SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF MEDICINAL PRODUCT

Name: IBUCAP CAPSULE (Ibuprofen, Paracetamol & Caffeine Capsule)
Dosage Strength:
Each hard gelatin capsule contains:
Ibuprofen BP……..200 mg
Paracetamol BP……325 mg
Caffeine BP……....30 mg

Pharmaceutical form: Capsule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen 200mg
Paracetamol 325mg
Caffeine 30mg

3. PHARMACEUTICAL FORM: Capsule

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Non-articular rheumatic conditions
- Osteo-arthritis
- Cervical spondylosis
- Infective inflammation
- Dental & traumatic inflammation
- Pain and fever associated with inflammation.

4.2. Posology and method of administration

IBUCAP - Adults: 4 to 6 capsules per day or as prescribed by the physician.

Route of Administration: Capsule (Oral)

4.2 Contraindications

Ibucap is contraindicated in patients with impaired kidney or liver function, cardiac arrhythmias, active peptic ulcer and gastrointestinal bleeding.

4.5 Interaction with other medicinal products

Cholestyramine: Reduces absorption of IBUCAP.
Activated charcoal: if administered immediately after administration of IBUCAP, reduces absorption of IBUCAP.
Domperidone & metoclopramide: Enhance absorption of IBUCAP.
Alcohol: Chronic excessive ingestion of alcohol potentiates hepatotoxicity of IBUCAP.
Zidovudine: Effects of zidovudine may be decreased. Lithium: Raised blood lithium levels. Aspirin and other NSAIDs: Increased risk of bleeding and or peptic ulcers.
Methotrexate: IBUCAP increases the risk of toxicity.

Diazepam: IBUCAP induces impairment of cognitive skills & relaxation of extra ocular muscles. Pentobarbital: IBUCAP activates the hypnotic effect of Pentobarbital. (e.g. warfarin).

4.6 Pregnancy and lactation

IBUCAP is not safe in pregnancy & in nursing mothers.

4.7 Effects on ability to drive and use machine

Some undesirable effects (e.g. dizziness/vertigo, drowsiness, visual disturbances) may impair the patient's ability to concentrate and react, and therefore may constitute a risk in situations where these abilities are of special importance (e.g. driving a car or operating machinery).

4.8 Undesirable effects

PARACETAMOL

Adverse reactions identified during post-marketing use of paracetamol are reported voluntarily from a population of uncertain size, the frequency of these reactions is unknown but likely to be very rare (<1/10,000).

body System	**Undesirable effect**
Blood and lymphatic system disorders	Thrombocytopenia Agranulocytosis
Immune system disorders	Very rare cases of serious skin reactions have been reported. Anaphylaxis Cutaneous hypersensitivity reactions including (amongst others) skin rashes and angioedema.
Metabolism and nutrition disorders	High anion gap metabolic acidosis (frequency not known – cannot be estimated from the available data) (cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients with risk factors using paracetamol (see section 4.4). Pyroglutamic acidosis may occur as a consequence of low glutathione levels in these patients).
Respiratory, thoracic and mediastinal disorders	Bronchospasm- more likely in patients sensitive to aspirin and other NSAIDs
Hepatobiliary disorders	Hepatic dysfunction

CAFFEINE

When the recommended paracetamol-caffeine dosing regimen is combined with dietary caffeine intake, the resulting higher dose of caffeine may increase the potential for caffeine-related adverse effects.

Body System	**Undesirable effect**
Central nervous system	Dizziness Headache
Cardiac disorders	Palpitation

Psychiatric disorders	Insomnia Restlessness Anxiety and irritability
Gastrointestinal disorders	Gastrointestinal disturbances

IBUPROFEN

Adverse events which have been associated with Ibuprofen are given below, listed by system organ class and frequency. Frequencies are defined as: very common (≥ 1/10), common (≥ 1/100 to <1/10), uncommon (≥ 1/1000 to <1/100), rare (≥ 1/10,000 to <1/1000), very rare (<1/10,000) and not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

The list of the following adverse events relates to those experienced with ibuprofen at OTC doses (maximum 1200mg per day) for short-term use. In the treatment of chronic conditions, under long-term treatment, additions adverse effects may occur.

The adverse events observed most often are gastrointestinal in nature. Adverse events are mostly dose-dependent, in particular the risk of occurrence of gastrointestinal bleeding is dependent on the dosage range and duration of treatment.

Clinical studies suggest that use of ibuprofen, particularly at a high dose (2400 mg/day) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke) (see section 4.4).

System Organ Class	**Frequency**	**Adverse Event**
Blood and Lymphatic System Disorders	Very rare:	Haematopoietic disorders (anaemia, leucopenia, thrombocytopenia, pancytopenia, agranulocytosis). First signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding and bruising.
Immune System Disorders	Uncommon	Hypersensitivity reactions consisting of[1]: Urticaria and pruritus
	Very rare	Severe hypersensitivity reactions. Symptoms could be facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension (anaphylaxis, angioedema or severe shock).
	Not Known	Respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm or dyspnoea.
Nervous System Disorders	Uncommon Very rare	Headache Aseptic meningitis [2].

