SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1 Name of the Finished Pharmaceutical product

Paarpin 500 Tablet (Paracetamol Tablet BP 500 mg)

2. Qualitative and Quantitative Composition

Each uncoated tablet contains,
Paracetamol BP..... 500 mg
Excipients .....q.s.

Sr. No.	Ingredients
1.	Paracetamol
2.	Maize Starch
3.	Colloidal Anhydrous silica
4.	Maize Starch
5.	Polyvidone (K-30)
6.	Purified Water
7.	Sodium Starch Glycolate
8.	Magnesium Stearate
9.	Talc
10.	Colloidal Anhydrous silica
11.	Sodium Lauryl Sulphate

3. Pharmaceutical form

Tablet

4. Clinical Particulars

4.1 Therapeutic indications

For the treatment of mild to moderate pain, including headache, neuralgia, toothache, period pains, aches and pains. Symptomatic relief of rheumatic aches and pains. Symptomatic relief of influenza, feverishness, feverish colds.

4.2 Posology and method of Administration

These tablets are for oral administration.

Adults, the elderly and children over 12 years:

Single dose: 0.5 g to 1 g (1 to 2 tablets).

Maximum daily dose: 4 g (8 tablets) in divided doses.

Children: Age 6 years to under 12 years: half tablet to one tablet.

Not for use in under 6 year olds.

Dosage instruction:

Take every 4 to 6 hours, as required. Do not take more frequently than every 4 hours. Not more than 4 doses should be administered in any 24 hour period. Dosage should not be continued for more than three days without consulting a doctor.

4.3 Contraindication

Hypersensitivity to paracetamol or any other ingredients. Alcoholics could be at risk in taking paracetamol. Contains sodium metabisulphite which may rarely cause severe hypersensitivity reactions and bronchospasm..

4.4 Warnings and Precautions

i) Do not exceed the stated dose.

ii) Consult a doctor if symptoms persist. Do not continue to use for longer than 3 days without consulting your doctor or pharmacist.

iii) Ask the doctor or pharmacist about taking the capsules if pregnant or already on a course of medication.

iv) This product contains paracetamol.

v) The label shall say: “Do not take with any other paracetamol-containing products” and “Immediate medical advice should be sought in the event of an overdose, even if you feel well”.

vi) The leaflet shall say: “Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage”.

vii) Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

viii) Keep out of the reach and sight of children.

4.5 Interactions with other FPP’s and other forms of interaction

• Anticoagulants - the effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding. Occasional doses have no significant effect.

• Metoclopramide – may increase speed of absorption of paracetamol.

• Domperidone – may increase speed of absorption of paracetamol.

• Colestyramine – may reduce absorption if given within one hour of paracetamol.

• Imatinib - restriction or avoidance of concomitant regular paracetamol use should be

taken with imatinib.

4.6 Pregnancy and Lactation

Pregnancy Category C.

Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol being used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. Paracetamol is excreted in breast milk but not in clinically significant quantities. Available published data do not contraindicate breast-feeding

4.8 Side Effects

Adverse effects of paracetamol are rare but hypersensitivity including skin rash can occur. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis and/or acute pancreatitis, but these were not necessarily causaly related to paracetamol.

4.9 Overdosage

Liver damage is possible in adults who have taken 10 g or more of paracetamol. Ingestion of 5 g or more of paracetamol may lead to liver damage in the patient has risk factors

5 Pharmacological Properties

5.1 Pharmacodynamic Properties

Paracetamol is an effective analgesic and antipyretic agent but has only weak antiinflammatory properties. Its mechanism of action is not fully understood, as it is only a weak inhibitor of prostaglandin bio-synthesis, but it has been suggested that it is more effective against enzymes in the CNS than those in the periphery. The drug has no effect on the cardiovascular and respiratory systems, and it does not cause gastric irritation or bleeding like salicylates.

5.2 Pharmacokinetic Properties

Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring 30 minutes to 2 hours after ingestion. It is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1-4 hours. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentration.A minor hydroxylated metabolite which is

usually produced in very small amounts by mixed-function oxidases in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following paracetamol overdosage and cause liver damage.

6. Pharmaceutical Particulars

6.1 List of Excipients

Maize Starch
Colloidal Anhydrous Silica
Povidone K-30
Purified Water
Sodium Starch Glycolate (Type A)
Magnesium Stearate
Purified Talc
Sodium Lauryl Sulphate

6.2 Incompatibilities

None

6.3 Shelf life

36 Months

6.4Special precaution for storage

Store below 30˚C. Protect from light.

6.5Nature and contents of container

PACK: ALU-PVC blister of 10 tablets. 10 such ALU-PVC blisters are packed in printed carton along with the pack insert.

