Ibuprofen and Paracetamol Tablets

Ibu Para

- **COMPOSITION:**
- Each uncoated tablet contains:
- Ibuprofen BP..... 400 mg
- Paracetamol BP..... 500 mg
- Excipients..... q.s.

INDICATIONS

Treatment of mild to moderate pain and inflammation in conditions such as dysmenorrhea, headache (including migraine), post-operative pain, toothache, musculoskeletal and joint disorders, periarticular disorders, and soft tissue disorders (sprains and strains). It also reduces fever.

DOSAGE AND ADMINISTRATION

Adults: 1 tablet 3 times daily.

Adults and adolescents weighing 40 kg or more (aged 12 years or older): Initial dose, 1 Linoflam tablet. If necessary, additional doses of Linoflam tablets may be taken. The appropriate dosing interval should be selected according to the observed symptoms and the maximum recommended daily dose. It should not be less than 6 hours. A total dose of 3 Linoflam tablets must not be exceeded within any 24-hour period.

For short-term use only.

In adults and adolescents (aged 12 to 18 years), Linoflam tablets should not be used for more than 3 days in cases of fever, or for more than 4 days for the treatment of pain, unless recommended by a physician. If symptoms persist or worsen, the patient is advised to consult a physician.

It is recommended that patients with sensitive stomachs take Linoflam tablets with food. If taken immediately after meals, the onset of action of Linoflam tablets may be delayed. If this occurs, do not take more Linoflam tablets than recommended, or until the appropriate re-dosing interval has elapsed.

CONTRAINDICATIONS

Linoflam tablets are contraindicated in:

- Patients with known hypersensitivity to paracetamol, ibuprofen, or any of the excipients.
- In patients with a history of hypersensitivity reactions (e.g., bronchospasm, angioedema, asthma, rhinitis, or urticaria) associated with acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs).
- In patients with a history of gastrointestinal ulceration/perforation or existing bleeding, including those associated with NSAIDs.
- Patients with coagulation disorders.
- In patients with severe hepatocellular insufficiency, severe renal insufficiency, or severe cardiac insufficiency.
- Active, or history of, recurrent or existing peptic ulcer/hemorrhage (two or more distinct episodes of proven ulceration or bleeding).
- Active cerebrovascular or other bleeding.
- Adolescents weighing less than 40 kg and children under 12 years of age.
- Patients with severe dehydration (caused by vomiting, diarrhea, or insufficient fluid intake).
- Third trimester of pregnancy.

PREGNANCY, LACTATION, AND FERTILITY

PREGNANCY:

Inhibition of prostaglandin synthesis may adversely affect pregnancy and/or embryonic/fetal development.

During the first and second trimesters of pregnancy, ibuprofen should not be administered unless clearly necessary. If ibuprofen is used by a woman attempting to conceive, or during the first and second trimesters of pregnancy, the dose should be kept as low as possible and the duration of treatment as short as possible. During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose:

- the fetus to:
  - Cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension)
  - Renal dysfunction, which may progress to renal failure with oligo-hydramnios

- the mother and the neonate, at the end of pregnancy, to:
  - Possible prolongation of bleeding time, an antiplatelet effect that may occur even at very low doses.
  - Inhibition of uterine contractions, resulting in delayed or prolonged labor.

Consequently, ibuprofen is contraindicated during the third trimester of pregnancy.

LACTATION:

Ibuprofen and its metabolites may pass into breast milk in low concentrations. No harmful effects on infants are known to date. Therefore, for short-term treatment at the recommended dosage for pain and fever, discontinuation of breastfeeding is generally not necessary.

FERTILITY

There is some evidence that drugs inhibiting cyclooxygenase/prostaglandin synthesis may cause a decrease in female fertility by affecting ovulation. This effect is reversible upon discontinuation of treatment.

