1. Name of the medicinal Product

Paracetamol Sustained Release Tablets 1000 mg

1.1 Strength

1000 mg/tablet

1.2 Pharmaceutical Form

Oral Tablets

2. Qualitative and Quantitative Composition

2.1 Qualitative declaration

Paracetamol BP

2.2 Quantitative declaration

For full list of Excipients, see section 6.1.

3. Pharmaceutical Form

Oral Tablets

White and pink coloured, capsule shaped, bilayered uncoated tablets, plain on both sides.

4. Clinical Particulars

4.1 Therapeutic Indications

Fever, Acute Pain , Chronic Pain

4.2 Posology

Pa 12 tablets are to be administered orally, with or without food.

Adults and children over 12 years: One tablet orally twice daily.

4.3 Method of Administration

Oral Route

4.4 Contraindications

Known hypersensitivity to Paracetamol or any ingredient in the formulation

4.5 Special Warnings and Special Precautions for Use

Pa 12 should be administered with caution to patients with hepatic or renal dysfunction.

Adults who are using warfarin should consult with a doctor or pharmacist before taking Paracetamol. Not recommended for children under 12 years of age. Adu1ts should not take Pa 12 for pain for more than 10 days or for fever for more than 3 days unless directed by a doctor Severe liver damage may occur if:

- Adult takes more than 4000 mg in 24 hours, which is the maximum daily amount
- Taken with other drugs containing Paracctamol
- Adult has 3 or more alcohol ic drinks everyday while using this product.

4.6 Paediatric Population

Children:

Not recommended for children under 12 years of age.

4.7 Interaction with other medicinal products and other forms of interaction

The absorption of Paracetamol may be altered by Metoclopramide &Anticholinergic Agents (e.g Propantheline, Glycopyrolate and Exanatide). The metabolism ofParacetamol may be altered by Alcohol, Isoniazid , Ascorbic Acid, Ciprotloxacin, Diflunisal , Lamotregine, Rifampicin, Omeprazole, Chloramphenicol, Oral Contraceptives, Probenecid, Propranolol, Sulfinpyrazone, Zidovudin, Lamotregine. Paracetamol is also having Drug interaction with Oral Anticoagulants, Frusemide,Ant iconvulsants (e.g. Hy dention, Carbamazepine).

4.8 Additional information on special populations

No specific Information

4.9 Paediatric Population

Not recommended for children under 12 years of age.

4.10 Pregnancy and Lactation

4.10.1 Pregnancy

If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency or better to consult a doctor before taking the medicine

4.10.2 Lactation

It is excreted in very low concentrations in the mother's milk and is not known to cause adverse effects to breast-fed children. It should not be used during breast-feeding

4.11 Effects on ability to Drive and use Machines

There are no data for adverse influence on the active attention, coordination of movements and reflexes when paracetamol is taken.

4.12 Undesirable Effects

Dermatologic: Rash

Endocrine & metabolic: May increase chloride, uric acid, glucose; may decrease sodium, bicarbonate, calcium

Hematologic: Anemia, blood dyscrasias (neutropenia, pancytopenia, leukopenia)

Hepatic: Bilirubin increased, alkaline phosphatase increased

Renal: Ammonia increased, nephrotoxicity with chronic overdose, analgesic nephropathy

4.13 Overdose

Do not use more than the recommended dose of Pa 12. Taking more than the recommended dose of Paracetamol may cause liver damage. Following suspected overdosage, evaluate necessity of antidote therapy.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Paracetamol, Para-aminophenol derivative is a peripherally acting analgesic and is well absorbed orally. Paracetamol produces analgesia by elevation of the pain threshold and antipyresis through action on the hypothalamic heat regulating center.

5.2 Pharmacokinetic Properties

Oral Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract primarily in the small intestine, with negligible absorption occurring in the stomach. The relative bioavailability ranges from 85% to 98%. Each Pa 12 tablet contains 300 mg immediate release in one layer and 700 mg sustained release designed to release slowly in other layer. The in vitro data indicate that Pa 12 tablet release 90% of drug within 8 hours. From the in vivo

data it is concluded that the average maximum plasma concentration occurs within 0.5 to 2 hours following ingestion and range from 6.86 ~g/mL to 10.37 ~g/mL among the individuals. Paracetamol appears to be widely distributed throughout most body fluids except fat & small proportions bound to plasma proteins. Paracetamol is primarily metabolized in the li ver. The elimination t112 of Paracetamol in healthy adults is approximately 2 to 3 hours in the usual dosage range. The mean elimination half-life ($t_{1/2}$) of Pa 12 is 4.84 hours.

5.3 Preclinical Safety Data

Not Applicable

6. Pharmaceutical Particulars

6.1 List of Excipients

Microcrystalline Cellulose (Plain),
Maize Starch,
Colour Carmoisine Supra,
Povidone (P.V.P.K.-30),
Glycerol,
Sodium Starch Glycolate,
Magnesium Stearate
Purified Talc,
Colloidal Anhydrous Silica (Aerosil),
Hypromellose (Metolose K-100 M),
Hypromellose (Metolose 90 SH 4000),
Isopropyl Alcohol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

Store under normal storage conditions (15°C - 30°C). Protect from Light.

6.5 Nature and Contents of Container

12 Tablets are packed in a Alu-PVC Blister Pack. Such 1 Alu-PVC Blister is packed in a printed baby carton along with package insert. Such 10 Baby Carton are packed in printed Mother Carton.

6.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder and Manufacturing Site Addresses

7.1 Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Tal.-Kalol,
Dist.- Gandhinagar, Gujarat, India.
Telephone no.: +91-079-41078096
Email: hiren@lincolnpharma.com
Website: www.lincolnpharma.com

7.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Tal.-Kalol,
Dist.- Gandhinagar, Gujarat, India.
Telephone no.: +91-079-41078096
Email: hiren@lincolnpharma.com
Website: www.lincolnpharma.com

8. Marketing Authorization Number

It will be applicable after registration of this product.

9. Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

10. Date of Revision of the Text

September, 2023

11. Dosimetry (If Applicable)

Not Applicable

12. Instructions for preparation of radiopharmaceuticals

Not Applicable