7.0 Marketing Authorization Holder

Pinnacle Life Science Pvt. Ltd.
3rd Floor, Mahendra Industrial Estate,
Road No. 29, Plot No. 109 D,
Sion (E) Mumbai 400022, INDIA

Address of Manufacturing Site:

Pinnacle Life Science Pvt. Ltd.
Khasra No. 1328-1330, Village-Manpura,
Tehsil-Baddi, Dist. Solan,
(H.P.) 174101 India

8. Number (s) in the National Register of Finished Pharmaceutical Products

MNB/08/729
05984/08036/NMR/2019

9. Date of First Authorisation / Renewal of the Authorisation

20-03-2009
Last renewal: May 24, 2021

10. Date of Revision of the text

1.7.1 Labelling Information (immediate and outer label)

Enclosed

As Per Actual Blister Size 94l x 39W/ Alu - Blue PVC

As per actual Blister Size: L98 x W54 x H44

PAARPIN 500
Paracetamol Tablets BP
10 x 10 Tablets
500 mg

Composition:
Each uncoated tablet contains :
Paracetamol BP ..... 500 mg
Excipients ..... q.s.

Dosage:
As directed by the Physician.

Storage: Store below 30°C.
Protect from light.

Read the patient information leaflet before use.

PAARPIN 500
Paracetamol Tablets BP
10 x 10 Tablets
500 mg

Mfg. Lic. No. : MNB/08/729
Manufactured by:
Pinnacle Life Science Private Limited,
Khasra No.- 1328-1330, Village - Manpura,
Tehsil-Baddi, District-Solan,
Himachal Pradesh-174101, INDIA

GTIN.18906082150221
B.No.E180157
MFG.08/20
EXP.08/20
SL.NO.SAMPLETEST00

2D BAR CODE

Unvarnished area

Note: Do not print Dotted Box "Unvarnished area size 50L x17 H mm"
Note: 2D CODE Barcode Specimen

Foil Size 204mm Printing Area 196mm
Repeat 64mm

similar size **Napomol**
Paracetamol Tablets BP 500 m

Blistter DIMENSION .....95L x 41w mm

64mm

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Code: 605-PE-F-00

4 | 28 | Print Area | 10 | 10 | 28 | Print Area | 4

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4 | 28 | Print Area | 10 | 10 | 28 | Print Area | 2 | 10 | 28 | Print Area | 4

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Code: 605-PE-F-00

1.7.2 Patient Information Leaflet

Enclosed

Insert size: 85L X 227 H mm **Front**

" For the use of Registered Medical Practitioner or Hospital or Laboratory Only "

Paarpin 650
Paracetamol Tablets BP

Composition :
Each uncoated tablet contains :

Paracetamol	BP	650 mg
Excipients		q.s.

Paarpin 500
Paracetamol Tablets BP

Composition :
Each uncoated tablet contains :

Paracetamol	BP	500 mg
Excipients		q.s.

Pharmacodynamics :
Paracetamol is an effective analgesic and antipyretic agent but has only weak antiinflammatory properties. Its mechanism of action is not fully understood, as it is only a weak inhibitor of prostaglandin bio-synthesis, but it has been suggested that it is more effective against enzymes in the CNS than those in the periphery. The drug has no effect on the cardiovascular and respiratory systems, and it does not cause gastric irritation or bleeding like salicylates.

Pharmacokinetic properties:
Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring 30 minutes to 2 hours after ingestion. It is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1-4 hours. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentration.A minor hydroxylated metabolite which is usually produced in very small amounts by mixed-function oxidases in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following paracetamol overdosage and cause liver damage.

Indications :
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Posology and method of administration:
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Single dose: 0.5 g to 1 g (1 to 2 tablets).
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Children: Age 6 years to under 12 years: half tablet to one tablet.
Not for use in under 6 year olds.
Dosage instruction:
Take every 4 to 6 hours, as required. Do not take more frequently than every 4 hours. Not more than 4 doses should be administered in any 24 hour period. Dosage should not be continued for more than three days without consulting a doctor.

Insert size: 85L X 227 H mm **Back**

CONTRAINDICATIONS : Hypersensitivity to paracetamol or Alcoholics could be at risk in taking paracetamol. Contains sodium metabisulphite which may rarely cause severe hypersensitivity reactions and bronchospasm.

Special warnings and precautions for use:
i) Do not exceed the stated dose.
ii) Consult a doctor if symptoms persist. Do not continue to use for longer than 3 days without consulting your doctor or pharmacist.
iii) Ask the doctor or pharmacist about taking the tablet if pregnant or already on a course of medication.
iv) "Do not take with any other paracetamol-containing products" and "Immediate medical advice should be sought in the event of an overdose, even if you feel well". because of the risk of delayed, serious liver damage".
v) Care is advised in the administration of paracetamol to patients with serve renal or severe hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.
vi) Keep out of reach of children.

Fertility, pregnancy and lactation:
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Side effects :
Adverse effects of paracetamol are rare but hypersensitivity including skin rash can occur. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis and/or acute pancreatitis, but these were not necessarily related to paracetamol.

Overdose:
Liver damage is possible in adults who have taken 10 g or more of paracetamol. Ingestion of 5 g or more of paracetamol may lead to liver damage in the patient has risk factors

Storage: Store below 30°C. Protect from light.

Packaging: Blister of 10 Tablets

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