

### 1.1.3.1 PACKAGE INSERT

SCHEDULING STATUS:

S1

PROPRIETARY NAME (AND DOSAGE FORM):

BETAGESIC (TABLET)

#### COMPOSITION:

Each film-coated tablet contains:

Ibuprofen 200 mg

Preservatives:

Methyl hydroxybenzoate 0,14 % m/m

Propyl hydroxybenzoate 0,06 % m/m

Sugar free

**EXCIPIENTS:** Colloidal anhydrous silica, Dichloromethane, Erythrosine Lake, Hypromellose E15, Light liquid paraffin, Maize starch, Methanol, Methyl hydroxybenzoate, Propyl hydroxybenzoate, Sodium acetate, Stearic acid, Talc, Titanium dioxide.

#### PHARMACOLOGICAL CLASSIFICATION:

A 2.7 Anti-pyretic or antipyretic and anti-inflammatory analgesic

#### PHARMACOLOGICAL ACTION:

**BETAGESIC** is a non-steroidal compound, with analgesic, anti-inflammatory and antipyretic activities.

#### INDICATIONS:

**BETAGESIC** is indicated for the relief of headache from musculo-skeletal origin, feverishness, muscular aches and pain, menstrual pain and dental pain.

#### CONTRAINDICATIONS:

**BETAGESIC** is not recommended for use by pregnant women.

**WARNINGS and SPECIAL PRECAUTIONS:**

Ibuprofen should be used with care in patients with impaired renal function.

**BETAGESIC** should not be given to patients with bleeding disorders, cardiovascular disease, peptic ulceration or a history of such ulceration. Caution is advised in those patients who are receiving coumarin anticoagulants. Patients who are sensitive to aspirin should not be given **BETAGESIC**.

**PREGNANCY AND LACTATION**

Safety in pregnancy not yet established

**DOSAGE AND DIRECTIONS FOR USE:**

*Adults and children over 12 years:* Initial dose 2 tablets with water, then if necessary, 1 or 2 tablets every four hours. Do not take more than 6 tablets in any 24 hours. Not to be given to children under 12 years.

If symptoms persist for more than 7 days, consult your doctor.

**SIDE EFFECTS**

Dyspepsia, gastrointestinal intolerance and bleeding may occur. Other side effects include nervousness, skin rash, pruritus, tinnitus, oedema, depression, drowsiness, headache, dizziness, insomnia and blurred vision and other visual field defects. Hypersensitivity reactions, abnormalities of liver function tests, impairment of renal function, agranulocytosis, and thrombocytopenia have 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 most likely symptoms of overdosage are epigastric pain and nausea. If recently taken, gastric lavage will remove any unabsorbed ibuprofen. Electrolytes may be corrected by intravenous infusions, if necessary. Dialysis may be done as ibuprofen is not strongly protein bound. There is no specific antidote to **BETAGESIC**.

**IDENTIFICATION:**

Red, circular, biconvex, film-coated tablets.

**PRESENTATION:**

15's, 20's and 42 in PVC/Al blister packs.

**STORAGE INSTRUCTIONS**

Store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

**REGISTRATION NUMBER:**

U/2.7/20

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

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