For the use of a Registered Medical Practitioner only

1.0 GENERIC NAME AND BRAND NAME

Ibuprofen Softgel Capsules 200 mg
BRUFEN® RAPID

2.0 QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each Soft Gelatin Capsule contains:
Ibuprofen I.P. 200mg
Excipients q.s.

3.0 DOSAGE FORM & STRENGTH:

Kindly Refer Section 1&2

4.0 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS:

For Chronic arthritic disorder and painful musculoskeletal conditions

4.2 POSOLOGY AND METHOD OF ADMINISTRATION:

Adults and children 12 years and above: 1 or 2 softgels every 4 hours as needed. Do not exceed 6 Softgels in 24 hours, unless directed by a physician.
If symptoms persist for more than 3 days, consult your doctor.

4.3 CONTRAINDICATIONS:

Contraindicated in person with known hypersensitivity to aspirin and other Nonsteroidal anti-inflammatory drugs (NSAIDs). Ibuprofen may cause a severe allergic reaction which may include hives, facial swelling, asthma or shock.

4.4 SPECIAL WARNINGS & PRECAUTIONS FOR USE:

Do not use:

- If the blister foil is broken
- If you have a stomach ulcer or other stomach disorders, kidney or heart problems « If you are allergic to aspirin, ibuprofen or other anti-inflammatory medicines « If you get an allergic reaction, stop taking and consult your doctor immediately
- Do not use this product during the first 6 months of pregnancy, except on doctor's advice

Special Warning for use: Do not use at all during the last 3 months of pregnancy
Bronchospasm may be precipitated in patient suffering from or with a previous history of bronchial asthma, Ibuprofen should not be given to patients in whom Aspirin and other Nonsteroidal anti-inflammatory drugs induce the symptoms of asthma, rhinitis or Urticaria.

4.5 DRUG INTERACTIONS

Ibuprofen should not be given to patients in whom Aspirin and other Non-Steroidal Anti-inflammatory drugs induce the symptoms of asthma, rhinitis or Urticaria.
Unless advised by your doctor, do not use:

- If you are taking other medicines regularly
- If you are taking other medicines containing aspirin, Ibuprofen or other anti-inflammatory medicines
- If you are aged 65 years or older
- If you have asthma
- In children suffering from dehydration through diarrhea and/or vomiting

4.6 USE IN SPECIAL POPULATIONS (SUCH AS PREGNANT WOMEN, LACTATING WOMEN, PAEDIATRIC PATIENTS, GERIATRIC PATIENTS ETC.)

Pregnancy and Lactation: Not recommended in lactating women and during pregnancy (especially during the last trimester) or during labor and delivery.

4.7 EFFECTS ON ABILITY TO DRIVE ANS USE MACHINES:

Ibuprofen 200 mg soft gelatin capsule is unlikely to cause any effect on your ability to drive or use machines.

4.8 UNDESIRABLE EFFECTS:

The most frequent adverse effects of Ibuprofen involve the irritation of gastrointestinal tract.
Do not exceed the recommended dose. Do not use for more than a few days at a time unless a doctor has told you to.
The most frequent adverse effects of Ibuprofen involve the irritation of gastrointestinal tract. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.

4.9 OVERDOSAGE:

Toxicity
Signs and symptoms of toxicity have generally not been observed at doses below 100 mg/kg in children or adults. However, supportive care may be needed in some cases. Children have been observed to manifest signs and symptoms of toxicity after ingestion of 400 mg/kg or greater.
Symptoms
Most patients who have ingested significant amounts of ibuprofen will manifest symptoms within 4 to 6 hours. The most frequently reported symptoms of overdose include nausea, vomiting, abdominal pain, lethargy and drowsiness. Central nervous system (CNS) effects include headache, tinnitus, dizziness, convulsion and loss of consciousness. Nystagmus, metabolic acidosis, hypothermia, renal effects, gastrointestinal bleeding, coma, apnea and depression of the CNS and respiratory system have also been rarely reported. Cardiovascular toxicity, including hypotension, bradycardia and tachycardia, has been reported. In cases of significant overdose, renal failure and liver damage are possible. Large overdoses are generally well tolerated when no other drugs are being taken. In serious poisoning metabolic acidosis may occur.
Treatment
There is no specific antidote for ibuprofen overdose. Gastric emptying followed by supportive measures is recommended if the quantity ingested exceeds 400 mg/kg within the previous hour.

