**INDICATIONS AND USAGE**

Diflunisal tablets are indicated for acute or long-term use for symptomatic treatment of the following:

- **Mild to moderate pain**
- **Rheumatoid arthritis**
- **Osteoarthritis**
- **Primary dysmenorrhea**
- **Ankylosing spondylitis**
- **Juvenile rheumatoid arthritis**
- **Juvenile ankylosing spondylitis**

**MECHANISM OF ACTION**

Diflunisal is a nonsteroidal anti-inflammatory drug (NSAID) that inhibits the enzymes cyclooxygenase-1 (COX-1) and cyclooxygenase-2 (COX-2). These enzymes are involved in the production of prostaglandins, which are responsible for pain and inflammation. Diflunisal also inhibits prostaglandin synthesis and reduces prostaglandin synthesis in the kidney, which can lead to increased urine output (natriuresis).

**CONTRAINDICATIONS**

Diflunisal tablets are contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft surgery. Diflunisal tablets are also contraindicated in patients with known hypersensitivity to diflunisal or the excipients (see **PRECAUTIONS**). Diflunisal tablets are contraindicated in patients with known asthmatic reactions to aspirin and other NSAIDs, including asthma that developed after aspirin or other NSAID therapy (see **ADVERSE REACTIONS**).

**WARNINGS**

- **Reye’s Syndrome and Hepatitis**
  - Diflunisal tablets are contraindicated in children and adolescents with chickenpox or other viral infections because of the risk of Reye’s syndrome. This condition can lead to severe liver disease and brain swelling, with a high mortality rate.

**ADVERSE REACTIONS**

**Gastrointestinal Effects**

- Diflunisal tablets can cause gastrointestinal (GI) adverse events, including inflammation, irritation, and ulceration of the GI tract. These effects can range from mild to severe and may include nausea, vomiting, dyspepsia, and diarrhea.

**Hepatotoxicity**

- Diflunisal can cause hepatic effects, such as jaundice, liver damage, and liver function test abnormalities. These effects may be more common in patients with pre-existing liver disease or those taking concomitant medications that can affect liver function.

**Renal Effects**

- Diflunisal can cause renal effects, including changes in blood pressure, decreased urine output, and kidney damage. These effects can be more common in patients with pre-existing kidney disease or those taking medications that can affect kidney function.

**Cardiovascular Effects**

- Diflunisal can cause cardiovascular effects, such as increased blood pressure, heart failure, and exacerbation of heart failure. These effects can be more common in patients with pre-existing cardiovascular disease or those taking medications that can affect cardiovascular function.

**Hypersensitivity Reactions**

- Diflunisal can cause hypersensitivity reactions, such as rash, itching, and anaphylaxis. These effects can be more common in patients with pre-existing skin conditions or those taking medications that can affect the skin.

**Drug Interactions**

- Diflunisal can interact with other medications, including corticosteroids, diuretics, and anticoagulants. These interactions can affect the dose and efficacy of treatment and may increase the risk of adverse effects.

**Overdosage**

- Overdosage of diflunisal can lead to serious adverse effects, including gastrointestinal bleeding, hepatic necrosis, and cardiovascular collapse. Treatment should include supportive care and monitoring of vital signs and laboratory parameters.

**Dosage and Administration**

- The recommended dosage of diflunisal tablets for adults is 500 mg twice daily, with or without food. The dosage may be increased to 1000 mg twice daily if necessary. The dosage should be individualized based on the patient’s response and the severity of the condition.

**PRECAUTIONS**

- Diflunisal tablets should be used with caution in patients with pre-existing cardiovascular disease, renal disease, or liver disease.

**Patient Counseling Information**

- Patients should be instructed to discontinue diflunisal tablets if they develop symptoms of GI bleeding or perforation, including melena, hematemesis, or unexplained anemia.

**Pharmacology**

- Diflunisal is rapidly absorbed after oral administration and reaches peak plasma concentrations within 1 to 3 hours. The elimination half-life is approximately 2 to 3 hours.

**Chemical Abstracts Service Registry Number**

121-13-2

**Molecular Formula**

C₁₃H₁₃F₂NO₂

**Molecular Weight**

234.26

**Uses**

Diflunisal tablets are indicated for the symptomatic treatment of mild to moderate pain, rheumatoid arthritis, osteoarthritis, primary dysmenorrhea, ankylosing spondylitis, juvenile rheumatoid arthritis, and juvenile ankylosing spondylitis.

