Mefenamic Acid

Dolfenal®

250 mg FILM-COATED TABLET

Non-Steroidal Anti-Inflammatory Drug

FORMULATION
Each film-coated tablet contains:
Mefenamic Acid…… 250 mg

PRODUCT DESCRIPTION
Mefenamic acid (Dolfenal) 250 mg Tablet: Pink, capsule-shaped film-coated tablet

WHAT IS IN THE MEDICINE?
This product contains mefenamic acid which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Like other NSAIDs, mefenamic acid works by changing the body's chemical response to pain, swelling and fever, resulting in relief of symptoms of inflammation (e.g., swelling, redness) and relief of pain.

STRENGTH OF THE MEDICINE
See Formulation.

WHAT IS THIS MEDICINE USED FOR?
• For the relief of mild to moderate pain including headache, dental pain, pain after childbirth or surgery, primary dysmenorrhea, and menorrhagia (heavy menstrual period) due to dysfunctional causes

• For the relief of pain associated with musculoskeletal and joint disorders including osteoarthritis and rheumatoid arthritis

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?
Like other NSAIDs, the lowest effective dose should be used for the shortest possible time. After observing the response to initial therapy with this product, the dose and frequency should be adjusted to suit individual patient needs.

This medicine is given orally and may be taken with food or milk if stomach upset occurs.

Usual Recommended Dose in Adults and Adolescents older than 14 years:
1 to 2 tablets every 8 hours, as needed, or, as directed by a doctor.

For the relief of dysmenorrhea and premenstrual syndrome (PMS):
1 to 2 tablets every 8 hours while symptoms persist ("period pains" and other associated symptoms), or, as directed by a doctor.

- For menstrual cramps (period pain), mefenamic acid is usually taken during each period as soon as the cramps begin and continued for a few days until the pain goes away.
- For heavy menstrual periods, mefenamic acid is taken from the beginning of the period and continued according to your doctor's advice.
- Do not take for more than 7 days unless directed by a doctor.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?
• If you are allergic to mefenamic acid, aspirin or any other NSAID, or to other ingredients in the product
• If you are currently taking aspirin or other NSAIDs
• If you have bronchospasm (constriction of air passages of the lungs), angioedema (rapid swelling that occurs in the tissue just below the surface of the skin), nasal polyps or allergic-type reactions after taking aspirin or other NSAIDs
• If you have had or are suffering from stomach ulcers, bleeding or other stomach problems such as inflammatory bowel disease
• If you had diarrhea with this medicine in the past. Diarrhea may recur if you take mefenamic acid again.
• If you have severe heart, liver or kidney disease
• Bleeding in the brain or other bleeding disorders
• High potassium in the blood
• Dengue fever, since NSAIDs may increase the risk of bleeding
• During the last 3 months of pregnancy
• Breastfeeding women, because of the potential for serious undesirable effects in breastfed infants
• Children and adolescents younger than 14 years old
• Right before or after heart surgery

UNDESIRABLE EFFECTS
The most frequently reported undesirable effects (1 to 10%) of mefenamic acid include abdominal pain, abnormal kidney function, anemia, constipation, diarrhea, dizziness, dyspepsia, edema, elevated liver enzymes (e.g., alanine transaminase or aspartate transaminase), flatulence, gastrointestinal ulcers (gastric/duodenal), gross bleeding/perforation, headache, heartburn, increased bleeding time, itching, nausea, rashes, ringing in the ears (tinnitus), and vomiting.

