Leaflet Froben Tablets
Size: 161mm x 136mm
Ammara Commercial Printers (Pvt.) Ltd.

<table>
<thead>
<tr>
<th>System/Organ/Class</th>
<th>Frequency</th>
<th>Adverse reaction (PT/Ha/DM/476)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood and lymphatic system disorders</td>
<td>Uncommon</td>
<td>Anemia</td>
</tr>
<tr>
<td>Immune system disorders</td>
<td>Very rare</td>
<td>Leucopenia, agranulocytosis, platelet agranulocytosis, eczematous, thrombocytopenia, haemolytic anaemia</td>
</tr>
<tr>
<td>Psychic system disorders</td>
<td>Rare</td>
<td>Depression, confusional state</td>
</tr>
<tr>
<td>Kidney disorders</td>
<td>Very rare</td>
<td>Nephrotoxicity</td>
</tr>
<tr>
<td>Respiratory, nose and throat disorders</td>
<td>Uncommon</td>
<td>Apnoea, laryngospasm</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>Common</td>
<td>Gastric, duodenal, erosive, vomiting, abdominal pain, flatulence, diarrhoea, constipation, dyspepsia, nausea, vomiting, gastritis, haemorrhagic gastritis, jejunitis, pancreatitis</td>
</tr>
<tr>
<td>Reproductive system disorders</td>
<td>Very rare</td>
<td>Premenstrual</td>
</tr>
<tr>
<td>Connective tissue disorders</td>
<td>Very rare</td>
<td>Arthritis, fasciitis, periarthritis</td>
</tr>
<tr>
<td>Sensory disorders</td>
<td>Very rare</td>
<td>Arachnoiditis, optic neuritis, optic atrophy, optic neuritis, optic atrophy</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>Very rare</td>
<td>Arthritis, fasciitis, periarthritis</td>
</tr>
<tr>
<td>Head and neck disorders</td>
<td>Rare</td>
<td>Nephrototoxicity, eosinophilia, granulomatous nephritis, nephrotic syndrome, renal failure and renal failure acute phase (section 4.4)</td>
</tr>
<tr>
<td>Not known</td>
<td>Common</td>
<td>Gynaecomastia, cholestatic jaundice</td>
</tr>
</tbody>
</table>

OVERDOSE
Symptoms of overdosage may include nausea, vomiting and gastrointestinal irritation. There is no specific antidote to Froben.

STORAGE
Proguard, light, and moisture.

HOW SUPPLIED
Froben Film-Coated Tablets in blister packs of 3 x 3s (Code No. N898)
Froben 100mg Film-Coated Tablets in blister packs of 3 x 3s (Code No. N899)

Manufactured by:
Abbott Laboratories (Pakistan) Ltd.
Landhi, Karachi.

SOLID 1000087344 v3.0 06-Nov-2014

Froben
(Flurbiprofen)
Tablets

PRODUCT DESCRIPTION
Froben is a non-steroidal anti-inflammatory drug (NSAID) with analgesic and antipyretic activity. Its molecular weight is 323.40 g/mol. Its empirical formula is C17H1BNO4. Its chemical name is 2-(4-fluorophenyl)-4-pyridylacetic acid.

INDICATIONS
Froben is indicated for the treatment of inflammatory arthritis, including juvenile arthritis and its dose, osteoarthritis, resolving soft-tissue, acute uveitis, musculoskeletal disorders and certain non-infectious, allergic, inflammatory and musculoskeletal disorders and certain ocular syndromes such as pterygium, frozen shoulder, bursitis, tendinitis, bicipital tendinitis, tenosynovitis, glomerulonephritis, interstitial nephritis, respiratory disorders, and asthma.

DOSE AND ADMINISTRATION
Adults
The recommended dose is 50 to 200 mg daily in three or four divided doses. In patients with severe symptoms or as a means of rapidity of drug effect, the dose is increased to 400 mg daily divided doses. For children, a dosage of 10 mg may be administered at the start of symptoms. Followed by 50 or 100 mg every four to six hours. The maximum total daily dose should not exceed 525 mg.

Geriatric population
Although Froben is generally well tolerated in the elderly, some patients, especially those with impaired renal function may be more severely affected. In these cases, Froben should be used with caution and renal function assessed weekly.

Pediaes
Froben tablets must not be recommended for use in children under 15 years.

PHARMACOLOGIC PROPERTIES
Froben has anti-inflammatory and analgesic properties, and is thought to act from the drug's ability to inhibit prostaglandin synthesis.

