Vimovo™
(naproxen/esomeprazole magnesium)
375/20•500/20 mg delayed-release tablets

Now Available

AstraZeneca is pleased to announce the availability of VIMOVO. VIMOVO is a fixed-dose combination of enteric-coated naproxen and immediate-release esomeprazole. VIMOVO is indicated for the relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis and to decrease the risk of developing gastric ulcers in patients at risk for NSAID-associated gastric ulcers. VIMOVO is not recommended for initial treatment of acute pain. VIMOVO is available in two dose strengths—500 mg naproxen/20 mg esomeprazole tablets and 375 mg naproxen/20 mg esomeprazole tablets. The lowest effective dose for the shortest duration is recommended based on the individual patient treatment goals.[1] Please refer to the Important Safety Information below. VIMOVO will be available starting July 12, 2010.

Dosing and Administration

VIMOVO should be administered as 1 tablet twice daily. The tablets should be swallowed whole with liquid. They should not be split, chewed, or crushed. VIMOVO should be taken at least 30 minutes before meals.[1] It is important that each patient to whom you dispense VIMOVO receives a copy of the patient Medication Guide, which is included in the VIMOVO Prescribing Information.

Strength	Size	NDC	Tablet
VIMOVO 500 mg/ 20 mg tablets	60-ct bottle	0186-0520-60	
VIMOVO 375 mg/ 20 mg tablets	60-ct bottle	0186-0510-60	

Tablets are not to scale.

The VIMOVO savings card

AstraZeneca offers VIMOVO savings cards so eligible patients can receive prescription savings. The process is simple—patients activate the card by calling 1-877-808-4668. Eligible patients who have not received a card can download one at www.VIMOVO.com

- Once enrolled, all patients receive a FREE 30-day supply (up to 60 tablets) of VIMOVO
- Refills cost $20 or less (up to a $100 savings limit)—for cash-pay or commercially-insured patients—for up to 11 refills*

* Rules and restrictions apply. See www.VIMOVO.com for full program details.

Learn More About VIMOVO

Find out more by calling our AstraZeneca Information Center at 1-800-236-9933, Monday through Friday, 8 AM to 6 PM ET, excluding holidays. You may also visit www.VIMOVOtouchpoints.com for more information.

Please see below for Important Safety Information and click here for full Prescribing Information, including Boxed Warnings.

Important Safety Information About VIMOVO

Cardiovascular Risk

- **Naproxen, a component of VIMOVO, may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.**
- **VIMOVO is contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery.**

Gastrointestinal Risk

- **NSAIDs, including naproxen, a component of VIMOVO, cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal (GI) events.**

VIMOVO is contraindicated in patients with known hypersensitivity to any component of VIMOVO or substituted benzimidazoles; in patients with a history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs; in patients during the perioperative period in the setting of coronary artery bypass graft (CABG) surgery; or in patients in the late stages of pregnancy.

Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals.

Treatment should be withdrawn when active and clinically significant bleeding from any source occurs.

As with all NSAIDs, VIMOVO can lead to the onset of new hypertension or worsening of preexisting hypertension, either of which may contribute to the increased incidence of CV events. Blood pressure should be monitored closely. NSAIDs, including VIMOVO, may diminish the antihypertensive effect of angiotensin converting enzyme (ACE) inhibitors and angiotensin II antagonists, beta-blockers, and in some patients can reduce the natriuretic effect of furosemide and thiazides.

Fluid retention and edema have been observed in some patients taking NSAIDs, including VIMOVO. NSAIDs should be used with caution in patients with fluid retention or heart failure.

Two large, controlled, clinical trials of a COX-2 selective NSAID for the treatment of pain in the first 10-14 days following CABG surgery found an increased incidence of myocardial infarction and stroke.

There is no consistent evidence that concurrent use of aspirin mitigates the increased risk of serious CV thrombotic events associated with NSAID use. VIMOVO can be administered with low-dose aspirin (≤325 mg/day) therapy. The concurrent use of aspirin and VIMOVO may increase the risk of serious adverse events. As with all NSAIDs, concurrent administration of naproxen and aspirin is not generally recommended because of the potential of increased adverse events.

NSAIDs, including VIMOVO, can cause serious GI adverse events, which can be fatal. The risk is greater in patients with a prior history of ulcer disease or GI bleeding, and in patients at high risk for GI events, especially the elderly. VIMOVO should be used with caution in these patients.

Epidemiological studies have demonstrated an association between use of psychotropic drugs that interfere with serotonin reuptake and the occurrence of upper gastrointestinal bleeding. In two studies, concurrent use of an NSAID, COX-2 inhibitor, or aspirin potentiated the risk of bleeding. Although these studies focused on upper gastrointestinal bleeding, bleeding at other sites cannot be ruled out.

NSAIDs should be given with care to patients with a history of inflammatory bowel disease (ulcerative colitis, Crohn's disease) as their condition may be exacerbated.

Symptomatic response to esomeprazole, a component of VIMOVO, does not preclude the presence of gastric malignancy.

Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long-term with omeprazole, of which VIMOVO contains an enantiomer.

Anaphylactoid reactions may occur in patients without known prior exposure to either component of VIMOVO. NSAIDs should not be given to patients with aspirin triad.

Serious skin adverse reactions such as exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, which can be fatal and can occur without warning. Discontinue VIMOVO at first appearance of skin rash or any other sign of hypersensitivity.

In late pregnancy, as with other NSAIDS, VIMOVO should be avoided because it may cause premature closure of the ductus arteriosus.

VIMOVO is not recommended in patients with moderate or severe renal insufficiency. In addition, NSAIDs may cause renal toxicity.

VIMOVO is not recommended in patients with severe hepatic insufficiency. Consider dose reduction in mild/moderate hepatic insufficiency. If abnormal liver enzymes persist or worsen discontinue use immediately.

Several studies and literature reports indicate that long-term proton pump inhibitor (PPI) therapy is associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine.

Esomeprazole, a component of VIMOVO, inhibits gastric acid secretion and may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability (eg, ketoconazole, iron salts, and digoxin).

Concomitant use of VIMOVO and warfarin may result in increased risk of bleeding complications. Monitor for increases in INR and prothrombin time.

The most commonly observed adverse events in clinical trials (experienced by >5% patients in the VIMOVO group) were erosive gastritis, dyspepsia, gastritis, diarrhea, gastric ulcer, upper abdominal pain, and nausea.

Indications

VIMOVO is indicated for the relief of signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers. VIMOVO is not recommended for initial treatment of acute pain because the absorption of naproxen is delayed compared to absorption from other naproxen-containing products. Controlled studies do not extend beyond 6 months.

Please click here for full Prescribing Information, including Boxed Warnings for VIMOVO.

Reference: 1. VIMOVO™ Prescribing Information. Wilmington, DE: AstraZeneca; 2010.

Please visit our Web site at www.VIMOVO.com

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