SUMMARY OF PRODUCTS CHARACTERISTICS

1.NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

1.1 Brand Name : **Ibuplus Suspension**
1.2 Generic Name : **Ibuprofen and Paracetamol Suspension**
1.3 Strength : **Ibuprofen 100mg + Paracetamol 125mg per 5ml**
1.4 Pharmaceutical Form: **Suspension**

2. QUALITATIVE & QUANTITATIVE COMPOSITION :

Each 5ml. contains:

Ibuprofen	BP	100mg.
Paracetamol	BP	125mg.
Flavoured base		q.s.

Colour: Sunset Yellow FCF

3. PHARMACEUTICAL FORM

Oral Suspension
Orange colored flavored palatable suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Ibuplus (Ibuprofen and Paracetamol Suspension) is indicated for the treatment of pain and inflammation in rheumatic disease, juvenile idiopathic arthritis, soft tissue injuries, systemic juvenile idiopathic arthritis and other musculoskeletal disorders, mild to moderate pain including dysmenorrhoea, postoperative analgesia, migraine, dental pain and pyrexia

with discomfort.This product is especially suitable for pain which requires stronger analgesia than Ibuprofen or Paracetamol alone.

4.2 Posology and method of administration

As prescribed by physician.

4.3 Contraindications

Ibuprofen should be contraindicated during active gastro-intestinal (GI) bleeding, ulceration, history of GI bleeding, GI perforation related to previous NSAID therapy, history of recurrent GI haemorrhage (two or more distinct episodes), severe heart failure. Ibuprofen is contraindicated to use in children under 3 months or body-weight under 5 kg. Paracetamol oral suspension 500 mg/5ml should not be used for use in children under 16 years. Paracetamol is contraindicated to use as prophylaxis of post immunisation pyrexia following immunisation with meningococcal group B vaccine.

4.4 Special warnings and special precautions for use

Ibuprofen: Allergic disorders (in adults), cardiac impairment (NSAIDs may impair renal function), cerebrovascular disease, coagulation defects, connective tissue disorders, Crohn's disease (may be exacerbated), elderly (risk of serious side-effects and fatalities) (in adults), heart failure, ischaemic heart disease, peripheral arterial disease, risk factors for cardiovascular events risk factors for cardiovascular events, ulcerative colitis (may be exacerbated),uncontrolled hypertension. High-dose Ibuprofen (≥ 2.4 g) daily a small increase in cardiovascular risk. Paracetamol: Before administering, check when Paracetamol last administered and cumulative Paracetamol dose over previous 24 hours, body-weight under 50 kg. Chronic alcohol consumption, dehydration, malnutrition, hepatocellular insufficiency, long-term use (especially in those who are malnourished).

4.5 Interaction with other FPPs and Other forms of Interaction

Fluconazole, Voriconazole increases plasma concentration of Ibuprofen. Antiplatelet effect of Aspirin possibly reduced by Ibuprofen. Excretion of Baclofen, Methotrexate reduced by Ibuprofen. Increased risk of nephrotoxicity when ibuprofen given with Tacrolimus.

Paracetamol: Lixisenatide possibly reduces the absorption of Paracetamol, Ketoconazole advises avoid concomitant use with Paracetamol. Carbamazepine possibly accelerates metabolism of Paracetamol. Colestyramine reduces absorption of Paracetamol. Anticoagulant effect of coumarins possibly enhanced by prolonged regular use of Paracetamol. Metoclopramide increases rate of absorption of Paracetamol.

4.6 Pregnancy and lactation

Pregnancy: Ibuprofen: Avoid unless the potential benefit outweighs the risk. Avoid during the third trimester (risk of closure of fetal ductus arteriosus in utero and possibly persistent pulmonary hypertension of the newborn); onset of labour may be delayed and duration may be increased. Paracetamol: Not known to be harmful.

Lactation: Use Ibuprofen with caution during breast-feeding. Ibuprofen and Paracetamol amount too small to be harmful.

4.7 Effects on ability to drive and use machines

Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances are possible after taking NSAIDs. If affected patients should not drive or operate machinery.

