to bright light and confusion
- Problems with your pancreas. Signs include severe stomach pain which spreads to your back
- Pale coloured stools which are a sign of serious liver problems (hepatitis). Serious liver problems may lead to liver failure and inflammation of the brain
- Colitis or worsening of inflammatory bowel disease such as Crohn’s disease or ulcerative colitis. Signs include stomach pain, diarrhoea, vomiting and weight loss
- Blood problems such as a reduced number of red cells (anaemia), white cells or platelets. This can cause weakness, bruising, fever, severe chills, sore throat or make infections more likely

- Low blood magnesium (which may result in low blood calcium and/or low blood potassium).
- Problems with the way your heart pumps blood around the body or damage to your blood vessels. Signs may include tiredness, shortness of breath, feeling faint, chest pain or general pain
- Fracture. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis)

Frequency unknown (cannot be estimated from available data)

- Subacute Cutaneous Lupus Erythematosus (SCLE)

Esomeprazole may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a **severely** reduced general condition, or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to give information about your medication at this time.

Medicines such as Vimovo may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

Other possible side effect includes severe diarrhoea which may be caused by an infection (*Clostridium difficile*) in your intestines.

Do not be concerned by this list of possible side effects. You may not get any of them.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the

website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Vimovo

- Storage

Keep out of the reach and sight of children.

Do not use Vimovo after the expiry date which is stated on the bottle after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

Store in the original package and keep the bottle tightly closed in order to protect from moisture. The bottles contain silica gel desiccant in the screw closure (to keep the tablets dry) or the bottles contain silica gel desiccant (to keep the tablets dry). Do not eat the sachet containing the desiccant.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Oval, biconvex, yellow tablet marked '500/20' in black ink.

- Ingredients

- Active ingredient(s)

Active ingredient: naproxen and esomeprazole.

- Inactive ingredients

Inactive ingredients: carnauba wax, colloidal silicon dioxide, croscarmellose sodium, glycerol monostearate 40-55, hypromellose, iron oxide (yellow and black), macrogol 8000, magnesium stearate, methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 per cent, polydextrose, polysorbate 80, povidone, propylene glycol, titanium dioxide, triethyl citrate, opadry white, opadry yellow, opadry clear, plasacryl, isopropyl

alcohol. Vimovo also contains preservatives (methyl parahydroxybenzoate (E218) and propylparahydroxybenzoate (E216)) at very low levels.

- MAL number:

MAL20112128ACRZ

Manufacturer

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Product Registration Holder

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