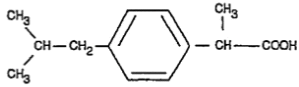
BLUDOL

(Ibuprofen)USP

TABLETS
SUSPENSION

DESCRIPTION:
Bludol contains the active ingredient ibuprofen, which is (±) - 2 - (p - isobutylphenyl) propionic acid. Ibuprofen is a white powder with a melting point of 75-78° C and is very slightly soluble in water (<1 mg/mL) and readily soluble in organic solvents such as ethanol and acetone. The structural formula is represented below:



Bludol Suspension, a nonsteroidal anti-inflammatory drug (NSAID), is available in 100mg/5ml for oral administration.

COMPOSITION:

1. Bludol Tablet 200mg:
Each tablet contains: Ibuprofen.....200mg
2. Bludol Tablet 400mg:
Each tablet contains: Ibuprofen.....400mg
3. Bludol Suspension:
Each 5ml contains: Ibuprofen.....100mg
In a Blackcurrant flavored suspension.
4. Bludol Suspension DS
Each 5ml contains: Ibuprofen.....200mg
In a Blackcurrant flavored suspension.

CLINICAL PHARMACOLOGY:
Bludol Suspension contains Ibuprofen which possesses analgesic and antipyretic activities. Its mode of action, like that of other NSAIDs, is not completely understood, but may be related to prostaglandin synthetase inhibition.

INDICATIONS AND USAGE:
Bludol Suspension exhibits potent antipyretic, analgesic and anti-inflammatory properties. It is therefore indicated in pyrexia, associated with upper respiratory tract infection and other disorders, juvenile rheumatoid arthritis soft tissue inflammation, traumatic-inflammation and non-specific aches.

CONTRAINDICATIONS:
Bludol Suspension is contraindicated in patients with known hypersensitivity to Ibuprofen.
Bludol Suspension should not be given to patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients. Bludol Suspension is contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery.

WARNINGS:

1. Cardiovascular Effects:
Cardiovascular Thrombotic Events Clinical trials of several COX-2 selective and nonselective NSAIDs of up to three years duration have shown an increased risk of serious cardiovascular (CV) thrombotic events, myocardial infarction, and stroke, which can be fatal. All NSAIDs, both COX-2 selective and nonselective, may have a similar risk. Patients with known CV disease or risk factors for CV disease may be at greater risk. To minimize the potential risk for an adverse CV event in patients treated with a NSAID, the lowest effective dose should be used for the shortest duration possible.

2. Hypertension:
NSAIDs, including Ibuprofen, should be used with caution in patients with hypertension. Blood Pressure (BP) should be monitored closely during the initiation of NSAID treatment and throughout the course of therapy.

3. Renal Effects:
Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury.

4. Congestive Heart Failure and Edema:
Fluid retention and edema have been observed in some patients taking NSAIDs. Bludol Suspension should be used with caution in patients with fluid retention or heart failure.

5. Gastrointestinal Effects - Risk of Ulceration, Bleeding, and Perforation:
NSAIDs, including Bludol Suspension, can cause serious gastrointestinal (GI) adverse events including inflammation, bleeding, ulceration, and perforation of the stomach, small intestine, or large intestine, which can be fatal.

6. Skin Reactions:
NSAIDs, including Ibuprofen, can cause serious skin adverse events such as exfoliative dermatitis, Stevens Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. These serious events may occur without warning. Patients should be informed about the signs and symptoms of serious skin manifestations and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

1. Pregnancy:
In late pregnancy, as with other NSAIDs, Bludol Suspension should be avoided because it may cause premature closure of the ductus arteriosus.

PRECAUTIONS:
General
Bludol Suspension cannot be expected to substitute for corticosteroids or to treat corticosteroid insufficiency.
Hepatic effects
Borderline elevations of one or more liver tests may occur in up to 15% of patients taking NSAIDs, including Bludol Suspension.
Hematological effects
Anemia is sometimes seen in patients receiving NSAIDs, including Bludol Suspension.
Pre-existing asthma
Patients with asthma may have aspirin-sensitive asthma. The use of aspirin in patients with aspirin-sensitive asthma has been associated with severe bronchospasm, which can be fatal.

Ophthalmological effects:
Blurred and/or diminished vision, scotoma, and/or changes in color vision have been reported

Aseptic Meningitis:
Aseptic meningitis with fever and coma has been observed on rare occasions in patients on ibuprofen therapy.