Less common undesirable effects (<1% of patients) include:

Blood: Abnormal enlargement of the lymph nodes, anemia, bacterial infection in the bloodstream or body tissues (sepsis), black or blue marks or bruises (ecchymosis), decreased hematocrit, low platelet count, low white blood cell count (i.e., leukopenia, neutropenia, agranulocytosis, eosinophilia, pancytopenia), red or purple discoloration of the skin (purpura)

Immune System: Allergic reactions including asthma, breathing difficulty, or skin reactions [e.g., rapid swelling beneath the skin (angioedema), widespread scaling of the skin (exfoliative dermatitis), Stevens-Johnson syndrome, toxic epidermal necrolysis, and erythema multiforme]

Metabolic: Appetite changes, fluid retention, high blood sugar, low sodium in blood, weight changes

Psychiatric: Confusion, depression, nervousness

Nervous System: Anxiety, coma, dream abnormalities, drowsiness, hallucination, inflammation of the meninges (meningitis), inflammation of the optic nerve (optic neuritis), insomnia, loss of strength, numbness or tingling of the skin, seizures, sleepiness, tremors, vertigo

Special Senses: Blurred vision, ear pain, eye irritation/pain, hearing impairment, inflammation or infection of the membrane lining the eyelids (conjunctivitis), reversible loss of color vision, visual disturbances

Cardiovascular: Abnormal heart rhythms, congestive heart failure, heart attack, high blood pressure, inflammation of the walls of blood vessels, loss of consciousness, low blood pressure, palpitations, rapid heart rate, stroke

Lungs: Asthma, breathing difficulty, respiratory depression, pneumonia

Stomach/Gut: Anorexia, belching, dry mouth, dyspepsia, inflammation of the mucous linings in the mouth, inflammation of the pancreas, inflammation of the stomach, inflammation of the tongue, inflammation or irritation of the esophagus, passing black or bloody stools, passing stools with excess fat, rectal bleeding, vomiting with blood, worsen inflammation of the intestine or colon

Liver: Abnormal liver function tests, abnormal yellowing of the skin (jaundice), inflammation of the liver (hepatitis), liver damage, liver failure

Skin: Hair loss, hives, itching, perspiration, photosensitivity, swelling of the face or voice box

Kidneys: Abnormal kidney function, decreased urine output, excess serum proteins in the urine, increased urine output, inflammation of the kidneys or urinary bladder, inflammation of the spaces between the kidney tubules (interstitial nephritis), kidney failure, pain when urinating, blood in the urine

Body as a Whole: Death, fatigue, fever, general ill feeling, infection, organ failure

Investigations: False-positive for bile in the urine

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?
Aspirin and Other NSAIDs: Mefenamic acid should not be given together with aspirin, salicylates or other NSAIDs (e.g., ketorolac, ibuprofen, naproxen) including COX-2 inhibitors (e.g., celecoxib, etoricoxib) because of the increased risk of stomach and intestinal bleeding.

Corticosteroids, Selective Serotonin-Reuptake Inhibitors (SSRIs), and Anti-platelet Agents: May increase the risk of stomach bleeding with mefenamic acid

Aminoglycosides: NSAIDs, such as mefenamic acid, increase aminoglycoside toxicity by decreasing the excretion of aminoglycoside antibiotics (e.g., amikacin, gentamicin, neomycin, tobramycin).

Antacids: The plasma levels of mefenamic acid may be increased when taken together with antacids such as magnesium hydroxide.

Antihypertensives and Diuretics: NSAIDS may reduce the effect of these drugs; diuretics may also cause acute reduction in kidney function of NSAIDs

Blood Thinning Medicines (Anticoagulants): NSAIDs may enhance the effects of these agents (e.g., warfarin). An increase in the International Normalized Ratio (INR), which may serve as a sign of increased risk for bleeding, may be observed when using paracetamol and warfarin at the same time.

Cardiac Glycosides: NSAIDs may worsen heart failure, reduce kidney function and increase blood levels of these medicines (e.g., digoxin)

Ciclosporin and Tacrolimus: Increased risk of kidney damage

Lithium and Methotrexate: Mefenamic acid increases the amount of lithium and methotrexate in the blood, thus increasing the risk of toxicity

Medicines Affecting Liver Enzymes: Medicines which hinder the enzymes responsible for the metabolism of mefenamic acid may alter its safety and efficacy

Medicines that Lower Blood Sugar (for Diabetes): Mefenamic acid may increase plasma levels of medicines used to treat diabetes (sulfonylureas such as gliclazide, glipizide, glimepiride) by inhibiting their metabolism.