5.0 PHARMACOLOGICAL PROPERTIES:

5.1 Mechanism of Action:

Ibuprofen has multiple actions in different inflammatory pathways involved in acute and chronic inflammation. The main effects reported in ibuprofen are related to the control of pain, fever and acute inflammation by the inhibition of the synthesis of prostanoids by COX-1 and COX-2. Pain relief is attributed to peripheral affected regions and central nervous system effects in the pain transmission mediated by the dorsal horn and higher spinothalamic tract. Some reports have tried to link the pain regulation with a possible enhancement on the synthesis of endogenous cannabinoids and action on the NMDA receptors. The effect on pain has been shown to be related to the cortically evoked potentials. The antipyretic effect is reported to be linked to the effect on the prostanoid synthesis due to the fact that the prostanoids are the main signaling mediator of pyresis in the hypothalamic-preoptic region

5.2 Pharmacodynamic Properties

Ibuprofen is a propionic acid derivative nonsteroidal anti-inflammatory drug (NSAID) with analgesic, anti-inflammatory and anti-pyretic effects. The drug's therapeutic effects are thought to result from its inhibitory effect on the enzyme cyclooxygenase, which results in a marked reduction in prostaglandin synthesis. These properties provide symptomatic relief of inflammation, pain and fever. Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose acetylsalicylic acid/aspirin on platelet aggregation when they are dosed concomitantly. Some pharmacodynamic studies show that when single doses of ibuprofen 400 mg were taken within 8 h before or within 30 min after immediate release acetylsalicylic acid/aspirin dosing (81 mg), a decreased effect of acetylsalicylic acid/aspirin on the formation of thromboxane or platelet aggregation occurred. Although there are uncertainties regarding extrapolation of these data to the clinical situation, the possibility that regular, long-term use of ibuprofen may reduce the cardioprotective effect of low-dose acetylsalicylic acid/aspirin cannot be excluded. No clinically relevant effect is considered to be likely for occasional ibuprofen use

5.3 Pharmacokinetic Properties

Absorption

Ibuprofen is rapidly absorbed from the gastrointestinal tract with a bioavailability of 80-90%. Peak serum concentrations occur one to two hours after administration of immediate release formulations.

Studies including a standard meal show that food does not markedly affect total bioavailability.

Distribution

Ibuprofen is extensively bound to plasma proteins (99%). Ibuprofen has a small volume of distribution being about 0.12-0.2 L/kg in adults.

Biotransformation

Ibuprofen is rapidly metabolized in the liver through cytochrome P450, preferentially CYP2C9, to two primary inactive metabolites, 2-hydroxyibuprofen and 3-carboxyibuprofen. Following oral ingestion of the drug, slightly less than 90% of an oral dose of ibuprofen can be accounted for in

the urine as oxidative metabolites and their glucuronic conjugates. Very little ibuprofen is excreted unchanged in the urine.

Elimination
Excretion by the kidney is both rapid and complete. The elimination half-life of immediate release formulations is approximately two hours. The excretion of ibuprofen is virtually complete 24 hours after the last dose.

6.0 NONCLINICAL PROPERTIES
6.1 ANIMAL TOXICOLOGY OR PHARMACOLOGY
No data available

7.0 DESCRIPTION:

BRUFEN RAPID is supplied for oral administration, as a softgel capsule of Ibuprofen. Each softgel capsule contains Ibuprofen 200 mg.

