Mefenamic Acid Capsules, USP

WARNINGS

NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events, including serious bleeding, perforation, and穿孔 rupture, which can be fatal. These events can occur without warning in patients treated with NSAIDs. Patients with a history of gastrointestinal disease are at higher risk for NSAID-related adverse events.

NSAIDs cause an increased risk of serious cardiovascular thrombotic events, including MI and stroke, which can be fatal. This risk may increase with duration of use. Patients with MI or stroke in the prior year, or with other risk factors for coronary disease, should be informed of the increased risk of serious cardiovascular events with NSAIDs. Caution should be used in patients with angina and those with a history of MI and stroke.

NSAIDs can be associated with an increased risk of congestive heart failure, which can be severe and occasionally fatal. This risk may increase with duration of use, and in patients with severe heart failure. Advise patients to stop the drug if they develop heart failure symptoms (see PRECAUTIONS; Renal/Respiratory/Concomitant AZ, Hypertension).

NSAIDs should be used with caution in patients with a history of cardiac surgery. NSAIDs can decrease the effectiveness of corticosteroids and anticoagulants. Patients who take NSAIDs should be warned of the increased risk of bleeding events and should be monitored for bleeding events.

Exacerbation of Asthma Related to Aspirin Sensitivity

Mefenamic acid may cause exacerbations of asthma symptoms in patients with a history of severe aspirin-sensitive asthma.

Hypersensitivity Reactions

Hypersensitivity reactions including anaphylaxis and severe, life-threatening reactions to mefenamic acid and other NSAIDs have been reported in patients with aspirin-sensitive asthma. Mefenamic acid should not be used in patients with a history of asthma, severe skin reactions including anaphylactic reactions, or a history of severe skin reactions to other NSAIDs.

Contraindications

Mefenamic acid is contraindicated in patients with a history of serious skin reactions to NSAIDs, including anaphylactic reactions and serious skin reactions such as Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous pemphigoid, or lupus-like syndrome. Mefenamic acid is also contraindicated in patients with a history of serious hypersensitivity reactions to medications containing sulfonamide, including mefenamic acid and other NSAIDs.

WARNINGS - Gastrointestinal Bleeding, Ulceration, and Perforation

NSAIDs, including mefenamic acid, can cause serious gastrointestinal events, including ulceration, bleeding, or perforation of the stomach or intestine, which can be fatal. These events can occur without warning at any time during treatment. Patients at an increased risk of gastrointestinal bleeding include the elderly, patients taking NSAIDs for long periods of time, and those with a previous history of gastrointestinal bleeding or ulcers. Patients should be monitored for signs of gastrointestinal bleeding (see PRECAUTIONS; Gastrointestinal/Intravascular). Use of NSAIDs in the elderly is associated with an increased risk of serious gastrointestinal events.

NSAIDs, including mefenamic acid, can cause a serious skin reaction, including a potentially fatal syndrome known as toxic epidermal necrolysis, and can cause anaphylaxis or serious skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis.

Mefenamic acid is active when taken with food, with or without the addition of a fatty meal. The rate of absorption and extent of bioavailability may be decreased when taken with food. Mefenamic acid is contraindicated in patients with previous serious skin reactions to NSAIDs, including anaphylactic reactions and serious skin reactions such as Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous pemphigoid, or lupus-like syndrome. Mefenamic acid is also contraindicated in patients with a history of serious hypersensitivity reactions to medications containing sulfonamide, including mefenamic acid and other NSAIDs.

Patients should be warned of the increased risk of bleeding events and should be monitored for bleeding events.

For treatment of primary dysmenorrhea.

For relief of mild to moderate pain in patients > 14 years of age, when a non-narcotic analgesic is effective.

PERIODIC SAFETY REVIEW (PSR)

The PSR is a periodic review of new and changing information about the long-term effects and risk-benefit profile of the medicine.

The PSR must be conducted in the 5 years following the assignment of a medicine by a Regulatory Affairs Committee. The PSR must be completed within 1 year of the assignment, and the report must be submitted to the relevant Regulatory Authority.

The PSR should be conducted by a team of experts, including a statistician, a clinical expert, and a patient representative. The PSR should assess the long-term safety and efficacy of the medicine, and should be submitted to the relevant Regulatory Authority prior to the medicine being marketed.

The PSR should include an analysis of the incidence and severity of adverse events reported during the review period. The PSR should also include a review of the drug's efficacy, and a comparison of the drug's effectiveness with other available treatments.

The PSR should be updated every 5 years, or whenever new information becomes available.

The PSR should be made available to the public, and should be accessible through the medicine's website or through a public database.

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Unusual weight gain

Concomitant use of mefenamic acid and antacids is not recommended because it has been observed to increase the risk of bleeding and decreases the efficacy of antacids.

Clinical Impact:

Methotrexate Administration

In the current context of the use of NSAIDs, the concomitant use of an NSAID and aspirin does not produce any greater therapeutic effect than the use of aspirin alone.

