

VIMOVO™

Naproxen and esomeprazole magnesium trihydrate

Consumer Medicine Information

Consumer Name

Consumer Address

What is in this leaflet

This leaflet answers some common questions about Vimovo. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Vimovo against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Vimovo is used for

Vimovo is used to treat the symptoms of rheumatoid arthritis, osteoarthritis and ankylosing spondylitis. Although Vimovo can relieve the symptoms of pain and inflammation (swelling, redness and heat), it will not cure your condition.

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

Naproxen

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

Esomeprazole

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 or other NSAIDs. Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out of the stomach. These can be caused in part by too much acid being made in the stomach.

Your doctor may have prescribed Vimovo for another reason. Ask your doctor if you have any questions about why Vimovo has been prescribed for you.

Vimovo is not recommended for use in children, as there have been no studies of its effects in children.

There is no evidence that Vimovo is addictive.

This medicine is available only with a doctor's prescription.

Before you take Vimovo

When you must not take it

Do not take Vimovo if:

1. you have an allergy to:

- naproxen, esomeprazole or any of the ingredients listed at the end of this leaflet
- aspirin
- any other NSAID medicine
- any other medicine containing a proton pump inhibitor

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines. If you are not sure if you are taking/using any of these medicines, ask your pharmacist.

Symptoms of an allergic reaction to these medicines may include:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- fainting

If you are allergic to aspirin, NSAID medicines or medicines containing a proton pump inhibitor and you take Vimovo, these symptoms may be severe.

2. you are in the last 3 months of pregnancy

Vimovo (naproxen) may delay labour and/or affect your developing baby.

3. you are vomiting blood or material that looks like coffee grounds

4. you are bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea

5. you lose a lot of weight for no reason and have problems swallowing

6. you have a peptic ulcer (i.e. stomach or duodenal ulcer)

7. you have severe problems with your liver, kidney or heart

8. you are taking a medicine containing atazanavir, nelfinavir (both used to treat HIV infection) or cilostazol (for intermittent claudication)

Please check with your doctor or pharmacist if you are taking these medicines. These medicines will be affected by Vimovo.

9. you are taking another medication containing naproxen (e.g. Naprosyn) or esomeprazole (e.g. Nexium)

10. you have severe heart failure

11. you have a type of bleeding disorder or have bleeding on the brain

12. you are aged 18 or under

Do not take Vimovo if the packaging is torn or shows signs of tampering.

Do not take Vimovo if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure whether you should start taking/using Vimovo, contact your doctor.

Do not give Vimovo to children.

The safety and effectiveness of Vimovo in children have not been established.

Before you start to take it

Tell your doctor if:

1. you have any allergies to:

- any other medicines including aspirin or other NSAID medicines or medicines containing proton pump inhibitors
- any other substances, such as foods, preservatives or dyes

2. you are pregnant or intend to become pregnant.

Vimovo may delay labour and/or affect your developing baby if you take it during pregnancy. If it is necessary for you to take Vimovo, your doctor will discuss the risks and benefits of taking it during pregnancy.

3. you are breast-feeding or plan to breast-feed.

Vimovo passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected. Your doctor will discuss the risks and benefits of taking Vimovo when breast-feeding.

4. you have or have had any medical conditions, especially the following:

- heartburn, indigestion, stomach ulcer or other stomach problems
- vomiting blood or bleeding from the back passage
- bowel or intestinal problems such as ulcerative colitis
- kidney or liver problems
- heart failure
- high blood pressure or heart problems
- blood circulation or clotting problems
- high cholesterol
- swelling of the ankles or feet
- a tendency to bleed or other blood problems, such as anaemia
- diabetes mellitus or sugar diabetes
- any other medical condition

5. you currently have an infection.

If you take Vimovo while you have an infection, it may hide some of the signs of an infection. This may make you think, mistakenly, that you are better or that it is not serious.

6. you plan to have surgery

Vimovo (naproxen) can prolong bleeding.

7. you are a smoker

If you have not told your doctor about any of the above, tell them before you take Vimovo.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor if you are taking another NSAID medicine or medicines containing proton pump inhibitors (e.g. esomeprazole) or H2 receptor antagonists (e.g. ranitidine)

or other medicines which are used to treat gastric or duodenal ulcers, reduce the risk of these ulcers or to treat other stomach or digestive tract problems. If your doctor prescribes you Vimovo, you will most likely no longer need to take these medicines. If you continue to take them while taking Vimovo, you increase your chance of having an adverse effect. You should review the medicines you are currently taking with your doctor and follow their advice.

Some medicines may be affected by Vimovo, or may affect how well it works. These include:

- antacids, medicines for treating indigestion and heartburn
- sodium bicarbonate for treating stomach upset or ulcers
- aspirin, salicylates or other NSAID medicines
- warfarin and heparin, medicines used to prevent blood clots
- lithium, a medicine used to treat some types of mental illness
- probenecid, a medicine used to treat gout
- diuretics, also called fluid or water tablets
- medicines used to treat high blood pressure
- steroids, medicines used to treat inflammation
- some medicines used to treat diabetes
- hydantoin such as phenytoin, a medicine used to treat epilepsy
- methotrexate, a medicine used to treat arthritis and some cancers
- cimetidine and sucralfate, medicines used to treat and prevent ulcers
- cholestyramine, a medicine for treating high cholesterol levels
- medicines used to treat fungal infections such as ketoconazole, itraconazole and voriconazole
- cisapride, a medicine used to treat reflux
- diazepam, a medicine used to treat anxiety and some other conditions
- medicines used to treat depression such as selective serotonin reuptake inhibitors (e.g. citalopram), clomipramine or imipramine
- clarithromycin, a medicine used to treat bacterial infections

- medicines for HIV treatment such as atazanavir and nelfinavir
- cilostazol, a medicine used to treat intermittent claudication (pain in the legs due to poor blood flow)

If you are taking these medicines, you may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Vimovo.