4.8 Undesirable effects

Ibuprofen may show side effects like-alveolitis, aseptic meningitis (patients with connective-tissue disorders such as systemic lupus erythematosus may be especially susceptible), hepatic damage, interstitial fibrosis associated with NSAIDs can lead to renal failure, pancreatitis, papillary necrosis associated with NSAIDs can lead to renal failure, pulmonary eosinophilia, Stevens-Johnson syndrome, toxic epidermal necrolysis, visual disturbances.Paracetamol may show rarely acute generalised exanthematous pustulosis, malaise, skin reactions, Stevens-Johnson syndrome, toxic epidermal necrolysis, blood disorders, leucopenia, neutropenia, thrombocytopenia.

4.9 Overdose

Overdosage with Ibuprofen may cause nausea, vomiting, epigastric pain, and tinnitus, but more serious toxicity is very uncommon, symptomatic measures are indicated if more than 100 mg/kg has been ingested within the preceding hour. Liver damage and less frequently renal damage can occur following overdose of Paracetamol. Nausea and vomiting, the only early features of poisoning, usually settle within 24 hours. Persistence beyond this time, often associated with the onset of right subcostal pain and tenderness, usually indicates development of hepatic necrosis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ibuprofen

Pharmacotherapeutic group: Analgesic; Anti-inflammatory

ATC Code: M01AE01

Mechanism of action: Ibuprofen: A non-steroidal anti-inflammatory drug which is very well-tolerated acts by inhibiting cyclo-oxygenase enzyme responsible for biosynthesis of prostaglandins. The main mechanism of action of ibuprofen is the non-selective, reversible inhibition of the cyclooxygenase enzymes COX-1 and COX-2 (coded for by PTGS1 and PTGS2, respectively). Ibuprofen exerts its anti-inflammatory and analgesic effects through inhibition of both COX isoforms.

Paracetamol

Pharmacotherapeutic group: Antipyretic

ATC Code: N02BE01

Mechanism of action: Paracetamol: It is a non-narcotic, non-opoid analgesic which produces analgesia by raising pain threshold in the brain and is particularly suitable as a day time analgesic. Encompasses complete pyrexia when given in combination with Ibuprofen.

5.2 Pharmacokinetic properties

Ibuprofen is well absorbed from the gastrointestinal tract and is extensively bound to plasma proteins. It diffuses into the synovial fluid, metabolised in the liver and excreted rapidly and completely by the kidney. The elimination half-life is approximately 2 hours. Paracetamol is readily absorbed from the gastrointestinal tract. Plasma protein binding is negligible at usual therapeutic concentrations, although this is dose-dependent. It is metabolised in the liver and excreted in the urine, less than 5% is excreted as unchanged Paracetamol. The elimination half-life is approximately 3 hours.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Innokot Resin (A5dl5009)	IH
Liquid Sorbitol (Sorbitol Solution 70%)	BP
Polysorbate-80	BP
Aspartame	BP
Colour Sunset Yellow FCF (15985)	IH
Essence Orange Sweet No.1	IH
Essence Pineapple (INT.22768)	IH
Purified Water	BP

6.2 Incompatibilities

Not sufficient data available

6.3 Shelf life

36 month from the date of manufacturing.

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C. Protect from light. Keep out of reach of Children

6.5 Nature and contents of container

100ml amber coloured PET bottle in an inner carton with measuring cup & PIL

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

LEBEN LABORATORIES PVT. LTD.,

Business Address:

RO & Works : Plot No. L-4, Phase-III, MIDC, AKOLA–444 104 (MS), INDIA
Ph.:0091-724-2258328, 2259401/02/03 & Fax: 2258371
E-mail - export@lebenlab.com, qad@lebenlab.com, ra@lebenlab.com

Mumbai Off. : 11, Mahavir Mansion, 70, Trinity Street, Near Metro Cinema,
MUMBAI–400 002 (MS), INDIA
Ph.: 0091-22-2207-5301, 02, Fax: 2207-5303
E-mail - mumbai@lebenlab.com

Country : INDIA

8. MARKETING AUTHORISATION NUMBER

06844/07297/NMR/2019

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Nov 28, 2021

10. DATE OF REVISION OF THE TEXT