Mifepristone: Mefenamic acid should not be used for 8 to 12 days after mifepristone administration because it can reduce the effect of mifepristone.

Probenecid: May reduce the metabolism and excretion of mefenamic acid, thus increasing the risk of mefenamic acid toxicity.

Quinolone Antibiotics: A possible increased risk of convulsions may occur with mefenamic acid

Zidovudine: An increased risk of blood problems such as bleeding into a joint (hemarthrosis) and bruising (hematoma) may result when given with mefenamic acid

Tell your doctor if you are taking other medicines, including vitamins, supplements, and herbal medicines.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?
If a dose is missed, take the next dose if still needed for pain and the subsequent dose every 8 hours thereafter.

Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?
Keep the product out of sight and reach of children.
Store at temperatures not exceeding 30°C.

SIGNS AND SYMPTOMS OF OVERDOSE
Symptoms following acute overdose of NSAIDs, such as mefenamic acid, are usually limited to lethargy (fatigue), drowsiness, nausea, vomiting and epigastric pain. Gastrointestinal bleeding can occur. Hypertension, acute kidney failure, respiratory depression and coma may also occur. Anaphylactoid reactions have been reported with recommended doses of NSAIDs, and may occur following an overdose.

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?
If more than the recommended dosage has been given, consult a doctor or contact a Poison Control Center right away.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE
• **Allergy Alert:** Mefenamic acid may cause a severe allergic reaction which may include:
  - o Hives (elevated, whitish or reddish patches on the skin with severe itching or pricking sensations);
  - o Shock (anaphylactic), a hypersensitivity reaction resulting to generalized skin lesions and itchiness, followed by vascular collapse and often accompanied by life-threatening respiratory distress
  - o Facial swelling
  - o Skin reddening
  - o Asthma (wheezing)
  - o Skin rash or skin blisters

• **Stomach Bleeding Warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:
  - o Are age 60 years or older
  - o Have had stomach ulcers or bleeding problems
  - o Take a blood thinning (anticoagulant) or steroid medicine
  - o Take other medicines containing prescription or nonprescription NSAIDs (aspirin, ibuprofen or others)
  - o Have 3 or more alcoholic drinks everyday while using this product
  - o Take more or for a longer time than directed

• The risk of heart attack or stroke may increase if you use more than or longer than directed.

• Mefenamic acid should be used with caution in elderly patients suffering from dehydration and kidney disease.

• Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

Ask a doctor before use if you are:
• Having problems or serious side effects from taking pain relievers or fever reducers
• Taking aspirin or other NSAIDs
• Taking other medicines
• Under a doctor's care for any serious condition
• Trying to become pregnant; NSAIDs may impair fertility in women. This effect is reversible upon stopping the medicine.

Ask a doctor before use if:
• Stomach bleeding warning applies to you
• You have heart problems, previous stroke or might be at risk of these conditions (e.g., high blood pressure, high cholesterol, diabetes, or if you are a smoker)
• You have a history of stomach problems, such as heartburn, Crohn's disease (inflammation of the digestive system) or ulcerative colitis (ulcers in the lining of the rectum and colon)
• You have liver or kidney problems
• You have asthma
• You suffer from systemic lupus erythematosus (SLE) or other auto-immune diseases

Stop use and ask a doctor if:
• You experience any of the following signs of stomach bleeding:
  - o Feel faint
  - o Vomit blood
  - o Have bloody or black stools
  - o Have stomach pain that does not get better
• An allergic reaction occurs
• New symptoms occur
• Symptoms do not get better
• Headache is persistent

If you are pregnant or breastfeeding, ask a doctor before use. It is especially important not to use mefenamic acid during the last three months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

ADVERSE DRUG REACTION REPORTING STATEMENT

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 858-1000 or productsafety@unilab.com.ph.
By reporting undesirable effects, you can help provide more information on the safety of this medicine.

AVAILABILITY:
Mefenamic Acid (Dolfenal®) 250 mg film-coated tablet in flex foil, box of 100s.

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