How to take Vimovo

How much to take/use

Take one tablet twice daily.

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

How to take it

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 food.

When to take it

Take the tablets at least 30 minutes before food.

Taking Vimovo with or just after food may reduce absorption of the medicine into your body.

How long to take/use it

Do not use Vimovo for longer than your doctor says.

As with other NSAID medicines, if you are using Vimovo for arthritis or ankylosing spondylitis, it will not cure your condition but it should help to control pain, swelling and stiffness. If you have arthritis or ankylosing

spondylitis, Vimovo should be taken every day for as long as your doctor prescribes.

If you are not sure how long to take Vimovo, talk to your doctor.

If you forget to take/use it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking/using your tablets as you would normally.

Do not take/use a double dose to make up for the dose that you missed.

If you have trouble remembering to take/use your medicine, ask your pharmacist for some hints.

If you take/use too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to casualty at your nearest hospital, if you think that you or anyone else may have taken too much Vimovo. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep these telephone numbers handy.

If you take/use too much Vimovo, you may experience drowsiness, pain or tenderness in the stomach, stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion or cramps.

While you are using Vimovo

Things you must do

If you become pregnant while taking Vimovo tell your doctor immediately.

If you are about to start taking any new medicine tell your doctor and pharmacist that you are taking/using Vimovo.

Tell all of the doctors, dentists, and pharmacists that are treating you that you are taking Vimovo.

If you are going to have surgery, tell your doctor you are taking Vimovo.

If you are going to have laboratory tests (e.g. blood or urine tests), tell your doctor you are taking Vimovo. Vimovo can affect the results of these tests.

If you get an infection while using Vimovo, tell your doctor.

Vimovo may hide some of the signs of an infection and may make you think, mistakenly, that you are better or that it is not serious. Signs of an infection may include fever, pain, swelling and redness.

Things you must not do

Do not give Vimovo to anyone else, even if they have the same condition as you.

Do not use Vimovo to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Vimovo affects you.

As with other NSAID medicines, Vimovo may cause dizziness or light-headedness in some people. Make sure you know how you react to Vimovo before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Vimovo.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion, cramps
- loss of appetite
- constipation, diarrhoea, pain in the stomach, wind
- dizziness, lightheadedness
- drowsiness, sleepiness, change in sleep patterns
- headache
- feeling thirsty, dry mouth
- mild skin rash or itchy skin

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- eye problems such as blurred vision, sore red eyes, itching
- severe dizziness, spinning sensation
- severe or persistent headache
- tingling or numbness of the hands or feet
- fast or irregular heartbeats, also called palpitations
- difficulty hearing, deafness
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- signs of anaemia, such as tiredness, being short of breath, and looking pale
- a change in the colour of urine passed, blood in the urine
- a change in the amount or frequency of urine passed, burning feeling when passing urine
- unusual weight gain, swelling of ankles or legs
- severe skin rashes
- mood changes, confusion or depression
- muscle pain or weakness
- increase in breast size (males)
- increased sweating
- hair loss

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, stop taking Vimovo and tell your doctor immediately or go to casualty at your nearest hospital:

- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing, shortness of breath
- severe dizziness or spinning sensation
- severe pain or tenderness in any part of the stomach
- sudden or severe itching, skin rash, hives
- reddening of your skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- pain or tightness in the chest
- signs of liver inflammation including yellowing of the skin and eyes (jaundice), feeling generally unwell, vomiting, loss of appetite.

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Occasionally, Vimovo may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Vimovo

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they will not keep well.

Keep the tablets in a cool dry place where the temperature stays below 30°C.

Do not store Vimovo or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking/using Vimovo or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Vimovo tablets are yellow and are printed with 500/20 in black ink. Vimovo is available in plastic bottles of 6 or 60 tablets.

Ingredients

Vimovo tablets contain naproxen 500 mg and esomeprazole 20 mg (as magnesium trihydrate) as the active ingredients. Other (inactive) ingredients are:

- carnauba wax
- colloidal silicon dioxide
- croscarmellose sodium
- glycerol monostearate 40-55
- hypromellose
- iron oxide (yellow, black)
- macrogol 8000
- magnesium stearate
- methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30%
- methylhydroxybenzoate (E218)
- polydextrose
- polysorbate 80
- povidone

- propylene glycol
- propylhydroxybenzoate (E216)
- titanium dioxide
- triethyl citrate.

Vimovo does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

AstraZeneca Pty Ltd
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NORTH RYDE NSW 2113

Australian Registration numbers

AUST R 170577
AUST R 170578*

*Not currently supplied in
Australia.

This leaflet was prepared 25th
October 2011.