Leaflet Brufen 600mg Tabs.
Size: 190 x 173mm
Ammara Commercial Printers (Pvt.) Ltd.

<table>
<thead>
<tr>
<th>Immune system disorders</th>
<th>Rare</th>
<th>Uncommon</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Amphotericin cation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Amphotericin oxonate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Neurological disorders</th>
<th>Uncommon</th>
<th>Uncommon</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Amphotericin citrate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Amphotericin oxonate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Eye disorders</th>
<th>Uncommon</th>
<th>Rare</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Tocopheryl succinate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tocopheryl succinate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Osteoarticular disorders</th>
<th>Uncommon</th>
<th>Rare</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Tocopheryl succinate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tocopheryl succinate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Venous disorders</th>
<th>Uncommon</th>
<th>Rare</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Tocopheryl succinate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tocopheryl succinate</td>
</tr>
</tbody>
</table>

**OVERDOSAGE**
The symptoms of overdose include nausea, vomiting, dizziness, loss of consciousness and depression of the CNS and respiratory system. Large overdoses are generally well tolerated, but other drugs and alcohol in particular may be serious in specific situations. In general, no specific antidote is known. However, fasting and forced diuresis may be useful in treating overdoses.

**STORAGE**
Store at room temperature, protected from light.

**MOPED Supplied**
Brufen 600mg tablets in blister packs of 3 (Pack size No. 1060)

---

Further information is available on request.
Manufactured by: Abbott Laboratories (Pakistan) Ltd.
Landhi, Karachi.

---

**BRUFEN**

**(Ibuprofen)**

600mg

Ibuprofen is a member of the propionic acid group of non-steroidal anti-inflammatory drugs (NSAIDs). It has shown anti-inflammatory, analgesic and antipyretic activity. These properties provide symptomatic relief of inflammation, pain and fever.

**INDICATIONS**
Ibuprofen is indicated for the treatment of headache, musculoskeletal pain, dental pain, and post-operative pain, such as fever and headache, post-operative pain. It is also used for the treatment of rheumatoid arthritis, osteoarthritis and peripheral joint conditions. It may also be used in the treatment of inflammatory conditions such as gout, psoriasis, psoriatic arthritis, ankylosing spondylitis, and rheumatoid arthritis. Ibuprofen is also used for the treatment of pain associated with gout, and for the symptomatic relief of headache including migraine headaches. Ibuprofen is used in the treatment of gout.

**CONTRAINDICATIONS**
Ibuprofen is contraindicated in patients with known hypersensitivity to any of the excipients in the formulation. It should not be used in patients with a history of peptic ulceration or bleeding, or in patients who have had previous gastrointestinal hemorrhage. It is also contraindicated in patients with a history of hepatic failure or renal impairment.

**PRECAUTIONS**
Ibuprofen should be used with caution in patients with a history of peptic ulceration or bleeding, or other gastrointestinal disorders since these conditions may be exacerbated by the use of NSAIDs. In addition, patients with a history of peptic ulceration or bleeding, or with a history of gastrointestinal hemorrhage, or with a history of peptic ulceration or bleeding, or with conditions that increase the risk of peptic ulceration or bleeding, such as anticoagulant use, corticosteroid use, or alcohol or tobacco use, should be monitored closely.

**DOSAGE AND ADMINISTRATION**
Ibuprofen is administered orally as a suspension or as a capsule. The dosage should be based on the patient's age and weight. The usual dosage range is 200 to 600 mg three times a day. The maximum daily dose should not exceed 1200 mg. The suspension may be administered to children 12 years of age and older, or to adults, at a dose of 200 to 400 mg every 6 to 8 hours. The capsule may be administered to children 12 years of age and older, or to adults, at a dose of 200 to 600 mg every 6 to 8 hours.

