1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC) - Enclosed

1. Name of the finished product: IBULOCK 400 (Ibuprofen Tablets BP 400mg)

2. Qualitative and Quantitative composition:

COMPOSITION:
Each film coated tablet contains:
Ibuprofen BP ……400 mg
Excipients ……. q.s

Sr. No.	Ingredients	Specification	Qty./Tab (mg)
1.	Ibuprofen *	BP	400.0
2.	Microcrystalline Cellulose	BP	300.0
3.	Pregelatinized Starch	USP	119.0
4.	Povidone (K-30)	BP	8.5
5.	Sodium Starch Glycolate	BP	7.5
6.	Magnesium Stearate	BP	7.5
7.	Colloidal Anhydrous silica	BP	7.5
8.	Instacoat Aqua III A03R20590 (Orange) IH (Hypromellose BP, Triacetin BP, Lactose Monohydrate BP, Purified Talc, Colour: Sunset Yellow, Quinoline Yellow & Titanium Dioxide	IH	25.0

BP: British Pharmacopoeia; USP : United States Pharmacopoeia; IH: In-House Specification

3. Pharmaceutical Form: Tablet

4. Clinical Particulars:

4.1 Therapeutic Indications
IBUPROFEN belongs to a group of medicines called non- steroidal anti- inflammatory drugs (NSAIDs), which helps to relieve pain, reduce swelling and fever. IBULOCK 400 tablets are useful in the following painful conditions.
IBULOCK 400 tablets are indicated for relief of the signs and symptoms of rheumatoid arthritis, osteoarthritis (painful swelling in joints) and ankylosing spondylitis (pain and stiffness in spine).
IBULOCK 400 tablets are useful for the relief of rheumatic or muscular pain, backache, headache including migraine headache, dental pain (toothache), dysmenorrhoea (period pain), painful swelling after soft tissue injuries. It can also be used to reduce fever and mild aches & pain due to colds and flu.

4.2 Posology and method of administration
Adult and children over 12 years:

Take one IBULOCK 400 tablet every six to eight hours, if you need to. Don't take more than 3 IBULOCK 400 tablets (1200 mg) in 24 hours.
Swallow each IBULOCK 400 tablet with water. Do not give to children under 12 years. Do not take more than the amount recommended above.

Oral administration only.

4.3 Contraindications
Hypersensitivity to Ibuprofen or any of the excipients in the product.
Have allergy to ibuprofen or any of the constituents of Ibuprofen
• Have severe heart, liver and kidney failure
• Have ulcers and bleeding in the digestive tract.
• Are taking aspirin with a daily dose above 75 mg
• Have abnormality in the rhythm of heartbeats (slow or fast heartbeats)
• Are pregnant

4.4 Special warnings and precautions for use
Ibuprofen is administered with caution to patients suffering from, or with a previous history of, bronchial asthma since ibuprofen has been reported to cause bronchospasm in such patients. Ibuprofen should only be given with care to patients with a history of gastrointestinal disease.
Caution is required in patients with renal, hepatic or cardiac impairment since the use of NSAIDs may result in deterioration of renal function. The dose should be kept as low as possible and renal function should be monitored in these patients.
Ibuprofen should be given with care to patients with a history of heart failure or hypertension since oedema has been reported in association with ibuprofen administration.
Patients with uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with ibuprofen after careful consideration. Similar consideration should be made before initiating longer term treatment of patients with risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking)

4.5 Interaction with other medicinal products and other forms of interaction
ACE-Inhibitors: Reports suggest that NSAIDs may diminish the antihypertensive effect of ACE inhibitors.
This interaction should be given consideration in patients taking NSAIDs concomitantly with ACE-inhibitors.
Aspirin: When ibuprofen tablets are administered with aspirin, its protein binding is reduced, although the clearance of free ibuprofen tablets is not altered. The clinical significance of this interaction is not known; however, as with other NSAIDs, concomitant administration of ibuprofen and aspirin is not generally recommended because of the potential for increased adverse effects.
Diuretics: Clinical studies, as well as post marketing observations, have shown that ibuprofen tablets can reduce the natriuretic effect-of furosemide and thiazides in some patients. This response has been attributed to inhibition of renal prostaglandin synthesis. During concomitant therapy with NSAIDs, the patient should be observed closely for signs of renal failure as well as to assure diuretic efficacy.
Lithium: Ibuprofen produced an elevation of plasma lithium levels and a reduction in renal lithium clearance in a study of eleven normal volunteers. The mean minimum lithium concentration increased 15% and the renal clearance of lithium was decreased by 19% during

