# SHALINA HEALTHCARE NIGERIA LIMITED

**National Agency for Food and Drug Administration and Control (NAFDAC)**

## SUMMARY OF PRODUCT CHARACTERISTICS

# IBUCAP CAPSULE

(Ibuprofen, Paracetamol & Caffeine Capsule)

| **Manufactured by:** | **Marketed by:** |
|---|---|
| **SHALINA HEALTHCARE NIGERIA LIMITED**<br>Block 3B, Westerner Industrial Avenue,<br>Off Lagos-Ibadan Expressway,<br>Isheri, IFO Local Government Area Ogun State, Nigeria.<br>Email: regulatory@shalina.com | **SHALINA HEALTHCARE NIGERIA LIMITED**<br>19, Fatai Atare Road (way), Matori, Mushin<br>Lagos, Nigeria, Tel: +2348107539933<br>Email: theophilus.adimoha@shalina.com |

**IBUCAP CAPSULE**

(**Ibuprofen, Paracetamol & Caffeine Capsule**)

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

**1.1 Product name:** IBUCAP CAPSULE (Ibuprofen, Paracetamol & Caffeine Capsule)

**1.2 Dosage Strength:**

Each capsule contains:
Ibuprofen BP……200 mg
Paracetamol BP……325 mg
Caffeine BP……...30 mg
Excipients…….q.s.

**1.3 Dosage Form:** Oral Capsule

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

| Ingredient | Specification | Quantity per Capsule (mg) | Standard batch Quantity In kg (1,00,000 Capsules) | Category |
|---|---|---|---|---|
| Ibuprofen | BP | 200.00 | 30.50 | Active |
| Paracetamol | BP | 325.00 | 20.0 | Active |
| Caffeine | BP | 30.00 | 3.0 | Active |
| Magnesium Stearate | BP | 6.000 | 0.6 | Lubricant |
| Purified Talc | BP | 8.000 | 0.8 | Glidant |
| Size “0” Empty Hard Gelatin Capsule light blue cap with “Shalina” logo printed in white colour & dark blue coloured body with “IBUCAP” printed in black. IH | IH | 1.0 No. | 1,00,000 No. | Unit dose holder |

**Definitions:** **BP:** British Pharmacopoeia
**IH:** In House

## 3. PHARMACEUTICAL FORM

**Oral Capsule**

Size ‘0’ hard gelatin capsule having light blue coloured cap with ‘SHALINA’ logo printed in white colour & dark blue coloured body with ‘IBUCAP’ printed in black color containing white amorphous powder

## 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)

## 4.3 Contraindications

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

## 4.4 Special warnings and precautions for use

Usage in Pregnancy & Lactation: **IBUCAP** is not safe in pregnancy & in nursing mothers.

## 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 machines

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 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)

## 4.9 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:**

**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:** | l.kg-1 | 0.9 l.kg-1 | 0.58 l.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 BP, Purified Talc BP, Size "0" Empty Hard Gelatin Capsule light blue cap with "Shalina" logo printed in white colour & dark blue coloured body with "IBUCAP" printed in black

### 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 container

1) 10 Capsule to be packed in a blister. Such 1 blister to be packed pouch. Such 20 pouches to be packed in outer Carton along with insert.
2) 10 Capsule to be packed in a blister. Such 25 blisters to be packed in carton along with leaflet.

## 7. MARKETING AUTHORISATION HOLDER

**SHALINA HEALTHCARE DMCC,**
30th Floor, Almas Towers,
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**Local Applicant in Nigeria:**

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