

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

Vimovo® 500/20 Tablet

Naproxen and Esomeprazole

Read all of this leaflet carefully before you start taking VIMOVO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider
- VIMOVO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What VIMOVO is and what it is used for
2. What you need to know before you take VIMOVO
3. How to take VIMOVO
4. Possible side effects
5. How to store VIMOVO
6. Contents of the pack and other information

1. What VIMOVO is and what it is used for

VIMOVO contains 2 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.

VIMOVO is used to treat inflammatory problems such as osteoarthritis, rheumatoid arthritis and ankylosing spondylitis in patients who need a “proton pump inhibitor” to reduce the risk of getting a stomach ulcer or an ulcer in the small intestine (gut) when treated with a Non-Steroidal Anti- Inflammatory Drug (NSAID).

2. What you need to know before you take VIMOVO

Do not take VIMOVO:

- If you are hypersensitive (allergic) to naproxen, esomeprazole or any of the other ingredients of VIMOVO (listed in section 6).
- If you are allergic to other proton pump inhibitor medicines.
- If 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-2 inhibitors have caused you to have asthma (wheeziness) or an allergic reaction such as itchiness or skin rash (urticaria).
- If you are in the last 3 months of pregnancy.
- If you have severe problems with your liver, kidney or heart.

Do not take VIMOVO if any of the above apply to you. If you are not sure, talk to your healthcare professional before taking VIMOVO.

You must not take VIMOVO and must talk to your healthcare professional 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).

Warnings and precautions

Take special care with VIMOVO

Check with your healthcare professional 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 medicines such as corticosteroids taken by mouth, warfarin, Serotonin Selective Reuptake Inhibitors (SSRIs), aspirin or NSAIDs including COX-2 inhibitors (see section Other medicines and VIMOVO”).

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

VIMOVO may be associated with an increase in the risk of you having a heart attack (myocardial infarction) or stroke. The 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.

Also, check with your doctor before taking VIMOVO 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.

Some population studies have indicated that the use of a proton pump inhibitor (which is a component of VIMOVO) may be associated with a small increased risk for osteoporotic bone fractures (osteoporosis is a condition where certain bones become brittle). However, other similar population-based studies found no such increased risk. It has not been established that VIMOVO causes fractures. Please inform your doctor if you have been diagnosed with osteoporosis (brittle bone disease).

Other medicines and VIMOVO

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Please inform your doctor if you are taking or have taken any medicines (including medicines taken some time ago), even those not prescribed. 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 VIMOVO 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, other NSAID medicines (including COX-2 inhibitors).
- 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).
- Hydantoin 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) such as fluoxetine (used to treat anxiety and depression).

- Sulphonylureas such as glimepiride (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 (such as enalapril), angiotensin II receptor antagonists (such as losartan) and beta-blockers (such as propranolol).
- Corticosteroid medicines such as hydrocortisone or prednisolone (used as anti-inflammatory medicines).
- Warfarin or clopidogrel (used 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).

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

VIMOVO with food and, drink and alcohol

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.

Pregnancy, breastfeeding and fertility

- The safety of VIMOVO in pregnancy has not been established.
- Talk to your doctor before taking this medicine if you are planning to get pregnant.

- Do not breastfeed 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.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking VIMOVO.

Driving and using machines

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

VIMOVO may contain methyl parahydroxybenzoate and propyl parahydroxybenzoate, which may cause allergic reactions. These reactions may not happen straight away.

3. How to take VIMOVO

- Always take VIMOVO exactly as your doctor or pharmacist has told you.
Check with your doctor or pharmacist if you are not sure.
- Do not share medicines prescribed for you.
- Swallow your tablets whole with a drink of water. Do not chew, split or crush the tablets. It is important that you take your tablets whole for your medicine to work properly.
- Take your tablets at least 30 minutes before you have a meal.
- If you are taking VIMOVO for a long time, your doctor will want to monitor you (particularly if you are taking it for more than a year).

How much to take

- Take 1 tablet twice a day.

If you take more VIMOVO than you should

- Talk to your doctor immediately.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take VIMOVO

- Take the last missed dose as soon as you remember. However, if it is almost time for your next dose, skip the missed dose.
- Do not take a double dose (2 doses at the same time) to make up for a forgotten dose.

4. Possible side effects

VIMOVO can have side effects. These are usually mild to moderate in intensity. Do not be alarmed by the list of side effects. You may not have any of them.

Not all side effects reported for VIMOVO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VIMOVO, please consult your doctor, pharmacist or other healthcare professional for advice.

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 ground coffee.

Other side effects include:

Frequent side effects:

- 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).

Less frequent side effects:

- 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 heart beat.
- 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 (water) urine or other kidney problems. You may have back pain.
- Difficulty breathing, which may slowly get worse (respiratory depression)
- Pneumonia (infection in the lungs)
- Fluid accumulation in your lungs (pulmonary oedema)

- 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.
- Worsening of inflammatory bowel disease such as Crohn's disease or ulcerative colitis. Signs include 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.
- 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.
- Low blood magnesium (which may result in low blood calcium and/ or low potassium).

Esomeprazole may 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.

VIMOVO may be associated with an increased risk of heart attack (myocardial infarction) or stroke.

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.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects you can help provide more information on the safety of VIMOVO.

5. How to store VIMOVO

Store all medicines out of reach of children.

Store at or below 25 °C.

Bottle: Store in the original package and keep the bottle tightly closed.

Blister: Do not remove the blisters from the outer carton until required for use.

Do not take your VIMOVO after the expiry date on the label or container.

If your doctor decides to stop your treatment, return all unused tablets to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VIMOVO contains

The active substances of VIMOVO are naproxen and esomeprazole.

The other ingredients are carnauba wax, colloidal silicon dioxide, croscarmellose sodium, glycerol monostearate, hypromellose, iron oxide (yellow and black), macrogol, magnesium stearate, methacrylic acid-ethyl acrylate copolymer, polydextrose, polysorbate 80, povidone, propylene glycol, titanium dioxide, triethyl citrate.

VIMOVO may also contain preservatives (methyl parahydroxybenzoate and propyl parahydroxybenzoate) at very low levels.

What VIMOVO looks like and contents of pack

A yellow, oval, film coated tablet, printed with 500/20 in black ink on one side.

White, square shaped HDPE bottle containing a desiccant, with a child resistant polypropylene white screw closure, in pack sizes of 6, 30, 60 or 100 tablets.

White, rectangular-shaped HDPE bottle containing a desiccant, with a non-child resistant polypropylene white screw closure, in a pack size of 500 tablets.

Cold formed silver Aluminium foil blister packages in pack sizes of 10, 30, 60 or 100 tablets.

The bottles and blister packs are packed into a cardboard carton.

Holder of certificate of registration

AstraZeneca Pharmaceuticals (Pty) Limited

Building 2, Northdowns Office Park

17 Georgian Crescent West,

Bryanston, Johannesburg

2191, South Africa

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Access to corresponding Professional Information

TBD

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