**INFORMATION FOR PATIENTS**

- Patients should be instructed to report any symptoms of allergic reactions, such as rash, itching, or trouble breathing, to their healthcare provider immediately.

**NURSE'S GUIDE**

- Nurses should monitor patients for signs of bleeding, renal function, and liver function.

**PHARMACIST'S GUIDE**

- Pharmacists should ensure that patients receive adequate pain management and provide guidance on the safe and effective use of diflunisal tablets.

**References**


**Further Reading**


**Contact Information**

- For more information, please contact the manufacturer's customer service department.

**Package Insert**

- The package insert contains detailed information on the product, including dosage, administration, precautions, and adverse effects.

**Additional Resources**

Dizziness.

Psychiatric

Gastrointestinal

Incidence Greater Than 1%

48 weeks, and 46 patients were treated for 96 weeks. In general, the adverse reactions listed below were 2 to 14 times

resulted in increased mortality and some cataracts, whereas the effects of diflunisal administration at doses up to 140

tablets in pediatric patients below the age of 12 is not recommended.

Pediatric Use

adverse reactions in nursing infants from diflunisal, a decision should be made whether to discontinue nursing or to

Diflunisal is excreted in human milk in concentrations of 2 to 7% of those in plasma. Because of the potential for serious

In rat studies with NSAIDs, as with other drugs known to inhibit prostaglandin synthesis, an increased incidence of

ductus arteriosus prenatally, tricuspid incompetence, and pulmonary hypertension; non-closure of the ductus

adequate and well controlled studies with diflunisal in pregnant women. Diflunisal tablets should be used in pregnancy

A dose of 60 mg/kg/day of diflunisal (equivalent to two times the maximum human dose) was maternotoxic, embryotoxic,

No evidence of impaired fertility was found in reproduction studies in rats at doses up to 50 mg/kg/day.

Diflunisal did not affect the type or incidence of neoplasia in a 105 week study in the rat given doses up to 40 mg/kg/day

Serum Salicylate Assays

Acute anaphylactic reaction with bronchospasm; angioedema; flushing. Hypersensitivity vasculitis. Hypersensitivity

Central Nervous System

Psychiatric

Hematologic

Gastrointestinal

Erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, urticaria, pruritus,

Stomach and Intestines

Serious Side effects include:

• stroke
• heart attack
• low red blood cells (anemia)
• chest pain
• shortness of breath or trouble breathing

see WARNINGS).

if you had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAID medicine

Keep a list of your medicines to show to your healthcare provider and pharmacist.

for the shortest time needed

exactly as prescribed

drinking alcohol

It is very important that your doctor or healthcare provider know if you are taking any of the following medicines:

Meloxicam
Indomethacin
Ibuprofen
Etodolac
Diclofenac
Naproxen
Ibuprofen Suspension
Ibuprofen suspension in pediatric/infant
Ibuprofen Suspension Oral Solution
Ibuprofen Suspension Pediatric
Ibuprofen Suspension Pediatric Oral Solution
Ibuprofen Tablets
Ibuprofen tablets
Ibuprofen Tablets Adult
Ibuprofen Tablets Adult Oral
Ibuprofen Tablets For Adults
Ibuprofen Tablets Pediatric
Ibuprofen Tablets Pediatric Oral
Ibuprofen Tablets Pediatric Oral Solution
Ibuprofen Tablets Pediatric Oral Suspension
Meloxicam Tablets
Meloxicam Tablets Adult
Meloxicam Tablets For Adults
Meloxicam Tablets Oral
Meloxicam Tablets Oral Suspension
Naproxen Sodium Tablets
Naproxen Sodium Tablets Adult
Naproxen Sodium Tablets For Adults
Naproxen Sodium Tablets Oral
Naproxen Sodium Tablets Oral Suspension
Naproxen Tablets
Naproxen Tablets Adult
Naproxen Tablets For Adults
Naproxen Tablets Oral
Naproxen Tablets Oral Suspension
Naproxen Tablets Oral Solution
Naproxen Tablets Pediatric
Naproxen Tablets Pediatric Oral
Naproxen Tablets Pediatric Oral Suspension
Naproxen Tablets Pediatric Oral Solution

Medication Guide for Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

Do not

In rare cases, diflunisal may cause death.

Methotrexate

Lithium

What are Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)?

Warfarin or other anticoagulants

the ductus arteriosus, resulting in death.

may cause death.

if you are breastfeeding.

if you are pregnant.

if you are allergic to any of the following medicines:

Stomach

Continued

Muscle cramps.