

1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC) - Enclosed

IBULOCK PLUS TABLET

(IBUPROFEN 400 mg & PARACETAMOL 500 mg TABLETS)

SUMMARY OF PRODUCT CHARACTERISTICS**1. NAME OF THE MEDICINAL PRODUCT****IBULOCK PLUS TABLET** (IBUPROFEN 400 mg & PARACETAMOL 500 mg TABLETS)**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Ingredient	Quantity per tablet (mg)
Ibuprofen BP	400.0
Paracetamol BP	500.0
Microcrystalline Cellulose BP	5.0
Maize Starch BP	18.0
Maize Starch BP (For paste)	50.0
PVP K -30 BP	10.0
Croscarmellose Sodium BP	5.0
Sodium Starch Glycolate BP	5.0
Colloidal Anhydrous Silica BP (Aerosil)	7.0
Purified Talc BP	3.0
Magnesium Stearate BP	5.0

Definitions: BP: British Pharmacopoeia**3. PHARMACEUTICAL FORM**

Tablets

4. CLINICAL PARTICULARS**4.1 Therapeutic indications**

IBULOCK PLUS tablet contain ibuprofen and paracetamol. Ibuprofen is a non-steroidal anti-inflammatory drugs (NSAIDs) which work by reducing pain, swelling and fever. Paracetamol is a pain killing medicine that also reduces fever.

IBULOCK PLUS tablet is used for headache, migraine, rheumatic pain, muscle and joint pain, arthritis pain, neck pain, menstrual pain, dental pain, pain and inflammation (swelling) associated with infection or injury.

4.2 Posology and method of administration

Adults and children above 12 years: One tablet 3 times a day after meals. Do not take more than 3 tablets in 24 hours.

Children below 12 years: Not recommended

4.3 Contraindications

Ibulock plus is contraindicated in persons:

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- Are allergic to ibuprofen, paracetamol, or any of the other ingredients listed in Section 6.
- Had a history of allergic reactions to aspirin, other NSAID medicines
- Have or ever had an ulcer or bleeding in your stomach or duodenum (small bowel) that may or may not related to previous NSAID medicines.
- Have severe liver, kidney or heart failure.
- Are in the last 3 months of pregnancy.

Take special care with IBULOCK PLUS If symptoms continue consult doctor or pharmacist. Check with doctor or pharmacist before us:

- If you have liver or kidney problems.
- If you are elder or undergoing surgery.

Taking other medicines:

Avoid use of two or more NSAIDs containing products including aspirin.

Do not take IBULOCK PLUS with

Mifepristone (used for pregnancy termination), Anti-platelet agents and selective serotonin-reuptake inhibitors (SSRIs – antidepressant medicines), HIV medicines, medicines for high cholesterol.

IBULOCK PLUS may affect or be affected by some other medicines. For example: medicines to reduce high blood pressure, diuretics (water pills), heart stimulants, lithium, corticosteroid, anti-coagulants (that cause blood thinning/prevent clotting), quinolone and chloramphenicol antibiotics, medicines to suppress the immune system (for example methotrexate, ciclosporine, tacrolimus), anti-sickness medicines (for example metoclopramide, domperidone).

4.4 Special warnings and precautions for use

IBULOCK PLUS is not safe in pregnant and breast-feeding women. Ask your doctor or pharmacist for advice before taking any medicine.

4.6 Pregnancy and lactation

IBULOCK PLUS is not safe in pregnant and breast-feeding women. Ask your doctor or pharmacist for advice before taking any medicine.

4.7 Adverse Reactions

IBULOCK PLUS can have side effects, although not everybody gets them.

IBULOCK PLUS can cause allergic reactions like difficult breathing, worsening of asthma, and various skin reactions. Long term usage may cause bleeding disorders, high blood pressure, malfunction of liver, kidney or heart. It may rarely cause nausea, vomiting, stomach discomfort, dizziness and headache. Taking excess amount of **IBULOCK PLUS** may cause severe liver malfunction.

4.8 Symptoms of Over dosage & Treatment

Contact health care provider immediately in the event of over dosage because of the risk of irreversible liver damage.

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4.9 Effects on ability to drive and use machines

IBULOCK PLUS may cause dizziness, drowsiness, fatigue and visual disturbances and therefore, you should not drive a car, operate machineries if such side effects occur.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ibuprofen plus is an antipyretic, analgesic & anti-inflammatory drug.

ATC Code: N02BE51

Pharmacodynamic effects:

Ibuprofen exerts its action by inhibiting the biosynthesis and release of prostaglandins. It works by blocking an enzyme in the body known as cyclo-oxygenase (COX). Cyclo-oxygenase is involved in the production of numerous chemicals in the body, including those known as prostaglandins. Prostaglandins are produced by the body in response to the presence of injury or disease and they make the nerves more sensitive to pain impulses. They have an important role in the production of pain, inflammation, and fever. By reducing the amount of prostaglandin produced and inhibiting its biosynthesis by the body, ibuprofen is able to relieve each of these symptoms. Paracetamol acts on CNS to produce analgesic and anti-pyretic effect. It has negligible anti-inflammatory action in therapeutic doses. It blocks prostaglandin synthesis by cyclo-oxygenase pathway.

5.2 Pharmacokinetic properties

Parameters	Ibuprofen	Paracetamol
Absorption (oral)	> 95%	> 95%
Presystemic metabolism	-	20%
Plasma half life Range	-	1.5- 3.0 hours
Volume of distribution	0.1 L/kg	0.1 L/kg
Plasma protein binding	99%	< 20%
Elimination	Bile & urine	Urine

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch BP, Microcrystalline Cellulose BP, Povidone BP, Sodium Starch Glycolate BP, Colloidal Anhydrous Silica BP, Croscarmellose Sodium BP, Purified Talc BP, Magnesium Stearate BP

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6.2 Incompatibilities

Not applicable.

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

IBULOCK PLUS Tablets is available in a pack of 10 strips of 10 Tablets in each strip

7. MARKETING AUTHORISATION HOLDER

SHALINA HEALTHCARE DMCC

30th Floor, Almas Towers,
Jumeirah Lakes Towers Dubai-UAE.

8. MANUFACTURER

SHALINA HEALTHCARE NIGERIA LTD.

Block 3B, Westerner Industrial Avenue,
Off Lagos-Ibadan Expressway, Isheri,
IFO Local Government Area,
Ogun State, Nigeria.

9. DATE OF REVISION OF TEXT

Every two years.