Studies to evaluate the mutagenic potential of mefenamic acid have not been performed. However, mefenamic acid is a prodrug that is metabolized to active metabolites, and it is possible that mefenamic acid or its metabolites could cause mutagenic effects.

NSAIDs can cause serious side effects, including:

- Increased risk of bleeding
- Ulcers and tears (perforation) of the stomach
- Increase risk of heart attack or stroke
- Damage to the kidneys

NSAIDs should be used with caution in patients at risk for these side effects, such as those with a history of bleeding disorders, anemia, or other coagulopathies.

NSAIDs should not be taken by:

- Patients who are allergic to mefenamic acid
- Patients who have a history of aspirin allergy
- Patients with a history of heart disease
- Patients with a history of gastrointestinal bleeding

NSAIDs should be taken only as directed by your healthcare provider. If you take too much of your NSAID, call your healthcare provider or get medical help right away.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.
Null
During concomitant use of mefenamic acid and other NSAIDs, the incidence of gastrointestinal adverse reactions may be higher than when a single NSAID is used. Concomitant use of other NSAIDs and aspirin may increase the risk of gastrointestinal bleeding, ulceration, and perforation when compared to use of NSAIDs alone.

**Gastrointestinal Bleeding, Ulceration and Perforation**

- Gastrointestinal bleeding, ulceration, and perforation have been observed in patients taking NSAIDs. These complications can be dramatic and may result in hospitalization and even death. The risk of having a serious gastrointestinal complication is greatest in patients with a history of gastrointestinal problems. The risk is also greater for patients who develop ulcers during treatment with NSAIDs and who use higher doses of these agents. Therefore, care should be taken in prescribing NSAIDs to patients with a history of gastrointestinal disease to ensure the lowest possible doses are used. Patients with a history of peptic ulcer disease or with a history of a gastrointestinal complication while taking NSAIDs should not use these agents.

**Heart Failure and Edema**

- NSAIDs can cause fluid retention and have been associated with congestive heart failure in patients with fluid retention or heart problems. NSAIDs can cause increased blood pressure and may affect blood flow to the kidneys, which could worsen an existing condition of fluid retention. Patients with heart problems or cardiovascular disease who take NSAIDs should be monitored for changes in their condition.

**Hypertension**

- NSAIDs can cause high blood pressure. This can be serious for people who already have high blood pressure or for people who develop high blood pressure while taking these agents. Patients who have high blood pressure should be closely monitored while taking NSAIDs.

**Dyspepsia**

- Dyspepsia (upset stomach) can be caused by NSAIDs. Patients should be advised to report any symptoms of dyspepsia to their healthcare provider.

**Gastrointestinal Bleeding, Ulceration, and Perforation**

- NSAIDs can cause gastrointestinal bleeding. The risk of bleeding is greater for older people and for those who have other risk factors, including those with a history of ulcers. Patients should be advised to report any symptoms of gastrointestinal bleeding to their healthcare provider.

**Hemorrhagic Diathesis**

- NSAIDs can cause a bleeding disorder, which may manifest as easy bruising, nosebleeds, or other symptoms. Patients should be advised to report any symptoms of hemorrhage to their healthcare provider.

**Renal Effects**

- NSAIDs can cause kidney problems, including decreased kidney function, which can lead to fluid retention and high blood pressure. It is important to monitor patients who have kidney disease or who have a history of kidney problems while taking NSAIDs.

**Hepatic Effects**

- NSAIDs can cause liver problems, including liver damage. Patients should be advised to report any symptoms of liver problems to their healthcare provider.

**Other AEs**

- NSAIDs can cause other adverse effects, including respiratory problems, skin reactions, and digestive system problems. Patients should be advised to report any symptoms of these problems to their healthcare provider.

**Flushing**

- NSAIDs can cause flushing, which may be a sign of an allergic reaction. Patients should be advised to report any symptoms of flushing to their healthcare provider.

**DOSAGE AND ADMINISTRATION**

- NSAIDs are available in a variety of strengths and formulations, including tablets, capsules, and suspensions. The dose and frequency of administration should be determined by the patient's age, weight, and medical condition.

**INDICATIONS AND USAGE**

- NSAIDs are used to treat pain, inflammation, and fever. They are available by prescription or over-the-counter (OTC) and can be used for a variety of conditions, including arthritis, dental pain, and headaches.

**CONTRAINDICATIONS**

- NSAIDs should not be used in patients with a known allergy to NSAIDs or other drugs in the same class. They should also not be used in patients with a history of asthma, bronchitis, or emphysema, or in patients with a history of ulcer disease or gastrointestinal bleeding.

**WARNINGS**

- NSAIDs can cause serious side effects, including kidney problems, liver problems, and gastrointestinal bleeding. Patients should be advised to report any symptoms of these problems to their healthcare provider.