8.0 PHARMACEUTICAL PARTICULARS
8.1 INCOMPATIBILITIES:

You must not take these capsules if you are taking certain other medicines – under section WARNINGS & PRECAUTIONS and Drug Interactions. This medicine may affect or be affected by some other medicines. For example:
• medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
• aspirin at low dose as an anti-platelet medicine (i.e. 75mg or below daily), as taking ibuprofen may reduce the effectiveness of the aspirin or cause stomach problems
• other medicines for thinning the blood (anti-coagulants)
• other NSAID painkillers, including cyclooxygenase-2 selective inhibitors
• medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
• antidepressants called selective-serotonin reuptake inhibitors (SSRIs) e.g. uoxetine
• corticosteroids (for skin problems and allergies e.g. cortisol)
• methotrexate (a medicine for cancer)
• cardiac glycosides (medicines used to treat heart failure e.g. digoxin)
• ciclosporin and tacrolimus (immunosuppressant medicines often used following organ transplants)
• mifepristone (a medicine used to terminate pregnancy – NSAIDs should not be used for 12 days after mifepristone)
• lithium (for depression or mental problems)
• zidovudine (a medicine to treat viruses)
• quinolone antibiotics (medicines used to treat bacterial infection e.g. ciprooxacin).
Some other medicines may also affect or be affected by the treatment of this medicine. You should therefore always seek the advice of your doctor or pharmacist before you use this medicine with other medicines

8.2 SHELF LIFE:

Refer pack

8.3 PACKAGING INFORMATION:

Refer pack

8.4 STORAGE & HANDLING INSTRUCTIONS:
Refer pack

9.0 Patient Counselling Information:
What is this drug used for?
• It is used to ease pain, swelling, and fever.
• It is used to ease painful period (menstrual) cycles.
• It is used to treat arthritis.
• It may be given to you for other reasons. Talk with the doctor.

Frequently reported side effects of this drug
• Heartburn
• Diarrhea
• Constipation
• Flatulence
Other side effects of this drug: Talk with your doctor right away if you have any of these signs of:
• Aseptic meningitis like headache, fever, chills, severe nausea or vomiting, stiff neck, rash, sensitivity to bright lights, fatigue, or confusion.
• Abdominal ulcers like severe abdominal or back pain; black, tarry, or bloody stools; vomiting blood or vomit that looks like coffee grounds; or weight gain or abnormal swelling.
• Bleeding like vomiting blood or vomit that looks like coffee grounds; coughing up blood; hematuria; black, red, or tarry stools; bleeding from the gums; abnormal vaginal bleeding; bruises without a reason or that get bigger; or any severe or persistent bleeding.
• Kidney problems like urinary retention, hematuria, change in amount of urine passed, or weight gain.
• High potassium like abnormal heartbeat, confusion, dizziness, passing out, weakness, shortness of breath, numbness or tingling feeling.
• Liver problems like dark urine, fatigue, lack of appetite, nausea, abdominal pain, light-colored stools, vomiting, or jaundice.
• Severe cerebrovascular disease like change in strength on one side is greater than the other, difficulty speaking or thinking, change in balance, or vision changes.
• Shortness of breath
• Excessive weight gain
• Swelling of arms or legs
• Chest pain
• Tachycardia
• Severe headache
• Severe dizziness
• Passing out

• Severe loss of strength and energy
• Tinnitus
• Severe nausea
• Vomiting
• Severe abdominal pain
• Severe back pain
• Vision changes
• Stevens-Johnson syndrome/toxic epidermal necrolysis like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in mouth, throat, nose, or eyes.
• Signs of a significant reaction like wheezing; chest tightness; fever; itching; bad cough; blue skin color; seizures; or swelling of face, lips, tongue, or throat.
Note: This is not a comprehensive list of all side effects. Talk to your doctor if you have questions.

10.0 DETAILS OF MANUFACTURER:
Refer Pack for manufacturer details.

MARKETED BY:
Abbott India Limited
Angel Space, Lifestyle Bldg. No. D-4,
Gala No. 7 to 10 & 17 to 20 Ground Floor,
107 to 110 & 117 to 120 First Floor,
Pimplas Village, Dist. Thane,
Bhiwandi - 421 302, India

® - Regd. Trademark of Abbott GMBH & CO.KG.
+ Based on IQVIA MIDAS Database Q1 2019 Release. *Data on File

11.0 DETAILS OF PERMISSION OR LICENSE NUMBER
Refer Pack for Permission/License details

12.0 DATE OF REVISION:
Version: 4.0 dated 04th September 2023

For Product Complaints/Adverse events or Queries please write to
webmasterindia@abbott.com