Summary Product Characteristics

1. Name of the medicinal product

PINNAFLAM PLUS Tablets

2. Quality and Quantitative Composition

Each uncoated tablet contains,

Diclofenac Sodium BP 50 mg

Paracetamol BP 500 mg

For a full list of excipients, see section 6.1.

3. Pharmaceutical Form

Tablet

White coloured, caplet shaped, biconvex uncoated tablet with break line on one side.

4. Clinical Particulars

4.1 Therapeutic indication

Short term relief of headache, dental pain, period pain, rheumatic pain, muscular pain, backache and the symptoms of colds and flu including fever.

Pain and fever. Paracetamol is used for the rapid relief of fever, pains and aches such as headache, earache, toothache, fibrosis, myalgia, neuralgia, arthralgia, osteoarthritis and postoperative pain.

For the reduction of fever and to be used as an adjunctive treatment to relieve symptoms of cold and flu.

4.2 Posology and method administration

The recommended dose of PINNAFLAM PLUS Tablets is 1 tablet twice daily. Generally, no dose adjustment is necessary in elderly patients and those with mild renal impairment. Safety and efficacy has not been established in children.

Method of administration: Oral

4.3 Contraindication

Contraindicated in patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs, having coronary artery bypass graft (CABG) surgery and hypersensitivity.

4.4 Special Warning and precautions for use

Caution should be exercised in patients with history of heart, kidney or liver disease, diabetes, stomach or bowel problems, high blood pressure, blood disorders, bone marrow problems, bleeding problems, blood vessel disease, dehydration, alcoholism, any allergy, who are taking other medications, elderly, children, during pregnancy and breastfeeding.

It may cause dizziness, do not drive a car or operate machinery while taking this medication. For external use only; avoid contact with eyes, nose, or mouth. It may cause harm if it is swallowed. Monitor kidney and liver function, blood electrolyte levels, complete blood cell counts, and blood pressure regularly while taking this medication.

4.5 Interaction with other medicinal products and other forms of interactions

Anti-hypertensives: Reduced anti-hypertensive effect. Cardiac Glycosides and Lithium: The plasma concentration of digoxin and lithium may be increased. NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma glycoside levels. Anti-coagulants: Although clinical investigations do not appear to indicate that Diclofenac has an influence on the effect of anticoagulants, there are isolated reports of an increased risk of haemorrhage with the combined use of Diclofenac and anticoagulant therapy. Therefore, to be certain that no change in anticoagulant dosage is required, close monitoring of such patients is necessary. As with other non-steroidal anti-inflammatory agents, Diclofenac can reversibly inhibit platelet aggregation.

Hypoglycaemics: Diclofenac does not appear to potentiate the effect of oral hypoglycaemics. However, caution is advised in patients receiving such combinations of treatment and close monitoring of such patients is required.

Cyclosporin: Cyclosporin nephrotoxicity may be increased by the effect of non-steroidal anti-inflammatory drugs on renal prostaglandins.

Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone. Other NSAIDs and Methotrexate: Caution should be exercised if NSAIDs and methotrexate are administered within 24 hours of each other, since NSAIDs may increase methotrexate plasma levels, resulting in increased toxicity.

Quinolone anti-microbials: Concomitant therapy with quinolone antimicrobials, may cause convulsions. This may occur in patients with or without a previous history of epilepsy or convulsions. Thus caution is

needed if introducing a quinolone anti-microbial to a patient already taking an NSAID.

The risk of Paracetamol toxicity may be increased in patients receiving other potentially heatotoxic drugs or drugs that induce hepatic microsomal enzymes. Coadministration of Paracetamol with rifampicin, isoniazid, chloramphenicol, anti-epileptic drugs and antiviral drugs is to be avoided. Metoclopromide may increase the absorption of Paracetamol whereas excretion and plasma concentration may be altered when coadministered with probenecid. Cholestyramine also reduces the absorption of Paracetamol.

4.6 Pregnancy and Lactation

Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

The most commonly-observed adverse events are gastrointestinal in nature. Peptic ulcers, perforation or GI bleeding, sometimes fatal, particularly in the elderly, may occur. Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease have been reported following administration. Less frequently, gastritis has been observed. Pancreatitis has been reported very rarely.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose and special antidotes

Overdosage may cause nausea, vomiting, pain abdomen, dizziness, somnolence, headache, sweating, pancreatitis, hepatic failure and acute renal failure. Treatment, if required, includes gastric lavage, activated charcoal and other symptomatic measures as per medical advice.