**ADVERSE REACTIONS**

- NSAIDs can cause a variety of adverse reactions, including gastrointestinal symptoms, urinary symptoms, and dermatological symptoms. Patients should be advised to report any symptoms of these reactions to their healthcare provider.

**PRECAUTIONS**

- NSAIDs can cause an increased risk of cardiovascular events, including heart attack, stroke, and vascular death. Patients with a history of cardiovascular disease or risk factors for cardiovascular disease should be advised to take NSAIDs only under close medical supervision.

**DOSAGE**

- The dosage of NSAIDs should be adjusted according to the patient's age, weight, and medical condition. The recommended dosage for adults is one or two tablets every 6 to 8 hours, depending on the severity of the condition. The dosage for children should be determined by the child's age and weight.

**ADMINISTRATION**

- NSAIDs can be administered by mouth or rectally. They can be given with or without food, but should not be given with milk.

**SIDE EFFECTS**

- The most common side effects of NSAIDs include gastrointestinal irritation, headache, dizziness, and drowsiness. Patients should be advised to report any symptoms of these side effects to their healthcare provider.

**NURSING MOTHERS**

- NSAIDs can be transferred to the nursing infant. Because of the potential for serious adverse effects, NSAIDs should not be used by breastfeeding women.

**LABOR AND DELIVERY**

- NSAIDs can cause the onset of bleeding and associated symptoms. Clinical studies indicate that NSAIDs may delay or prevent rupture of ovarian follicles, which can lead to women being unable to become pregnant. Patients who are trying to conceive should not use NSAIDs.

**PREGNANCY**

- NSAIDs can cause serious side effects in pregnant women. They should not be used during the first trimester of pregnancy. Patients who are pregnant or planning to become pregnant should not use NSAIDs.

**INFERTILITY**

- NSAIDs can cause infertility. They should not be used by patients who are trying to conceive.
NSAIDs can cause serious side effects, including:
- unusual weight gain
- life-threatening allergic reactions
- low red blood cells (anemia)
- kidney problems including kidney failure
- liver problems including liver failure
- heart failure
- medicines called Nonsteroidal Anti-inflammatory Drugs (NSAIDs) can cause serious side effects, so tell your healthcare provider first. Call your healthcare provider or pharmacist immediately if you get any of the following symptoms:
  - unusual weight gain
  - life-threatening allergic reactions
  - low red blood cells (anemia)
  - kidney problems including kidney failure
  - liver problems including liver failure
  - heart failure

See "What is the most important information I should know about medicines called Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?" for more information.

Medication Guide for Nonsteroidal Anti-inflammatory Drugs (NSAIDs)

Some NSAIDs are sold in lower doses under the brand names Advil®, Aleve®, and others. NSAIDs not increase the chance of a heart attack.

Before taking any new medicine without talking to your healthcare provider first.

Do not give NSAIDs to other people, even if they have the same symptoms that you have. It may harm them.

Do not give any of the following symptoms:
- unusual weight gain
- life-threatening allergic reactions
- low red blood cells (anemia)
- kidney problems including kidney failure
- liver problems including liver failure
- heart failure

See "What is the most important information I should know about medicines called Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?" for more information.

If you would like more information about NSAIDs, talk with your healthcare provider.

If you have any questions about this Medication Guide or any other information about NSAIDs, call your healthcare provider or pharmacist.

See "Other information about NSAIDs" for more information.

Other information about NSAIDs.

Medication Guide for Mefenamic Acid (mef-e-NAM-ik AS-id)

Mefenamic Acid (mef-e-NAM-ik AS-id)

Who should not take NSAIDs? Do not take NSAIDs if you:
- have just had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAIDs
- are allergic to any of these ingredients
- have ever had an allergic reaction to any medicine
- are allergic to any of the ingredients in this medicine (ask your healthcare provider or pharmacist about the ingredients)

Who should use NSAIDs?

Meet all of the following criteria:
- no history of stomach or intestinal bleeding with use of aspirin
- use of aspirin with lower risk of bleeding
- no reason for aspirin to cause ulcers
- no reason for aspirin to cause bleeding
- no reason for aspirin to increase the chance of a heart attack

What is NSAIDs?

NSAIDs are used to treat pain and redness, swelling, heat, inflammation from many medical conditions such as different types of short-term pain.

Medical conditions such as different types of short-term pain.

After taking NSAIDs, tell your healthcare provider:
- if you get any of the following symptoms:
- unusual weight gain
- life-threatening allergic reactions
- low red blood cells (anemia)
- kidney problems including kidney failure
- liver problems including liver failure
- heart failure

See "What is the most important information I should know about medicines called Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?" for more information.

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See "What is the most important information I should know about medicines called Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?" for more information.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured by:
Maeve Labs Limited
Princeton, NJ 08540

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Contract Giver/PL holder:
MICRO LABS LIMITED

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Specific text:

NSAIDs

Medication Guide

Nonsteroidal Anti-inflammatory Drugs (NSAIDs)

Mefenamic Acid (mef-e-NAM-ik AS-id)

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