

BRUFIO Plus Oral Suspension



Composition:

Each 5 ml of BRUFIO Plus oral suspension contains: Ibuprofen 100 mg and Paracetamol 125 mg.

Mechanism of Action:

Ibuprofen is a NSAID that possesses anti-inflammatory, analgesic and antipyretic activity. These pharmacological effects are due to their inhibitory effect on the enzyme cyclooxygenase, which results in a marked reduction in prostaglandin synthesis. Paracetamol has analgesic and antipyretic effects, by inhibiting prostaglandin synthesis in the central nervous system.

Pharmacokinetics:

Ibuprofen is rapidly absorbed from the gastrointestinal tract, peaking in serum concentrations 1-2 hours after administration. Ibuprofen is highly bound to plasma proteins, has a half-life of about 2 hours, ibuprofen is metabolized in the liver to two inactive metabolites, more than 90% of the ingested dose is excreted in the urine as metabolites or conjugates. Paracetamol is well and almost completely absorbed after oral administration. It's metabolized in the liver primarily by conjugation. Paracetamol has half-life of 1 to 4 hours, time to peak concentration of 0.5 to 2 hours, time to peak effect of 1 to 3 hours and the duration of action from 3 to 4 hours. It is mainly excreted in the urine as metabolites, and 3% of the dose may be excreted unchanged.

Indications:

BRUFIO Plus is indicated for the treatment of inflammation and relief of mild to moderate pain in conditions such as headaches, including migraines, post-operative pain, dental pain and musculo-skeletal joint disorders. It is also used to reduce fever.

Contraindications:

BRUFIO Plus is contraindicated in:

- Patients who are hypersensitive to the active substance, to other NSAIDs, or to any of the components of the preparation.
- Patients who have previously shown hypersensitivity reactions (e.g., asthma, angioedema or rhinitis) after taking aspirin or other NSAIDs.
- Patients with peptic ulcer active or history of recurrent peptic ulcer or GI perforation or GI bleeding (two or more distinct episodes of proven ulceration or bleeding).
- Patients with defects in coagulation.
- Patients with severe hepatocellular insufficiency, severe renal failure or severe heart failure.

Warnings & Precautions: Caution is required in patients with:

- Gastrointestinal diseases including chronic inflammatory intestinal disease (Ulcerative Colitis, Crohn's disease).
 - Glucose-6-phosphate-dehydrogenase deficiency.
 - Allergies, hay fever, chronic swelling of nasal mucosa, chronic obstructive pulmonary disease, or bronchial asthma.
 - Chronic alcohol use.
 - Mild to moderate congestive heart failure and hypertension.
 - Reduced renal function and Hepatic dysfunction.
 - Systemic lupus erythematosus and mixed connective tissue disease disorders.
 - Disturbed haematopoiesis and blood coagulation defects
- Gastrointestinal bleeding, ulceration and perforation has been reported with all NSAIDs at any time during treatment, with or without warning symptoms.

Pregnancy & Lactation:

Pregnancy: The use of BRUFIO Plus should be avoided in the first six months of pregnancy and contraindicated in the last three months of pregnancy.

Lactation: It is not necessary to interrupt breastfeeding for short-term treatment with the recommended dose.

Drug Interactions:

- Anticoagulants: BRUFIO Plus may enhance the effects of anticoagulants, such as warfarin.
- Antihypertensives (e.g., beta-blockers, diuretics): BRUFIO Plus may reduce the effect of these drugs.
- Aspirin and other NSAIDs: increased adverse effects.
- Metoclopramide and Domperidone: These drugs may increase the absorption of paracetamol when one of them is used concomitantly.
- Cholestyramine: The speed of absorption of paracetamol and ibuprofen is reduced by cholestyramine. Therefore, should not be taken within an hour of taking them.
- Methotrexate, Aminoglycosides and Lithium: NSAIDs may reduce clearance of these drugs.
- Barbiturates and Alcohol: May increase the hepatotoxicity of paracetamol.
- CYP2C9 Inhibitors (like voriconazole or fluconazole): Reduction of the BRUFIO Plus dose should be considered when potent CYP2C9 inhibitors are administered concomitantly.

Side Effects:

Undesirable effects may be minimized by using the lowest effective dose for the shortest duration and by taking the medicine with food. Common side effects: heartburn, dyspepsia, abdominal pain, nausea, flatulence, diarrhea, constipation, gastrointestinal ulcers, sometimes with bleeding and perforation, drowsiness, dizziness,

fatigue, restlessness and irritability.

Rare and Uncommon side effects: decrease in haemoglobin and haematocrit values, inhibition of platelet aggregation, prolonged bleeding time and photosensitivity.

Driving & Using Machines:

BRUFIO Plus generally has no adverse effects on the ability to drive and use machinery.

Dosage & Administration:

BRUFIO Plus is indicated in the treatment of minor pains and for reduction of fever.

Dosage in children:

Age	Dosage
Infants 3 - 6 months (Weighing more than 5 kg) *	2 - 2.5 ml dose may be taken 3 times daily
> 6 months - 12 months	2 -2.5 ml dose may be taken 3 to 4 times daily
1- 4 years	4 -4.5 ml dose may be taken 3 to 4 times daily
4 -7 years	4 -8 ml dose may be taken 3 to 4 times daily
7 -10 years	8 -10 ml dose may be taken 3 to 4 times daily
10 -12 years	8 -15 ml dose may be taken 3 to 4 times daily

* BRUFIO Plus is not recommended for children weighing less than 5 kg.

Overdose:

Symptoms include nausea, vomiting, dizziness and rarely loss of consciousness. Large overdoses are generally well tolerated when no other drugs are involved. Treatment consists of gastric lavage and if necessary, correction of serum electrolytes and appropriate supportive measures.

There is no specific antidote to ibuprofen.

The hepatic changes produced by over dosage of paracetamol result from the accumulation of a highly active intermediate metabolite in the hepatocytes.

N-acetylcysteine intravenously or 1- methionine orally protects the liver within 10-12 hours of taking the overdose.

Storage: Keep out of reach of children. Store below 25° C.

Packaging: Each BRUFIO Plus carton box contains amber glass bottle of 100 ml.

*A medication is a product which affects your health, and it's consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist experts in medicine, it's benefits and risks.
- Do not repeat the same prescription without consulting your doctor.
KEEP THE MEDICAMENTS OUT OF REACH OF CHILDREN
Council of Arab Pharmaceutical Industry - Union of Arab Pharmacists

Revva Pharmaceutical Industry - Syria