OVERDOSAGE

Paracetamol

Elderly patients, young children, patients with hepatic disorders, chronic alcohol consumption, or chronic malnutrition—as well as patients concomitantly treated with enzyme-inducing drugs—are at increased risk of intoxication, including fatal outcomes.

Signs and Symptoms:

Nausea, vomiting, anorexia, pallor, and abdominal pain typically appear within the first 24 hours following a paracetamol overdose. Paracetamol overdose may cause hepatic cytolysis, which can lead to hepatocellular failure, gastrointestinal bleeding, metabolic acidosis, encephalopathy, disseminated intravascular coagulation, coma, and death. Elevated levels of hepatic transaminases, lactate dehydrogenase, and bilirubin—accompanied by a reduction in prothrombin levels—may appear 12 to 48 hours after an acute overdose. It may also lead to pancreatitis, acute renal failure, and pancytopenia.

Management:

Despite the absence of significant initial symptoms, patients should be referred to a hospital urgently for immediate medical attention. Treatment involves gastric aspiration and lavage, preferably within 4 hours of ingestion.

Determination of plasma paracetamol concentration is recommended.

Plasma paracetamol concentration should be measured 4 hours or more after ingestion (earlier concentrations are unreliable).

When paracetamol intoxication is suspected, the intravenous administration of SH-group donors, such as N-acetylcysteine, is indicated within the first 10 hours after ingestion. Although N-acetylcysteine is most effective if initiated during this period, it may still offer some degree of protection if administered up to 48 hours after ingestion; in this case, it is administered for a longer duration.

Other measures will depend on the severity, nature, and course of the clinical symptoms of paracetamol intoxication and should follow standard intensive care protocols.

Ibuprofen:

Ibuprofen overdose may cause metabolic acidosis.

Signs and Symptoms:

Symptoms of overdose may include CNS-related symptoms such as headache, dizziness, vertigo, and loss of consciousness (also myoclonic seizures in children); abdominal pain, nausea, vomiting, gastrointestinal bleeding, hepatic and renal dysfunction, hypotension, respiratory depression, and cyanosis.

Ibuprofen overdose may cause metabolic acidosis.

Management:

There is no specific antidote.

Oral administration of activated charcoal should be considered if the patient presents within 1 hour of ingesting a potentially toxic amount.

STORAGE:

Store below 30°C in a dry place. Protect from light.

Keep this medicine out of the reach of children.

PRESENTATION: One pack of 10 x 10 tablets.

Manufactured by:

US Pharma® (INDIA) Private Limited

Pioneering Excellence. Redefining Quality.

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INDICATIONS
Management of mild to moderate pain and inflammation in conditions such as dysmenorrhoea, headache, including migraine, post-operative pain, dental pain, musculoskeletal and joint disorders, peri-articular disorders and soft tissue disorders (sprains and strains). It also reduces fever.

DOSAGE AND ADMINISTRATION
Adults: 1 tablet 3 times a day.
Adults and adolescents weighing from 40 kg body weight (aged 12 years and above): Initial dose, 1 tablet of Linoflam tablet. If necessary, additional doses of Linoflam tablet can be taken. The respective dosing interval should be chosen in line with the observed symptoms and the maximum recommended daily dose. It should not be below 6 hours. A total dose of 3 tablet of Linoflam tablet should not be exceeded in any 24-hour period.
For short-term use only.
In adults and adolescents (12 to 18 years) Linoflam tablet should not be used for more than 3 days in the case of fever or for more than 4 days for the treatment of pain unless it is recommended by a physician. If the symptoms persist or worsen the patient is advised to consult a physician.
It is recommended that patients with sensitive stomachs take Linoflam tablet with food. If taken shortly after eating, the onset of actions of Linoflam tablet may be delayed. If this happens, do not take more Linoflam tablet than recommended or until the correct re-dosing interval has passed.