5. Pharmacological Properties Clinical Particulars

5.1 Pharmacodynamic Properties

Diclofenac is a nonsteroidal anti-inflammatory drug (NSAID). In pharmacologic studies, Diclofenac has shown anti-inflammatory, analgesic, and antipyretic activity. As with other NSAIDs, its mode of action is not known; its ability to inhibit prostaglandin synthesis, however, may be involved in its anti-inflammatory activity.

Diclofenac has potent anti-inflammatory, analgesic and antipyretic actions. It inhibits the enzyme, cyclo oxygenase, thus resulting in reduced synthesis of prostaglandin precursors.

Paracetamol is a clinically proven analgesic and antipyretic agent with weak anti-inflammatory effect. Analgesic action: The central analgesic action of Paracetamol resembles that of aspirin. It produces analgesia by raising pain threshold.

Antipyretic effect: The antipyretic effect of Paracetamol is attributed to its ability to inhibit COX in the brain where peroxide tone is low. Recent evidence suggests inhibition of COX-3 (believed to be splice variant product of the COX-1 gene) could represent a primary central mechanism by which Paracetamol decreases pain and possibly fever.

5.2 Pharmacokinetic properties Absorption

Diclofenac Sodium

It is well absorbed following oral administration. It undergoes first-pass metabolism; only 50–60% of a dose reaches systemic circulation as unchanged drug. Peak plasma concentration usually attained within about 1 hour (diclofenac potassium conventional tablets), 2 hours (diclofenac sodium delayed-release tablets), or 5.25 hours (diclofenac sodium extended-release tablets). Absorbed into systemic circulation following topical administration as gel or transdermal system; plasma concentrations generally very low compared with oral administration. Following application of a single diclofenac epolamine transdermal system to intact skin on the upper arm, peak plasma concentrations occur in 10–20 hours. Following topical application of diclofenac gel, peak plasma concentrations occur in about 10–14 hours. Moderate exercise does not alter systemic absorption of topically applied diclofenac (transdermal system or 1% gel). Not established whether application of heat following gel application affects systemic absorption as application of a heat patch for 15 minutes before application of the 1% gel did not affect systemic absorption. Onset: Single 50- or 100-mg doses of diclofenac potassium provide pain relief within 30 minutes. Duration: Pain relief lasts up to 8 hours following administration of single 50- or 100-mg doses of diclofenac sodium. Food: Food delays time to reach

peak plasma concentration but do not affect extent of absorption following administration as conventional, delayed-release, or extended-release Paracetamol

Rapid and complete from the GI tract. Tmax is 0.5 to 2 h; 4 h after over dosage.

Distribution

Diclofenac Sodium

Following oral administration, concentrations in synovial fluid may exceed those in plasma. Plasma Protein Binding: >99%.

Paracetamol

Distributed throughout most body fluids. Binding to plasma proteins is variable.

Metabolism

Diclofenac Sodium

Metabolized in the liver via hydroxylation and conjugation. Some metabolites may exhibit anti-inflammatory activity.

Paracetamol

Primarily metabolized by hepatic conjugation (94%), and about 4% is metabolized by CYP-450 oxidize to toxic metabolite.

Elimination

Diclofenac Sodium

Excreted in urine (65%) and in feces via biliary elimination (35%) as metabolites Half-life: Oral preparations: 1–2 hours. Diclofenac epolamine transdermal system: approximately 12 hours. Special Populations: In geriatric patients, pharmacokinetic profile similar to that in younger adults. In patients with renal impairment, plasma clearance not substantially altered, although clearance of metabolites may be decreased.

5.3 Pre clinical safety data

Paracetamol

The t½ is about 2 hr 90% to 100% is recovered in the urine within the first day, primarily as inactive metabolites. 5% is excreted as unchanged drug. Protein binding - 25 % pKa - 9.51 at 25°C Predicted LogP- 0.51

6. Pharmaceutical Particulars

6.1 List of Excipients

Maize Starch BP

Microcrystalline Cellulose BP

Polyvidone K- 30 BP

Purified Water BP

Talc BP

Sodium starch Glycolate BP

Magnesium stearate BP

6.2 Incompatibilities

None

6.3 Shelf Life

24 months

6.4 Special precaution for storage

Store below 300C. Protect from light.

6.5 Nature and content of container

PVC blister of 10 tablets. 10 such PVC blisters are packed in a printed carton along with the pack insert.

7. Marketing Authorization Holder

Pinnacle Life Science Pvt. Ltd.

Mahendra Industrial Estate, Ground Floor Plot no .109-D, Rd no 29

Sion (East), Mumbai 400 022, INDIA

Manufacturer:

Pinnacle Life Science Pvt. Ltd.

Khasra No. 1328-1330,

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India.

8. Marketing Authorization Number
H2024/CTD7226/14216

9. Date of first authorization/ renewal of the authorization
31/07/2024

10. Date of the revision of the text
24/08/2026