**ADVERSE REACTIONS**
The most common adverse reactions are gastrointestinal and include nausea, vomiting, diarrhea, anorexia, abdominal pain, dyspepsia, and diarrhea. Other common adverse reactions include headache, dizziness, and confusion. Rare adverse reactions include dermatological reactions, such as urticaria, erythema multiforme, and angioedema. Severe adverse reactions include anaphylaxis, Stevens-Johnson syndrome, and toxic epidermal necrolysis. These adverse reactions are rare but may occur and should be reported to the manufacturer. In addition, patients with a history of gastrointestinal disorders, such as peptic ulceration or bleeding, should be monitored closely.

**CONTRAINDICATIONS**
Ibuprofen is contraindicated in patients with a history of peptic ulceration or bleeding, or with a history of gastrointestinal hemorrhage, or with a history of peptic ulceration or bleeding, or with conditions that increase the risk of peptic ulceration or bleeding, such as anticoagulant use, corticosteroid use, or alcohol or tobacco use, should be monitored closely.

**PRECAUTIONS**
Ibuprofen should be used with caution in patients with a history of peptic ulceration or bleeding, or other gastrointestinal disorders since these conditions may be exacerbated by the use of NSAIDs. In addition, patients with a history of peptic ulceration or bleeding, or with a history of gastrointestinal hemorrhage, or with a history of peptic ulceration or bleeding, or with conditions that increase the risk of peptic ulceration or bleeding, such as anticoagulant use, corticosteroid use, or alcohol or tobacco use, should be monitored closely.

**DOSAGE AND ADMINISTRATION**
Ibuprofen is administered orally as a suspension or as a capsule. The dosage should be based on the patient's age and weight. The usual dosage range is 200 to 600 mg three times a day. The maximum daily dose should not exceed 1200 mg. The suspension may be administered to children 12 years of age and older, or to adults, at a dose of 200 to 400 mg every 6 to 8 hours. The capsule may be administered to children 12 years of age and older, or to adults, at a dose of 200 to 600 mg every 6 to 8 hours.

**ADVERSE REACTIONS**
The most common adverse reactions are gastrointestinal and include nausea, vomiting, diarrhea, anorexia, abdominal pain, dyspepsia, and diarrhea. Other common adverse reactions include headache, dizziness, and confusion. Rare adverse reactions include dermatological reactions, such as urticaria, erythema multiforme, and angioedema. Severe adverse reactions include anaphylaxis, Stevens-Johnson syndrome, and toxic epidermal necrolysis. These adverse reactions are rare but may occur and should be reported to the manufacturer. In addition, patients with a history of gastrointestinal disorders, such as peptic ulceration or bleeding, should be monitored closely.
Drug interaction

Concomitant use of bifurogen with: | Possible effects:
---|---
Other NSDAs, including clopidogrel: 2 selective inhibitors | Concomitant use with other NSDAs, including clopidogrel-2 selective inhibitors, should be avoided due to the potential for additive effects.
Cardio glycosides | NSDAs may exacerbate heart failure, reduce glomerular filtration rate and increase plasma level of cardiovascular.
Anticoagulants | Increased risk of gastrointestinal ulceration or bleeding with NSDAs.
Anticoagulants | NSDAs may enhance the effects of anticoagulants, such as warfarin.
Anticoagulants, agents & selective serotonin reuptake inhibitors (SSRIs) (e.g. paroxetine, sertraline) | Increased risk of gastrointestinal bleeding with NSDAs.
Asystolic acidosis is an As well as other products containing NSDAs, concomitant administration of bifurogen and asystolic acidosis is not generally recommended because of the potential for increased adverse effects.
Lithium | NSDAs may increase antihypertensive effects.
Anti-hypertensive, beta-blockers and Calcium channel blockers | NSDAs may reduce the effect of anti-hypertensive, such as ACE inhibitors, angiotensin II receptor antagonists, beta-blockers and calcium channel blockers.
Methotrexate | NSDAs may inhibit the tubular secretion of methotrexate and reduce clearance of methotrexate.
Cyclosporine | Increased risk of nephrotoxicity with NSDAs.
Tetracyclines | Possible increased risk of nephrotoxicity when NSDAs are given with tetracyclines.
Zidovudine | Increased risk of hemolytic anemia when NSDAs are given with zidovudine.
Quinolone antibiotics | Animal data indicate that NSDAs can increase the risk of convolution associated with quinolone antibiotics. Patients taking NSDAs and quinolone antibiotics may have an increased risk of developing convulsions.
CYP450 inhibitors | Concomitant administration of bifurogen with CYP450 inhibitors may increase the exposure to bifurogen (CYP450 substrates) by a study with voriconazole and fluconazole (CYP3A4 inhibitors), an increase in CYP450 3A4 expression by approximately 100% has been seen. Reduction of the bifurogen dose should be considered when CYP450 inhibitors are administered concurrently, particularly when high-dose bifurogen is administered.
Sulfonamides | NSDAs may potentiate the effects of sulfonamide medications. There have been rare reports of hypoglycemia in patients on sulfonamide medications receiving bifurogen.
Cholestatics | The concomitant administration of bifurogen and cholestatics may reduce the excretion of bile in the gastrointestinal tract. However, the clinical significance of this interaction has not been established.
Anticoagulants | NSDAs may decrease the efficacy of anticoagulants.
Herbal remedies | Ginkgo biloba may potentiate the risk of bleeding with NSDAs.