CONTRAINDICATIONS
Linoflam tablet is contraindicated in:
• Patients with known hypersensitivity to paracetamol, ibuprofen or any of the excipients.
• In patients with a history of hypersensitivity reactions (eg. bronchospasm, angioedema, asthma, rhinitis or urticaria) associated with acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs).
• In patients with a history of, or an existing gastrointestinal ulceration/ perforation or bleeding, including that associated with NSAIDs.
• Patients with defects in coagulation.
• In patients with severe hepatocellular insufficiency, severe renal failure or severe heart failure.
• Active, or history of recurrent or existing peptic ulcer/haemorrhages (two or more distinct episodes of proven ulceration or bleeding).
• cerebrovascular or other active bleeding
• Adolescents under 40 kg body weight and children below 12 years of age.
• Patients with severe dehydration (caused by vomiting, diarrhoea or insufficient fluid intake).
• third trimester of pregnancy

PREGNANCY LACTATION AND FERTILITY
PREGNANCY:
Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/fetal development.
During the first and second trimester of pregnancy, ibuprofen should not be given unless clearly necessary. If ibuprofen is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.
During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose:
• the fetus to:

- Cardiopulmonary toxicity (with premature closure of the ductus arteriosus and Pulmonary hypertension)
- Renal dysfunction, which may progress to renal failure with oligo-hydroamniosis
• the mother and the neonate, at the end of pregnancy to:

- Possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses
- Inhibition of uterine contractions resulting in delayed or prolonged labor.
Consequently, ibuprofen is contraindicated during the third trimester of pregnancy.

LACTATION:
Ibuprofen and its metabolites can pass in low concentrations into the breast milk. No harmful effects to infants are known to date. Therefore, for short-term treatment with the recommended dose for pain and fever, interruption of breast-feeding would generally not be necessary.
FERTILITY
There is some evidence that drugs which inhibit cyclo-oxygenase/ prostaglandin synthesis may cause impairment of female fertility by an effect on ovulation. This is reversible on withdrawal of treatment

OVERDOSE
Paracetamol
Elderly persons, small children, patients with liver disorders, chronic alcohol consumption or chronic malnutrition, as well as patients concomitantly treated with enzyme-inducing drugs are at an increased risk of intoxication, including fatal outcome.

Signs and Symptoms:
Nausea, vomiting, anorexia, pallor, abdominal pain, generally appear during the first 24 hours of overdosage with paracetamol. Overdosage with paracetamol may cause hepatic cytolysis which can lead to hepatocellular insufficiency, gastrointestinal bleeding, metabolic acidosis, encephalopathy, disseminated intravascular coagulation, coma and death. Increased levels of hepatic transaminases, lactate deshydrogenase and bilirubin with a reduction in prothrombin level can appear 12 to 48 hours after acute overdosage. It can also lead to pancreatitis, acute renal failure and pancytopenia.
Management:
Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention.
Treatment involves gastric aspiration and lavage, preferably within 4 hours of ingestion.
Determinations of the plasma concentration of paracetamol are recommended.
Plasma concentration of paracetamol should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable).
Where paracetamol intoxication is suspected, intravenous administration of SH group donators such as N-acetylcysteine within the first 10 hours after ingestion is indicated. Although N-acetylcysteine is most effective if initiated within this period, it can still offer some degree of protection if given as late as 48 hours after ingestion; in this case, it is taken for longer.
Further measures will depend on the severity, nature and course of clinical symptoms of paracetamol intoxication and should follow standard intensive care protocols.
Ibuprofen:
Ibuprofen overdose may cause metabolic acidosis.
Signs and Symptoms:
The symptoms of overdose can include CNS-related symptoms such as headache, dizziness, light-headedness and unconsciousness (also myoclonic convulsions in children), abdominal pain, nausea, vomiting, gastrointestinal bleeding and hepatic and renal dysfunction, hypotension, respiratory depression and cyanosis.
Ibuprofen overdose may cause metabolic acidosis
Management:
A specific antidote does not exist.
Oral administration of activated charcoal is to be considered, if the patient presents within 1 hour of ingestion of a potentially toxic amount.