CONTRAINDICATIONS
Froben is contraindicated in patients with known hypersensitivity to the active substance or to any of the excipients. This drug should not be given to patients who have experienced serious, urticarial drug hypersensitivity reactions such as anaphylaxis, angioedema, asthma, or bronchospasm.

Froben also contraindicated in patients with a history of gastrointestinal bleeding or perforation, related to previous NSAID therapy. Froben is not to be used in patients with active, or a history of, ulcerative colitis, Crohn’s disease, recurrent peptic ulceration or gastrointestinal haemorrhage defined as two or more distinct episodes of proven ulceration or bleeding.

Froben is contraindicated in severe heart failure, renal failure or hepatic failure. Froben is contraindicated in intravascular volume depletion.

PRECAUTIONS
Caution is necessary if Froben is given to patients with a history of heart failure or hypertension with severe signs of fluid retention have been reported in association with Froben administration. Froben, like other NSAIDs, may inhibit platelet aggregation and prolong bleeding time, which may be severe in patients on concurrent antiplatelet therapy, such as aspirin therapy. Use of NSAIDs may be associated with the formation of renal scars.

Gastrointestinal Bleeding, Ulceration and Perforation
Froben should be given with caution to patients with a history of peptic ulceration or other gastrointestinal disease. Froben should be given with caution to patients with a history of peptic ulceration and other gastrointestinal disease. Patients on concurrent antiplatelet therapy, such as aspirin therapy, may be at higher risk. Use of NSAIDs may be associated with the formation of renal scars.

Froben is not recommended for use in patients with a history of gastrointestinal bleeding or perforation. The use of oral gastrointestinal bleeding or perforation has been reported at all NSAIDs at any time during treatment. These adverse events can be fatal and may occur with or without symptoms or previous history of such gastrointestinal events.

The use of gastrointestinal bleeding or perforation higher with increasing Flurbiprofen dose in patients with a history of ulcers, particularly if complicated with hemorrhage or perforation, and in the elderly. These patients should be monitored closely. Combination therapy with protective agents (e.g., aspirin or proton pump inhibitor) should be considered for these patients.

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patients, as well as patients requiring continuous dialysis access, or for other drugs likely to increase gastrointestinal risk. Patients with a history of gastrointestinal disease, particularly peptic ulcer disease, should have any known abdominal symptoms (including gastrointestinal bleeding) evaluated at the start of treatment. If gastrointestinal symptoms of ulceration or perforation occur, treatment should be withdrawn.

Disorders
Breast cancer has been reported with high or low dose adenosine use in patients with a history of breast cancer.

Cardiovascular and Hypertensive
Cardiovascular disease is a patient's risk of cardiovascular disease, but the study found that high dose adenosine administration may delay the function of adenosine signs and symptoms and cause more rapid development of coronary artery disease. Increased use of coronary angiography to reduce the risk of catheterization in non-cardiac patients should be reduced.

Contraindication and Cardiovascular
Patients receiving antiplatelet drugs or anticoagulants should be monitored for increased risk of adverse events, such as myocardial infarction and stroke. There is evidence of increased risk of these events in patients receiving antiplatelet drugs or anticoagulants.

Dermoscopy
Some patients may have a history of cardiovascular disease or hypertension. However, there is no evidence to suggest that adenosine administration increases the risk of cardiovascular disease or hypertension. In these patients, the risk of these events may be higher than in patients taking antiplatelet drugs or anticoagulants.

Drug Interactions
Adenosine may increase the risk of adverse reactions to other drugs. Therefore, it is important to monitor for adverse reactions to other drugs, such as antiplatelet drugs or anticoagulants, and to avoid the use of other drugs that may increase the risk of adverse reactions to adenosine.

Gastroesophageal Reflux Disease
Patients with a history of gastroesophageal reflux disease, particularly peptic ulcer disease, should be monitored for increased risk of these events in patients receiving adenosine administration.

Immunosuppression
The use of adenosine may impair immune function and may be detrimental to patients receiving immunosuppressive therapy. In women with a history of ovarian cancer, an increased risk of adverse reactions to adenosine may be observed.

Lactic Acidosis
Lactic acidosis is a potential complication of adenosine administration. In patients with a history of cardiovascular disease, particularly peptic ulcer disease, the risk of lactic acidosis may be higher than in patients not receiving adenosine.

PERIODIC REVIEWS
The use of adenosine may impair immune function and may be detrimental to patients receiving immunosuppressive therapy. In women with a history of ovarian cancer, an increased risk of adverse reactions to adenosine may be observed.