

1.3.3 PACKAGE INSERT

SCHEDULING STATUS: S1

PROPRIETARY NAME: **ADCO-IBUPROFEN 400 mg**
(AND DOSAGE FORM) **(TABLET)**

COMPOSITION:

Each sugar-coated tablet contains 400 mg ibuprofen

Contains sugars: lactose	0,07266 g
sucrose	0,28813 g

Contains TARTRAZINE.

Inactive ingredients:

aerosil 200, avicel pH101, explotab (primojel), starch 1500, polyvinylpyrrolidone K25, maize starch, stearic acid powder, sodium lauryl sulphate, crosscarmellose; opagloss regular; opalux green; acacia powder, carnuba wax light; beeswax light

PHARMACOLOGICAL CLASSIFICATION:

A 3.1 Antirheumatics (anti-inflammatory agents)

PHARMACOLOGICAL ACTION:

ADCO-IBUPROFEN 400 mg contains ibuprofen, which is a non-steroidal, anti-inflammatory, antipyretic and analgesic agent. It inhibits the synthesis of prostaglandins. Ibuprofen is absorbed from the gastro-intestinal tract producing peak plasma concentrations after one to two hours.

INDICATIONS:

ADCO-IBUPROFEN 400 mg is indicated in the treatment of mild to moderate pain of inflammatory origin and for the emergency treatment of gout attacks.

CONTRAINDICATIONS:

It should be given with care to patients with peptic ulceration or a history of such ulceration, bleeding disorders, cardiovascular disease and those on oral anticoagulants. It should not be given to patients who are sensitive to aspirin. **ADCO-IBUPROFEN 400 mg** should be administered with care in patients with asthma, especially those who have developed bronchospasm with other non-steroidal agents.

WARNINGS AND SPECIAL PRECAUTIONS:

Contains tartrazine, which may cause allergic type reactions (including bronchial asthma) in certain individuals. The overall incidence of tartrazine sensitivity is low; it is however frequently seen in patients who also have aspirin sensitivity.

In view of the product's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.

Contains lactose and sucrose: Patients with the rare hereditary conditions of galactose or fructose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose mal-absorption or fructose intolerance or sucrose-isomaltase insufficiency should not take **ADCO-IBUPROFEN 400 mg**.

PREGNANCY AND LACTATION:

ADCO-IBUPROFEN 400 mg should not be administered during pregnancy and is not recommended for use by breast-feeding women.

Regular use of NSAIDs during the third trimester of pregnancy may result in premature closure of the foetal *ductus arteriosus in utero* and possibly in persistent pulmonary hypertension of the new-born. The onset of labour may be delayed and its duration increased.

DOSAGE AND DIRECTIONS FOR USE:*Adults:*

600 mg to 1 200 mg daily in divided doses.

Children:

20 mg/kg body mass per day but not to exceed 500 mg per day in children weighing less than 30 kg.

SIDE EFFECTS:

ADCO-IBUPROFEN 400 mg may cause nausea, vomiting, dyspepsia, diarrhoea, stomatitis, or gastrointestinal haemorrhage. Headache, dizziness, nervousness and other central nervous system effects, skin rash, thrombocytopenia, agranulocytosis, toxic amblyopia, bronchospasm, oedema, tinnitus, pruritus, depression, drowsiness, insomnia and blurred vision may occur. Abnormalities of liver function tests and impairment of renal function has been observed. Acute reversible renal failure has been reported. Ibuprofen should be used with care in patients with impaired renal function.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

The main symptoms of over dosage are epigastric pain, nausea, heartburn and abdominal discomfort.

Treatment:

The stomach should be emptied by inducing emesis or by aspiration and gastric lavage. Blood-electrolyte balance should be maintained. Further treatment is supportive and symptomatic.

IDENTIFICATION:

Green, sugar-coated tablets.

PRESENTATION:

Blister packs of 12 and 24 tablets

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

R/3.1/186

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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