SUMMARY OF PRODUCT CHARACTERISTICS[SmPC]

PARASTEO TABLET

[Paracetamol BP 500mg + Diclofenac Potassium BP 50mg]

SUBMITTED BY

IMPULSE PHARMA PVT LTD

PLOT NO. J-201,202/1, MIDC,

TARAPUR, BOISAR, TAL & DIST.: PALGHAR – 401 506,

INDIA

1. NAME OF THE MEDICINAL PRODUCT

PARASTEO TABLET
[Paracetamol BP 500mg + Diclofenac Potassium BP 50mg **]**

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

COMPOSITION:
Each Uncoated Tablet contains
Diclofenac Potassium B.P. 50mg
Paracetamol B.P. 500mg

3. PHARMACEUTICAL FORM

Oral solid preparation

4. CLINICAL PARTICULARS

4.1Therapeutic indications

Parasteo Tablet is indicated in the treatment of fever, body pain, headache, toothache, dysmenorrhea, neuralgia, rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis; periarticular disorders such as bursitis and tendinitis; soft- tissue disorders such as sprains and strains; and other painful conditions such as renal colic, acute gout and migraine.

DOSAGE: By mouth: Adult: 1 tablet of Parasteo Tablet 8hourly or 12hourly daily after food.
CHILD: Not recommended.

Special warnings and precautions for use

Parasteo Tablet should be used with caution in the elderly, in allergic disorders, in patients with a history of hypersensitivity to aspirin or any other NSAID, especially in individuals in whom attacks of asthma, angioedema, urticaria or rhinitis have been precipitated by aspirin or any other NSAID.
The risk of paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce liver microsomal enzymes. The absorption of paracetamol may be accelerated by drugs such as metoclopramide. Excretion may be affected and plasma concentrations altered when given with probenecid. Cholestyramine reduces the absorption of the drug if given within I hour of Parasteo Tablet administration.
The safety of Parasteo Tablet during pregnancy and/or in breast-feeding is not guaranteed.

4.3 Contraindications

Parasteo Tablet is contraindicated in patients with impaired kidney or liver function. It should be given with care to patients with alcohol dependence. It is also contraindicated in patients with a history of hypersensitivity to aspirin or any other NSAID. Pregnancy and breastfeeding, coagulation defects, severe heart failure, previous or active peptic ulceration, haemophilia.

PREGNANCY AND BREAST-FEEDING: The safety of Parasteo Tablet during pregnancy and/or in breast-feeding is not guaranteed.

4.5 drug interaction

The risk of paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce liver microsomal enzymes. The absorption of paracetamol may be accelerated by drugs such as metoclopramide. Excretion may be affected and plasma concentrations altered when given with probenecid. Cholestyramine reduces the absorption of the drug if given within I hour of Parasteo Tablet administration.

The safety of Parasteo Tablet during pregnancy and/or in breast-feeding is not guaranteed.

Overdose

In cases of overdosage, gastric lavage and correction of blood electrolytes are recommended.

Pharmacology and toxicology

Parasteo Tablet is a combination of Paracetamol and Diclofenac Potassium . Paracetamol is non-opoid analgesic. It has analgesic and antipyretic actions similar to, but weaker than, those of Aspirin. It has weak anti-inflammatory properties. Its mechanism of action is by the inhibition of the biosynthesis and release of prostaglandins in the cells. Diclofenac Potassium is a non-steroidal anti-inflammatory drug (NSAID). It has a lasting analgesic and an anti-inflammatory effect . Its mechanism of action is by the inhibition of the enzyme cyclo-oxygenase , and ultimately the reduction of prostaglandins production

Pharmacokinetics

Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral doses. It is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma-protein binding is negligible at usual therapeutic concentrations. The elimination half-life of paracetamol varies from about 1 to 3 hours. Paracetamol is metabolized mainly in the liver and excreted in the urine mainly as the glucuronide and sulfate conjugates. Less

than 5% is excreted as unchanged paracetamol. A minor hydroxylated metabolite(N-acetyl-p-benzoquinoneimine), is usually produced in small amounts by cytochrome P450 isoenzymes (mainly CYP2EI and CYP3A4) in the liver and kidney. It is usually detoxified by conjugation with glutathione but may accumulate after paracetamol overdosage and cause damage.

Diclofenac Potassium is rapidly absorbed when given as oral tablet. Although diclofenac given orally is almost completely absorbed, it is subject to first-pass metabolism so that about 50% of the drug reaches the systemic circulation in the unchanged form. At therapeutic concentrations, it is more than 99% bound to plasma proteins. Diclofenac penetrates synovial fluid where concentrations may persist even when plasma concentrations fall; small amounts are distributed into breast milk. The terminal plasma half-life is about 1 to 2 hours. Diclofenac is metabolized to 4'-hydroxydiclofenac, 5-hydroxydiclofenac, 3' –hydroxydiclofenac and 4',5-dihydroxydiclofenac. It is then excreted in the form of glucuronide and sulfate conjugates, mainly in the urine (about 60%) but also in the bile (about 35%); less than 1% is excreted as unchanged diclofenac.

Undesirable effects

Gastrointestinal discomfort, nausea, diarrhea, and occasionally bleeding and ulceration occur. Hypersensitivty reactions particularly rashes, angioedema, and bronchospasm, headache, dizziness, nervousness, depression, drowsiness, insomnia, vertigo, hearing disturbances such as tinnitus, photosensitivity, and haematuria. Other rare side effects include hepatic damage, alveolitis, pulmonary eosinophilia, pancreatitis, eye changes, Steven-Johnson syndrome, toxic epidermal necrolysis, induction of or exacerbation of colitis and aseptic meningitis.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch

microcrystalline cellulose

polysorbate 80

pregelatinized starch

sodium carboxymethyl starch

magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

3years.

6.4 Special precautions for storage

Store below 30^{o}C in a cool and dry place. Protect from heat and moisture.
KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

Tablets in PVC blister sachets of 1 x 10 Tablets; 10 x 10 Tablets in a packet.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

TOP UGOLIFE PHARM. CO. LTD.,
13, Prince Joseph Adebayor Street, Ago, Okota,
Lagos State, Nigeria.

8. MANUFACTURED BY:

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