Drug Interactions:
ACE-inhibitors
Reports suggest that NSAIDs may diminish the antihypertensive effect of ACE-inhibitors. This interaction should be given consideration in patients taking NSAIDs
concomitantly with ACE-inhibitors.

Aspirin
When Bludol Suspension is administered with aspirin, its protein binding is reduced, although the clearance of free Bludol tablets/suspension is not altered. The clinical significance of this interaction is not known; however, as with other NSAIDs, concomitant administration of Ibuprofen and aspirin is not generally recommended because of the potential for increased adverse effects.
Diuretics
Clinical studies, as well as post marketing observations, have shown that Bludol Suspension can reduce the natriuretic effect of furosemide and thiazides in some patients. This response has been attributed to inhibition of renal prostaglandin synthesis. During concomitant therapy with NSAIDs, the patient should be observed closely for signs of renal failure as well as to assure diuretic efficacy.
Lithium
Ibuprofen produced an elevation of plasma lithium levels and a reduction in renal lithium clearance in a study of eleven normal volunteers. The mean minimum lithium concentration increased 15% and the renal clearance of lithium was decreased by 19% during this period of concomitant drug administration. This effect has been attributed to inhibition of renal prostaglandin synthesis by ibuprofen. Thus, when ibuprofen and lithium are administered concurrently, subjects should be observed carefully for signs of lithium toxicity.
Methotrexate
NSAIDs have been reported to competitively inhibit methotrexate accumulation in rabbit kidney slices. This may indicate that they could enhance the toxicity of methotrexate. Caution should be used when NSAIDs are administered concomitantly with methotrexate.
Warfarin-type anticoagulants
Several short-term controlled studies failed to show that Bludol Suspension significantly affected prothrombin times or a variety of other clotting factors when administered to individuals on coumarin-type anticoagulants. However, because bleeding has been reported when Bludol Suspension and other NSAIDs have been administered to patients on coumarin-type anticoagulants, the physician should be cautious when administering Bludol Suspension to patients on anticoagulants. The effects of warfarin and NSAIDs on GI bleeding are synergistic, such that the users of both drugs together have a risk of serious GI bleeding higher than users of either drug alone.
H-2 Antagonists
In studies with human volunteers, co-administration of cimetidine or ranitidine with ibuprofen had no substantive effect on ibuprofen serum concentrations.
Pregnancy
Teratogenic effects-Pregnancy Category C
Nursing Mothers
It is not known whether this drug is excreted in human milk.
Pediatric Use
Safety and effectiveness of Bludol Suspension in pediatric patients have not been established.
Geriatric Use
As with any NSAIDs, caution should be exercised in treating the elderly (65 years and older).
ADVERSE REACTIONS
The most frequent type of adverse reaction occurring with Bludol Suspension is gastrointestinal.

- upset stomach, mild heartburn, nausea, vomiting;
- bloating, gas, diarrhea, constipation;
- dizziness, headache, nervousness;
- decreased appetite;
- mild itching or rash; or.
- ringing in your ears.

OVERDOSAGE:
In cases of acute overdosage, the stomach should be emptied by vomiting or lavage, though little drug will likely be recovered if more than an hour has elapsed since ingestion. Because the drug is acidic and is excreted in the urine, it is theoretically beneficial to administer alkali and induce diuresis. In addition to supportive measures, the use of oral activated charcoal may help to reduce the absorption and re-absorption of Bludol Suspension.
INSTRUCTIONS:
Store at 15-30°C.
Protect from heat and light.
Keep all medicines out of the reach of children.
To be sold on the prescription of a registered medical practitioner only.
Shake well before use.
DOSAGE AND ADMINISTRATION:
For Bludol Suspension:
6 months – 2 years: 20mg/kg/day in divided doses.
2 years – 6 years: One teaspoon three to four times daily.
6 years – 12 years: Two teaspoons three to four times daily, or as directed by the physician.
For Bludol DS Suspension:
3 years – 7 years: Half teaspoon three to four times daily.
8 years – 12 years: One teaspoon three to four times daily, or as directed by the physician.

بلوڈول

(آئبوپروفن) یو ایس پی

خوراک:
بچوں کے لئے:
تین سے سات سال کی عمر تک: چائے کا آدھا چمچ دن میں تین سے چار مرتبہ
آٹھ سے بارہ سال کی عمر تک: چائے کا ایک چمچ دن میں تین سے چار مرتبہ
یا ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات:
دوا کو 15-30° سینٹی گریڈ پر رکھیں۔
گرمی اور روشنی سے محفوظ رکھیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔
صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔
استعمال سے پہلے اچھی طرح ہلائیں۔

Manufactured by:
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