Adverse reactions

A decrease in the efficacy of the medicinal product can be observed due to the drug-drug interactions of NSDAs, including warfarin and dabigatran. However, the clinical significance of this interaction has not been established. Furthermore, NSDAs may reduce the risk of bleeding, but does not reduce the clinical efficacy of medicated treatment for primary prevention.

Fertility

Use of bifurogen may impair female fertility and is not recommended in women attempting to conceive. In women who require fertility treatment, it is recommended to discontinue bifurogen prior to conception. Bifurogen is contraindicated in breastfeeding mothers.

Pregnancy

Bifurogen is not recommended during pregnancy. Data from epidemiological studies suggest that there is a risk of increased risk of congenital malformations and gestational diabetes with the use of a prophylactic anticoagulant during pregnancy. In general, the administration of a prophylactic anticoagulant during pregnancy is not recommended. During the first two trimesters of pregnancy, bifurogen should not be given unless clearly necessary. If bifurogen is used during pregnancy, it should be discontinued at least 2 weeks postpartum.

Lactation

Bifurogen is not recommended during lactation. The drug is excreted into breast milk.

Effects on Ability to Drive and Use Machines

Following treatment with bifurogen, patients should be aware that they may experience dizziness and/or昏睡, which may affect their ability to drive or use machines.

Adverse reactions

The most common observed adverse effects are gastrointestinal in nature. Nausea, vomiting, diarrhea, bloating, constipation, dyspepsia, abdominal pain, flatulence, and diarrhea are reported. However, these effects are usually mild and self-limiting. In rare cases, serious adverse reactions such as Stevens-Johnson syndrome, drug-induced eosinophilic necrotizing vasculitis, or aplastic anemia have been reported.

Gastrointestinal disorders

Gastrointestinal disorders, which are the most common observed adverse effects, are usually mild and self-limiting. They include nausea, vomiting, diarrhea, bloating, constipation, abdominal pain, flatulence, and diarrhea.

Cardiovascular disorders

Cardiovascular disorders are not common and include atrial fibrillation, heart failure, and angina.

Skin and cutaneous disorders

Skin and cutaneous disorders, which are not common, include pruritus, rash, erythema, and urticaria.

Infections and infestations

Infections and infestations are not common and include pneumonia, urinary tract infection, and skin infections.

System organ class | Frequency | Adverse reaction
---|---|---
Nervous system | Rare | Nausea, vomiting, diarrhea, constipation, dyspepsia, abdominal pain, flatulence, and diarrhea.
Respiratory system | Rare | Aplastic anemia and eosinophilic necrotizing vasculitis.
Kidney and urinary tract | Rare | Nephrotic syndrome, drug-induced eosinophilic necrotizing vasculitis, or aplastic anemia.