BIORAJ PHARMACEUTICALS LIMITED	
BRAND NAME: BIORAJ PARACETAMOL & DICLOFENAC POTASSIUM CAPLETS	**GENERIC NAME:** PARACETAMOL BP. (500mg) DICLOFENAC POTASSIUM BP. (50mg)
SUMMARY OF PRODUCT CHARACTERISTICS	

1 .NAME OF THE MEDICINAL PRODUCT

Bioraj Paracetamol & Diclofenac Potassium Caplets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Uncoated Tablet contains

Diclofenac Potassium B.P. 50mg

Paracetamol B.P. 500mg

3. PHARMACEUTICAL FORM

Oral tablet.

A light green caplet with BPL on one side and break line on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Management of mild to moderate acute pain such as musculoskeletal pain, gout, primary dysmenorrhea, post-operative pain, dental pain and in feverish conditions.
Diclofenac is a non-steroidal anti-inflammatory drug which inhibits COX 1 and COX 2 responsible for prostaglandin synthesis. Diclofenac has a lasting analgesic and anti-inflammatory effect which makes it useful for pain management.
Paracetamol is an analgesic and antipyretic agent with low anti-inflammatory activity, used for mild to moderate pain including headache and acute migraine attacks.

4.2 Posology and method of administration

Posology

Adult: One caplet every 8 or 12 hours or as directed by physician. Do not take more than 3 caplets daily.

Method of administration

For oral administration

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4.3 Contraindications

This product is contra-indicated in patients with known hypersensitivity to its contents. It should not be used by patients with peptic ulcer.

Bioraj Diclofenac & Potassium Caplets 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.

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Excessive or prolong use should be avoided to prevent liver or kidney damage. Patients with these conditions should take this product under medical supervision. Consult your physician if no relief is obtained from the recommended dose. This product is not recommended for use in children, pregnancy and lactation.

4.5 Interaction with other medicinal products and other forms of 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 product administration.

The concurrent use of acetylsalicylic acid and diclofenac potassium leads to decrease in the blood concentration of diclofenac potassium.

4.6 Fertility, pregnancy and lactation

Pregnancy

Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of

their doctor regarding its use. A large amount of data on pregnant women indicates neither malformative, nor feto/neonatal toxicity.

Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy if clinically needed however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

Breastfeeding

Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding.

4.7 Effects on ability to drive and use machines

This product may cause drowsiness. If affected, the patient should not drive or operate machinery.

4.8 Undesirable effects

Skin rashes and other allergic reactions may occur.The rashes is usually erythematous or urticarial but sometimes more serious and may be accompanied by fever and mucosal lesions.The use of paracetamol has been associated with the occurence of neutropenia, thrombocytopenia, pancytopenia and leucopenia.

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.

4.9 Overdose

Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors. In cases of overdosage, gastric lavage and correction of blood electrolytes are recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Bioraj Diclofenac & Potassium Caplets 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.

5.2 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch

Purified talc

Methyl paraben

Propyl paraben

Gelatin

Magnesium stearate

Fast green

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30^0C and protect from light.

Keep out of reach of children.

6.5 Nature and contents of container

Polypropylene containers

Pack size: 1 × 10 caplets

Blister strips: 10 Caplets are packed in ALU-PVC blister pack. 10 such ALU-PVC blister is packed in a printed carton with a printed insert.

Pack sizes: 10 × 10

6.6 Special precautions for disposal and other handling

Not applicable

7.0 MANUFACTURER

Bioraj Pharmaceuticals Limited

No 405 Kaiama Road, Ilorin

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