this period of concomitant drug administration. This effect has been attributed to inhibition of renal prostaglandin synthesis by ibuprofen. Thus, when ibuprofen and lithium are administered concurrently subjects should be observed carefully for signs of lithium toxicity.
(Read circulars for lithium preparation before use of such concurrent therapy.) Methotrexate: NSAIDs
have been reported to competitively inhibit methotrexate accumulation in rabbit kidney slices. This may indicate that they could enhance the toxicity of methotrexate. Caution should be used when NSAIDs are administered concomitantly with methotrexate.
Warfarin-type anticoagulants:
Several short-term controlled studies failed to show that ibuprofen tablets significantly affected prothrombin times or a variety of other clotting factors when administered to individuals on coumarin type anticoagulants. However, because bleeding has been reported when ibuprofen tablets and other NSAIDs have been administered to patients on coumarin-type anticoagulants, the physician should be cautious when administering ibuprofen tablets to patients on anticoagulants. The effects of Warfarin and NSAIDs on GI bleeding are synergistic, such that the users of both drugs together have a risk of
serious GI bleeding higher than users of either drug alone.
H-2 Antagonists:
In studies with human volunteers, co-administration of cimetidine or ranitidine with ibuprofen had no substantive effect on ibuprofen serum concentrations.

4.6 Pregnancy and Lactation
Pregnant or breast-feeding women should not take IBULOCK 400 tablets.

4.7 Effects on the ability to drive and use machines
It is not expected to have any effect on your ability to drive or use machines.

4.8 Undesirable effects
IBUPROFEN is well-tolerated in majority of patients. It may cause following side effects rarely when taken for longer period: Stomach pain and ulcer in the digestive tract, allergy and asthma, increase in blood pressure and heart rate, sleeplessness, loss of balance and impairment in liver and kidney functions.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.
Unexplained wheezing (asthma), worsening of existing asthma, difficulty in breathing, swelling of the face, tongue, neck or throat, fast heart rate, feeling faint or dizzy or collapse (severe allergic reactions)
• High blood pressure, heart failure (you may be tired, have difficulty breathing or swollen legs)
• Kidney problems, which may lead to kidney failure.

4.9 Overdose
Symptoms of overdose include headache, nausea, vomiting, epigastric pain, vertigo, sleepiness, hypotension, ataxia and very occasionally coma.
No specific antidote is available. Treatment is supportive with gastric lavage and correction of serum electrolyte imbalance if required.
Ibuprofen is rapidly absorbed after oral administration, is strongly plasma protein bound, and is excreted mainly in the urine as metabolites. The drug has a plasma half-life of 2 hours.

5. Pharmacological Particulars:

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, nonsteroidal; propionic acid derivatives.
ATC Code: M01AE01

Pharmacological action:
Ibuprofen is a propionic acid derivative with analgesic, anti-inflammatory and anti- pyretic activity. The drug's therapeutic effects as an NSAID are thought to result from its inhibitory effect on the enzyme cyclo-oxygenase, which results in a marked reduction in prostaglandin synthesis.

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. The half- life of Ibuprofen is about 2 hours.

5.3 Pre-clinical Safety:

Not applicable.

6. Pharmaceutical Particulars:

6.1 List of Excipients:

Microcrystalline Cellulose	BP
Pregelatinized Starch	USP
Povidone (K-30)	BP
Purified Water	BP
Sodium Starch Glycolate	BP
Colloidal Anhydrous Silica	BP
Magnesium Stearate	BP
Purified Talc	BP
Hypromellose	BP
Triacetin	BP
Lactose Monohydrate	BP
Sunset Yellow	IH
Quinoline Yellow	IH
Titanium dioxide	IH

6.2 Incompatibilities: Nil

6.3 Shelf Life: 36 months

6.4 Special Precautions for storage:

Do not store above 30˚C. Protect from the sunlight and moisture. Keep out of the reach of children.

6.5 Nature and contents of container:
10 tablets Alu-PVC blister. 10 such blister packed in Printed carton with pack insert.

6.6 Instructions for use and handling
None

7. Marketing Authorization Holder:
SHALINA HEALTHCARE DMCC
30th Floor, Almas Towers,
Jumeirah Lakes Towers Dubai - UAE.
Local Applicant in Nigeria
SHALINA HEALTHCARE NIGERIA LIMITED
19, Fatai Atare Road (way), Matori, Mushin,Lagos, Nigeria

8. Manufacturing Site :
Shalina Healthcare Nigeria Ltd.
Block 3B, Westerner Industrial Avenue,
Off Lagos-Ibadan Expressway, Isheri,
IFO Local Government Area,
Ogun State, Nigeria.

9. Date of first Authorization /renewal of the authorization: New product application for registration.

10. Date of revision of text: December 2021