1.6.1 PRESCRIBING INFORMATION (SUMMARY OF PRODUCTS CHARACTERISTICS)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Bren-200 (Ibuprofen Tablets BP 200mg)

1.1 Strength

Each Film Coated Tablets contains:

Ibuprofen BP 200 mg,

1.2 Pharmaceutical Form

Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Qualitative declaration:

Each Film Coated Tablets contains:

Ibuprofen BP 200 mg

2.2 Quantitative declaration:

Qualitative declaration:

Each Film Coated Tablets contains:

Ibuprofen BP 200 mg

Quantitative declaration:

Sr. No.	Ingredients	Qty /tab (In mg)	Function	Reference
(i) Active ingredients				
1.	Ibuprofen	200	Active Component	BP
(ii) Inactive ingredients				
2.	Stearic Acid	1.5	lubricant	BP
3.	Purified Talc	1	Glidant	
4.	Colloidal Anhydrous Silica	2.5	Glidant	BP
5.	Maize Starch	36	Disintegrant	BP
6.	Sodium Lauryl Sulphate	2.5	Dissolution enhancer	BP
7.	Sodium Starch Glycollate	4	Disintegrant	BP
	Film coating**			
8.	Hydroxypropyl Methylcellulose	3.125	Film former	USP/NF
9.	Povidone K-30	0.113	binder	BP
10.	Macrogol (PEG 6000)	1.130	plasticizer	USP/NF
11.	Talc (Purified)	1.130	Glidant	BP
12.	Colour Erythrosine Lake	0.150	Colouring agent	IH
13.	Titanium Dioxide [E171]	0.400	Opacifier	BP
14.	Purified Water#	QS	Process solvent	BP

#- process solvent does not contribute to weight of tablet

** 10% Extra quantity taken to compensate losses during coating.

USP/NF - United States Pharmacopoeia/National Formulary
BP-British Pharmacopoeia
IH-In-House Specification

2.3 Salts and hydrates

Pure form present No Salt or hydrate form.

2.4 Esters and pro-drugs

Not applicable

2.5 Oral Powders for solution or suspension

Not applicable

2.6 Parenterals excluding powders for reconstitution

Not applicable

2.7 Powders for reconstitution prior to parenteral administration

Not applicable

2.8 Concentrates

Not applicable

2.9 Transdermal patches

Not applicable

2.10 Multidose solid or semi-solid products

Not applicable

2.11 Biological medicinal products

Not applicable

3. Pharmaceutical form

Description:

Pink colored Circular Slightly Biconvex Coated Tablets..

4 Clinical Particulars

4.1 Therapeutic indications

Ibuprofen tablets are indicated for the treatment of Pain and inflammation in the rheumatic disease (including juvenile idiopathic arthritis) and other musculoskeletal disorders, Mild to moderate pain including dysmennorrhoea, postoperative analgesia, Migrane, Dental pain, Fever with discomfort and pain in children, Post immunization pyrexia.

4.2 Posology and Method of Administration

Posology:

- Adult and child over 12 years, initially 300-400mg 3-4 times daily; increased if necessary to max 2.4g daily; maintenance dose of 0.6-1.2 g daily may be adequate.
- Pain and fever in children, child 1-4 years, 100 mg 3 times daily (max 30 mg/kg daily in 3-4 divided doses);
- Child 4-7 years, 150 mg 3 times daily (max 30mg/kg daily in 3-4 divided doses);
- Child 7-10 years, 200 mg 3 times daily (up to 30mg/kg daily max 2.4 g in 3-4 divided doses);
- Child 10-12 years, 300 mg 3 times daily (up to 30mg/kg) daily max 2.4g in 3-4 divided doses
- Rheumatic disease in children (incuding juvenile idiopathic arthritis) Child 3 months -18 years (30-40 mg/kg max 2.4 g daily in 3-4 divided doses.
- Systemic juvenile idiopathic arthritis, up to 60mg/kg max 2.4g daily in 4-6 divided doses.

Route of administration: Oral

4.3 Method of Administration:

Bren-400 should be swallowed with glass of water.

4.4 Contraindications

- NSAIDs should be used with caution in the elderly, in allergic disorders and in coagulation defects.
- In patients with cardiac impairment, caution is required since NSAIDs may impair renal function. All NSAIDs are contraindicated in severe heart failure. Ibuprofen should be used with caution in uncontrolled hypertension , heart failure, ischemic heart diseases, pheripheral artery disease, cerebrovascular disease and when used long-term in patients with risk factors for cardiovascular events. All NSAIDs including ibuprofen is contra-indicated.
- In patients with active gastro-intestinal ulceration or bleeding.
- Patients at risk of gastro-intestinal ulceration (including the elderly), who need NSAID treatment should receive gastroprotective treatment.
- Hepatic impairment: NSAIDs should be used with caution in patients with hepatic impairment.
- Renal impairment: NSAIDs should be avoided if possible or used with caution in patients with renal impairment; the lowest effective dose should be used for the shortest possible duration, and renal function should be monitored. Sodium and water retention may occur and renal function may deteriorate, possibly leading to renal failure.

4.5 Special warnings and precautions for use

WARNINGS

GI bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with a hemorrhage or perforation and in the elderly. These patients should commence treatment on the lowest dose available. Combination therapy wih protective agents.

