1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC) - Enclosed

IBUCAP CAPSULES

(Ibuprofen, Paracetamol & Caffeine Capsules)

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

IBUCAP CAPSULES (Ibuprofen, Paracetamol & Caffeine Capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

No	Name	Quantity per capsule (mg)
1	Ibuprofen BP	200.00
2	Paracetamol BP	325.00
3	Caffeine (Anhydrous) BP	30.00
4	Magnesium Stearate BP	6.00
5	Purified Talc BP	8.00
6	Size “0” Empty Hard Gelatin Capsule light blue cap with “Shalina” logo printed in white colour & dark blue colored body with “IBUCAP” printed in black. IH	1No.

Definitions: BP: British Pharmacopoeia

IH: In-House Specifications

3. PHARMACEUTICAL FORM

Oral Capsules

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

IBUCAP is indicated for the treatment of:

- 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

Dosage: 1-2 capsules three times per day or as prescribed by Physician.

Route of Administration: Capsules (Oral)

Condition of Administration: Capsules are to be taken with food or after meals with sufficient water or as prescribed by the physician.

Method of administration: Oral use.

4.3 Contraindications

IBUCAP is contraindicated in patients with impaired kidney or liver function, cardiac arrhythmias, active peptic ulcer and gastrointestinal bleeding. IBUCAP is also not suitable for the patients with known hypersensitivity to any of the ingredients of the drug.

4.4 Special warnings and precautions for use

Warnings:

IBUCAP is to be advocated with caution in liver & kidney damage, elderly, patients requiring Surgery, anemia, bronchial asthma, stomatitis, compromised cardiac function, heart failure, Pre-existing edema, systemic lupus erythematosus.

Safe use of IBUCAP in pregnancy and lactation has not been established. IBUCAP should not be preferably co-administered with other NSAIDs, corticosteroids, hypoglycemics, digoxin, lithium, methotrexate, cyclosporine, coagulants & anticoagulants, bone marrow suppressants as well as probenecid. Abrupt stoppage of Caffeine-containing products is not advisable since it could cause withdrawal symptoms such as headache, anxiety, or muscle tension within 12 to 18 hours.

Special precautions:

IBUCAP is to be advocated with caution in liver & kidney damage, elderly, patients requiring Surgery, anemia, bronchial asthma, stomatitis, compromised cardiac function, heart failure, Pre-existing edema, systemic lupus erythematosus.

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4.5 Interaction with other medicinal products and other forms of interaction

- 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.

4.6 Pregnancy and lactation

Safe use of IBUCAP in pregnancy and lactation has not been established. IBUCAP should not be preferably co-administered with other NSAIDs, corticosteroids, hypoglycemics, digoxin, lithium, methotrexate, cyclosporine, coagulants & anticoagulants, bone marrow suppressants as well as probenecid. Abrupt stoppage of Caffeine-containing products is not advisable since it could cause withdrawal symptoms such as headache, anxiety, or muscle tension within 12 to 18 hours. IBUCAP is not safe in pregnancy & in nursing mothers.

4.7 Adverse Reactions

Long-term use may lead to gastric ulcer, anti-inflammatory drug induced allergy, asthma, hypertension, hepatic, renal dysfunction, insomnia, vertigo and abdominal pain. Large doses may cause restlessness, excitement, muscle tremor, tachycardia, liver damage & renal failure with acute tubular necrosis.

4.8 Symptoms of Overdosage & Treatment

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:

Ibuprofen BP Analgesic & Anti-inflammatory, ATC code: M01AE01

Paracetamol BP : Analgesic & Antipyretic, ATC code: N02BE01

Caffeine BP : Central Nervous System Stimulant, ATC code: N06BC01

IBUCAP CAPSULES

(Ibuprofen, Paracetamol & Caffeine Capsules)

Pharmacological Category:

Ibuprofen BP : Analgesic & Anti-inflammatory

Paracetamol BP : Analgesic & Antipyretic

Caffeine BP : Central Nervous System Stimulant

Pharmacological Action :

In IBUCAP, Paracetamol exhibits analgesic action by peripheral blockage of pain impulse generation. It produces anti-pyresis by inhibiting the hypothalamic heat-regulating centre. 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:

Ibuprofen is well absorbed from the gastrointestinal tract and is extensively bound to plasma Proteins. Ibuprofen diffuses into the synovial fluid. Plasma levels of ibuprofen from this product are detected from 5 minutes with peak plasma concentrations achieved within 1 2 hours after ingestion on an empty stomach. When this product was taken with food peak ibuprofen plasma levels were lower and delayed by a median of 25 minutes, but overall extent of absorption was equivalent.

Ibuprofen is metabolised in the liver to two major metabolites with primary excretion via the Kidneys, either as such or as major conjugates, together with a negligible amount of unchanged ibuprofen. Excretion by the kidney is both rapid and complete. The elimination halflife is approximately 2 hours.

In limited studies, ibuprofen appears in the breast milk in very low concentrations. No significant differences in ibuprofen pharmacokinetic profile are observed in the elderly.

The bioavailability and pharmacokinetic profiles of ibuprofen and paracetamol taken as this Product is not altered when taken in combination as a single or repeat dose. This product is formulated using a technology which releases both Ibuprofen and Paracetamol simultaneously, so that the active ingredients deliver a combination effect.

Paracetamol:

Paracetamol is readily absorbed from the gastrointestinal tract. Plasma protein binding is Negligible at usual therapeutic concentrations, although this is dose dependent. Plasma levels of paracetamol from this product are detected from 5 minutes with peak plasma concentrations

occurring at 0.5-0.67 hours after ingestion on an empty stomach. When this product was taken with food peak paracetamol plasma levels were lower and delayed by a median of 55 minutes, but overall extent of absorption was equivalent.

Paracetamol is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates, with about 10% as glutathione conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life is approximately 3 hours. A minor hydroxylated metabolite, which is usually produced in very small amounts by mixed function oxidases in the liver and detoxified by conjugation with liver glutathione, may accumulate following paracetamol overdose and cause liver damage.

No significant differences in the paracetamol pharmacokinetic profile are observed in the elderly.

Caffeine:

Caffeine is absorbed readily after oral administration, maximal plasma concentration are acheived within one hour and the plasma half-life is about 3.5 hours. 65 – 80 % of administered Caffeine is excreted in the urine as 1-Methyluric acid and 1-methylxanine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Name of Excipients
Ibuprofen BP
Paracetamol BP
Caffeine (Anhydrous) BP
Magnesium Stearate BP
Purified Talc BP
Size “0” Empty Hard Gelatin Capsule light blue cap with “Shalina” logo printed in white colour & dark blue colored body with “IBUCAP” printed in black. IH

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. Keep out of reach of children.

6.5 Nature and contents of container

1) Ibucap Capsules is available in blister pack of 10 Capsules. 20 such filled blisters are packed in a Bambam (Pouch Pack).
2) Ibucap Capsules is available in blister pack of 10 Capsules. 25 such filled blisters are packed in a printed carton along with one leaflet.

7. MARKETING AUTHORISATION HOLDER

SHALINA LABORATORIES PVT. LTD.

96, Maker Chambers VI, Nariman Point,

Mumbai - 400 021, India.

8. MARKETING AUTHORISATION IN OTHER COUNTRIES

Product is registered in Ghana, Kenya, and D.R.Congo & Central African Republic.