SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1 Name of the Finished Pharmaceutical product

Pinnaflam Plus (Diclofenac Sodium and Paracetamol Tablet 50 + 500mg)

2. Qualitative and Quantitative Composition

Label claim:

Each uncoated tablet contains,

Diclofenac Sodium BP..... 50 mg

Paracetamol BP..... 500 mg

Excipients.....q.s.

S.No	**Ingredients**
	Dry Mixing
1.	Diclofeanc Sodium*
2.	Paracetamol**
3.	Maize Starch@
4.	Microcrystalline Cellulose
	Binder
4.	Maize Starch
5.	Polyvidone (K-30)
6.	Purified Water***
	Lubrication
7.	Sodium starch Glycolate (Type A)
8.	Magnesium Stearate
9.	Purified Talc
10	Colloidal Anhydrous Silica

3. Pharmaceutical form

Tablet

4. Clinical Particulars

4.1. Therapeutic indications

Tablet is indicated for symptoms accompanying a rise in temperature (febrile states). It is indicated for fever of varied etiology. It is indicated for headache, body pain, inflammation, rheumatism, arthritis, neuralgia, dysmenorrhoea, menstrual pain, dental pain, bursitis, sciatica and lower back pain. It is also indicated for sports and accident injuries.

4.2 Posology and method of administration

Tablets are administered orally. Generally, the dosage for adults is 1 tablet, 2-3 times a day. The drug should be taken after meals. For long term therapy, 1 tablet, 2 times a day is sufficient.

The score line included in the tablets is for better identification of the tablets and for the purpose of increasing aesthetic appearance of the tablets and should not be used to split the tablets into two equal halves.

4.3 Contraindications

Contraindicated in patients who are allergic to paracetamol or to any of the components of the formulation. Diclofenac is contraindicated in gastroduodenal ulcer, severe hepato-cellular insufficiency, severe renal insufficiency and in children less than 15 years of age.

4.4 Special warnings and precautions for use

Use in pregnancy and lactation: Tablet is contraindicated in during second and third trimester of pregnancy. It is contraindicated during lactation.

4.5 Interaction with other medicinal products and other forms of interaction

Tablet is contraindicated in patients receiving oral anticoagulants in combination with other NSAIDs. Consult doctor if you are taking any other prescription, non-prescription, herbal medicine or dietary supplement.

4.6 Fertility, pregnancy and lactation

Tablet is contraindicated in during second and third trimester of pregnancy. It is contraindicated during lactation.

Tablet is contraindicated in during second and third trimester of pregnancy. It is contraindicated during lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Adverse effects are rare. Gastro-intestinal disorders, nausea, diarrhoea, epigastric pain have been observed.

4.9 Overdose

Diclofenac : The toxic dose of Diclofenac has not been determined and there is no experience of overdosage. Intensification of the pharmacological effects may occur with overdosage. Management of acute poisoning with Diclofenac essentially consists of supportive and symptomatic measures. It is reasonable to take measures to reduce absorption of any recently consumed drug by forced emesis, gastric lavage or activated charcoal.

Paracetamol : Symptoms of overdosage include nausea and vomiting. Liver damage which may be fatal may only appear after a few days. Kidney failure has been described following acute intoxication. In the event of an overdose, consult your doctor immediately or take the patient to the nearest hospital at once. Specialised treatment is essential as soon as possible.

5. **Pharmacological properties**

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti inflammatory and Analgesic

ATC Code: Diclofenac Sodium: M01AB05 and Paracetamol : N02BE01

Distribution category : Pharmacy only medicine

Diclofenac belongs to a group of drugs called as Non-steroidal anti-inflammatory drugs. (NSAIDS). It exerts a potent blocking action on the prostaglandin synthesis. During

phagocytation of the immune complex by the leucocytes, prostaglandins are released on two levels- direct release of prostaglandins as well as other substances like histamine, serotonin and kinins.They are the cause of acute vascular inflammation phenomena- indirect release of prostaglandins by enzymes such as phospholipase, which acts on the phospholipids in the inflamed cell membrane. NSAIDs also exert an inhibiting activity on the platelet aggregation. Paracetamol is a peripheral analgesic. It is a centrally acting anti-pyretic, which acts on the hypothalamus thermal control centre by inhibition of prostaglandin synthesis.

5.2 Pharmacokinetic properties

The life-span of Diclofenac is estimated at 12 hours in both the plasma fluid and synovial fluid, where the concentration of the active substance is highest. The life span of Paracetamol is estimated at 2 to 2.5 hours and it is rapidly and fully absorbed. The plasma concentrations are reached within 20-30 minutes after ingestion. Diclofenac is mainly excreted via urine. About 90% of the total dose is excreted in the first 96 hours. Paracetamol is excreted 60-80% in the urine in glucuroconjugated form and 20-30% in the sulphoconjugated form. Less than 5% is excreted unchanged.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC

6. Pharmaceutical Particulars

6.1 List of Excipients

Maize Starch, Microcrystalline Cellulose, Polyvidone K- 30, Purified Water, Sodium Starch Glycolate, Magnesium Stearate, Talc, Colloidal Anahydrous Silica.

6.2 Incompatibilities

None

6.3 Shelf life

The shelf life of the medicinal product as package for sale

24 Months

The shelf life after dilution or reconstitution according to directions

Not Applicable.

The shelf life after first opening the container

Not Applicable

6.4 Special precaution for storage

Store below 30°C. Protect from light.

6.5 Nature and contents of container

UNIT PACK: The final product is well packed in an ALU- PVC blister of 10 tablets. 10 such ALU- PVC blister are packed in a printed carton along with the pack insert.

6.6 Special precautions for disposal and other handling

No special requirement.

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

8. Marketing Authorization Number :

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9. Manufacturer Name :
Pinnacle Life Science Pvt. Ltd.
Khasra No. 1328-1330, Village Manpura, Tehsil-Baddi,
Distt. Solan, Himachal Pradesh (H.P.) - 174101, India.

10. Date of first authorization/ renewal of the authorization

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11. Date of the revision of the text