PRECAUTIONS

Elderly, increased risk of gastrointestinal bleeding and perforation, ulceration who need NSAID treatment should receive gastroprotection treatment.

Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or anti-platlet agents

Respiratory disorder- caution is required if ibuprofen is administered to patients suffering from, or with a previous history of bronchial asthma since NSAIDs have been reported to precipitate broncospasm in such patients. Associated with increased risk of thrombotic events.

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4.6 Interactions with other medicinal products and other forms of interactions

Analgesics: Ibuprofen reduces antiplatleteffect of aspirin.

Antifungals: Plasma concentration of ibuprofen increased by fluconazole and vericonazole.

Cytotoxics: Ibuprofen reduces excretion of methotrexate (increased risk of toxicity)

Muscle relaxants: Ibuprofen reduces excretion of baclofen (increased risk of toxicity)

Tacrolimus: Incresed risk of nephrotoxicity.

4.6 Pregnancy and Lactation

Pregnancy: Ibuprofen should be avoided in pregnancy.

Lactation: Ibuprofen should be avoided during brest-feeding.

4.7 Effects on ability to drive and use machine

None expected at recommended doses and duration of therapy.

4.8 Undesirable effects

Gastro-intestinal disturbances including discomfort, nausea, diarrhoea, and occasionally bleeding and ulceration. Hypersensitivity reactions particularly rashes, angioedema and bronchospasm; Headache, dizziness, nervousness, depression, drowsiness, Insomnia, vertigo, hearing disturbances such as tinnitus, photosensitivity and haematuria, Blood disorders , Fluid retention. Renal failure may be provoked especially in patients with pre-existing renal impairment (rarely, Papillary necrosis or interstitial fibrosis) can lead to renal failure.

4.9 Overdose and antidote

The most frequently reported symptoms of overdose include nausea, vomiting, abdominal pain, lethargy and drowsiness. Patients should be treated symptomatically as required. Within one hour of ingestion of a potentially toxic amount, activated charcoal should be considered. Alternatively, in adults, gastric lavage should be considered within one hour of ingestion of a potentially life-threatening overdose. Good urine output should be ensured. Renal and liver function should be closely monitored. Patients should be observed for at least four hours after ingestion of potentially toxic amounts. Frequent or prolonged convulsions should be treated with intravenous diazepam. Other measures may be indicated by the patient's clinical condition.

5.0 Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:

Nonsteroidalanti- inflammatory drug (NSAID) derivative of propionic acid with anti-inflammatory,analgesic, and antipyretic properties.

ATC code: MO1AE01.

Ibuprofen is Phenylpropionic acid derivatives. NSAID that has demonstrated its efficacy by non-selective, reversible inhibition of the cyclooxygenase enzyme COX-1 and COX-2. Furthermore, ibuprofen reversibly inhibits platelet aggregation. Ibuprofen exerts its anti-inflammatory and analgesic effect through inhibition of both COX isoforms. In addition, ibuprofen scavenges HO. radical, NO and ONOO-and can potentiate or inhibit nitric oxide synthase (NOS) isoforms. Ibuprofen may activate anti-nociceptive axis through binding to the cannabinoid receptors and through inhibition of fatty acid amide hydrolase (FAAH) that metabolizes endocannabinoid anandamide.

5.2 Pharmacokinetic properties

Ibuprofen is rapidly absorbed following administration and is rapidly distributed throughout the whole body. The excretion is rapid and complete via the kidneys.
Maximum plasma concentrations are reached 45 minutes after ingestion if taken on an empty stomach. When taken with food, peak levels are observed after **1** to 2 hours. These times may vary with different dosage forms.
The half-life of ibuprofen is about 2 hours.
Ibuprofen appears in the breast milk in very low concentrations.

5.3 Pre-clinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to those already included in other sections. Non-clinical data reveal no special hazards for humans based on conventional studies of safety, pharmacology, repeat–dose toxicity or genotoxicity.

6.0 Pharmaceutical Particulars

6.1 List of Excipients

Sr No.	Approved Name	Specification
1	Stearic Acid	BP
2	Purified Talc	BP
3	Colloidal Anhydrous Silica	BP
4	Maize Starch	BP
5	Sodium Lauryl Sulphate	BP
6	Sodium Starch Glycollate	BP
7	Hydroxypropyl Methylcellulose	USP/NF
8	Povidone K-30	BP
9	Macrogol (PEG 6000)	USP/NF
10	Colour Erythrosine Lake	IH
11	Titanium Dioxide [E171]	BP

BP-British Pharmacopoeia
IH-In-House Specification

6.2 Incompatibilities:

None

6.3 Shelf life

Proposed shelf life: 36 Months (3 years)

6.4 Special precautions for storage:

Store below 30°C. Protect from light.

6.5 Nature and contents of container

Primary: Alu/Pvc Blister,

Secondary: Paperboard carton

6.6 Special precautions for disposal and other handling

None.

7. Marketing authorization holder.

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Manufacturer

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India

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8. Marketing authorization registration number(s).

Applied for registration

9. Date of first authorization registration/renewal of the authorization

Not applicable

10. Date of revision (if any) of this text.

Not applicable

11. DOSIMETRY (IF APPLICABLE)

Not applicable

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IFAPPLICABLE)

Not applicable