Cardiac Disorders	Not Known	Kounis syndrome, Cardiac failure and oedema
Vascular Disorders	Not Known	Hypertension
Gastrointestinal Disorders	Uncommon	Abdominal pain, nausea, dyspepsia
	Rare	Diarrhoea, flatulence, constipation and vomiting
	Very rare	Peptic ulcer, perforation or gastrointestinal haemorrhage, melaena, haematemesis, sometimes fatal, particularly in the elderly. Ulcerative stomatitis, gastritis
	Not Known	Exacerbation of colitis and Crohn's disease (section 4.4).
Hepatobiliary Disorders	Very rare	Liver disorders
Skin and Subcutaneous Tissue Disorders	Uncommon	Various skin rashes
	Very rare	Severe cutaneous adverse reactions (SCARs) (including Erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis)
	Not known	Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome) Acute generalised exanthematous pustulosis (AGEP) photosensitivity reactions
Renal and Urinary Disorders	Very rare	Acute renal failure, papillary necrosis, especially in long-term use, associated with increased serum urea and oedema.
	Not Known	Renal insufficiency, Renal tubular acidosis[3]
Investigations	Very rare	Decreased haemoglobin levels
Metabolism and Nutrition Disorders	Not Known	Hypokalaemia[3]

Description of Selected Adverse Reactions:

[1] Hypersensitivity reactions have been reported following treatment with ibuprofen. These may consist of (a) non-specific allergic reactions and anaphylaxis, (b) respiratory tract activity comprising asthma, aggravated asthma, bronchospasm, dyspnoea or (c) assorted skin disorders, including rashes of various types pruritus, urticaria, purpura, angioedema and more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme).

[2] The pathogenic mechanism of drug-Induced aseptic meningitis is not fully understood. However, the available data on NSAID-related aseptic meningitis points to a hypersensitivity

reaction (due to a temporal relationship with drug intake, and disappearance of symptoms after drug discontinuation). Of note, single cases of symptoms of aseptic meningitis (such as stiff neck, headache, nausea, vomiting, fever or disorientation) have been observed during treatment with ibuprofen, in patients with existing auto-immune disorders (such as systemic lupus erythematosus, mixed connective tissue disease).

[3] Renal tubular acidosis and hypokalaemia have been reported in the post-marketing setting typically following prolonged use of the ibuprofen component at higher than recommended doses.

4.9 Overdose

Ibuprofen: Symptoms include nausea, vomiting, epigastric pain, and headache. Gastric lavage or induced emesis may be used for the treatment. Treatment is supportive.

Paracetamol: Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, diarrhoea, anorexia, abdominal pain and increased sweating. Liver damage may become apparent 12 to 48 hours after ingestion. Gastric lavage or induced emesis may be used for the treatment. Specific therapy with an antidote such as acetylcysteine or methionine may be necessary.

Caffeine: symptoms include recurrent coffee ground emesis, diuresis, tachycardia, and CNS stimulation.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: IBUCAP is an antipyretic, analgesic & anti-inflammatory drug.
ATC code:
Paracetamol: N02BE51
Ibuprofen, Fixed dose combinations: M01AE51
Caffeine: N06BC01
Pharmacodynamic effects: In IBUCAP, Paracetamol exhibits analgesic action by peripheral blockage of pain impulse generation. It produces antipyresis by inhibiting the hypothalamic heat-regulating center. Ibuprofen inhibits prostaglandin production around the body by blocking the cyclooxygenase enzymes known as COX-1 and COX-2. Caffeine acts as Central nervous system stimulant due to a blockade of receptors for the neurotransmitter / neuromodulator adenosine.

5.2. Pharmacokinetic properties

	Ibuprofen	Paracetamol	Caffeine
Absorption-oral:	> 95%	> 95%	> 95%
Pre systemic	-	20%	none
Metabolism			

Plasma half-life Range	-	1.5-3.0 hours	1.9 -12.2 hours
Mean:	2hours	2.3 hours	4.9 hours
Volume of distribution:	I.kg-1	0.9 I.kg-1	0.58 I.kg-1
Plasma protein binding	99%	<20%	35%
Elimination:	Via bile & urine	urine	Via urine

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Stearate
Purified talc

6.2 Incompatibilities

None

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not Store above 30°C. Protect from Sunlight and moisture. Keep out of reach of children.

6.5 Nature and contents of the container

10 Capsule to be packed in a blister. Such 1 blister to be packed in Pouch. Such 20 Pouches to be packed in outer Carton along with leaflet.
2) 10 Capsule to be packed in a blister. Such 1 blister to be packed in inner carton along with leaflet. Such 20 inner carton to be packed in outer Carton.
3) 10 Capsule to be packed in a blister. Such 25 blisters to be packed in carton along with leaflet.
4) 2 Capsules in a blister. Such 50 blisters to be packed in carton along with insert

6.6 Special precautions for disposal and other handling

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

Shalina Healthcare Dmcc

30th Floor, Almas Towers,

Jumeirah Lakes Towers Dubai-UAE.

Manufacturing Site Address:

Shalina Laboratories Pvt. Ltd.

E-2 & E-3, M.I.D.C. Jejuri,

Tal: Purandar, Dist.: Pune,

Maharashtra, India

8. MARKETING AUTHORIZATION NUMBER

H2012/CTD27/155

9. DATE OF FIRST REGISTRATION

17/05/2012

10. DATE OF REVISION OF THE TEXT

03/03/2026