1. Name of the medicinal Product

Anticold Tablets

1.1 Strength

Paracetamol BP 500 mg + Phenylephrine Hydrochloride BP 5 mg + Chlorphenamine Maleate BP 2 mg + Anhydrous Caffeine BP 30 mg

1.2 Pharmaceutical Form

Oral Tablets

2. Qualitative and Quantitative Composition

2.1 Qualitative declaration

Paracetamol + Phenylephrine Hydrochloride + Chlorphenamine Maleate + Anhydrous Caffeine

2.2 Quantitative declaration

Sr. No	Ingredients Chemical Name	Specification	Quantity (mg/tablet)	Reason for Inclusion
1	Paracetamol	BP	500.0	Antipyretic/ Analgesic
2	Phenylephrine Hydrochloride	BP	5.000	Alpha-Adrenoceptor agonist
3	Chlorphenamine Maleate	BP	2.000	Antihistamine.
4	Anhydrous Caffeine	BP	30.00	Central nervous system stimulant
5	Lactose	BP	30.00	Diluent
6	Potassium Dihydrogen Phosphate	BP	1.000	Buffering Agent
7	Povidone (PVPK-30)	BP	7.000	Binding Agent
8	Magnesium Stearate	BP	10.00	Lubricant
9	Purified Talc	BP	10.00	Glident
10	Sodium Starch Glycolate (Type-A)	BP	15.00	Disintegrant

Sr. No	Ingredients Chemical Name	Specification	Quantity (mg/tablet)	Reason for Inclusion
11	Colour Ponceau 4R (Supra)	In-House	0.500	Colouring Agent
12	Purified Water	BP	Q.S.	Vehicle

3. Pharmaceutical Form

Oral Tablets

Pink coloured, round shaped, flat, uncoated tablet breakline on one side and plain on other side.

4. Clinical Particulars

4.1 Therapeutic Indications

For the symptomatic relief of Fever, Headache, Nasal Congestion & Rhinitis, assoaciated with Influenza and common cold.

4.2 Posology

Adult: 1 Tablet, 3 to 4 times a day

Children (6 to 12 years): 1/2 Tablet, 3 to 4 times a day

Children (2 to 6 years): 1/4 Tablet, 3 to 4 times a day

OR

As directed by the Physician.

4.3 Method of Administration

Orally

4.4 Contraindications

Not to be taken by asthmatic patients or by patients with a known hypersensitivity to any of the active ingredients. Do not administer concurrently with monoamine oxidase inhibitors or within 14 days of stopping such treatment.

Contra-indicated in most types of cardiovascular disease, hypotension, hyperthyroidism, hyperexcitability, Phaeochromocytoma, closed-angle glaucoma, diabetes mellitus, peptic ulceration and epilepsy.

4.5 Special Warnings and Special Precautions for Use

Avoid driving a motor vehicle or operating machinery while taking this drug. Keep all the medicines out of reach of children.

Do not take additional fever-reducing and pain-relieving medicines or medicines for common cold without consulting a doctor or a pharmacist, in order to prevent Paracetamol toxicity

4.6 Paediatric Population

Children (6 to 12 years): 1/2 Tablet, 3 to 4 times a day

Children (2 to 6 years): 1/4 Tablet, 3 to 4 times a day

4.7 Interaction with other medicinal products and other forms of interaction

Aspirin and salicylates, drugs affecting the Central Nervous System (e.g. sedatives, drugs for pain and fever, hypnotics, drugs for Parkinsonism, epilepsy), cough and cold preparations, antiasthmatic preparations, non-steroidal anti-inflammatory agents, antidepressants from the monoamine oxidase inhibitor group, or aminoglycoside antibiotics.

4.8 Additional information on special populations

No specific Information

4.9 Paediatric Population

No specific Information

4.10 Pregnancy and Lactation

4.10.1 Pregnancy

Category C. There are no adequate and well-controlled studies in pregnant women. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

4.10.2 Lactation

It may excrete in breast milk. Caution should be exercised when used in lactating mother.

4.11 Effects on ability to Drive and use Machines

Not applicable

4.12 Undesirable Effects

Slight to moderate drowsiness may occur. Other possible adverse reactions may include restlessness, dry mouth, nervousness, visual disturbances, dermatitis, weakness and nausea. In therapeutic doses, paracetamol is relatively non-toxic. Chronic use of large doses of Paracetamol may produce more significant toxicity. Hepatic toxicity has been associated with Paracetamol in overdose.

Neutropenia and thrombocytopenia purpura have been reported and rarely Agranulocytosis. Laryngeal edema, Angioedema and Anaphylactoid reactions may occur. May aggravate Bronchospasm in patients sensitive to Acetyl Salicylic Acid other analgesics.

4.13 Overdose

Symptoms: Symptoms may include blurred vision; confusion; hallucinations; seizures; severe dizziness, lightheadedness, or headache; severe drowsiness; unusually fast, slow, or irregular heartbeat; vomiting.

Treatment: Treatment should be symptomatic and supportive.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Paracetamol exerts analgesic and antipyretic effect.

Phenylephrine hydrochloride is a decongestant of the mucous membrane of the respiratory tract. Chlorphenamine maleate is an antihistamine for cases in which allergic symptoms are a factor and may also produce some subjective relief due to inhibition of nasal discharge. Caffeine stimulate the CNS and gives a sense of well-being. Caffeine potentiates effects of paracetamol.

5.2 Pharmacokinetic Properties

Paracetamol: Paracetamol is rapidly and almost completely absorbed from gastrointestinal tract with peak plasma concentrations (Cmax) occurring about 10 to 60 minutes after oral administration. Plasma protein binding is negligible at usual therapeutic concentration but increases with increasing concentrations. It is relatively uniformly distributed throughout most

body fluids. The plasma half life (t1/2) 2-3 hours and the effect after oral dose lasts for 3-5 hours. Paracetamol is metabolized predominantly in liver and excreted in the urine mainly as glucuronide and sulfate conjugate. Less than 5% is excreted unchanged.

Chlorphenamine maleate: Chlorphenamine is well absorbed from gastrointestinal tract, peak plasma concentration is achieved in 2-3 hours and the effect lasts for 4-6 hours. It is metabolized in the liver and excreted primarily in urine.

Caffeine: Caffeine is rapidly absorbed from the gastrointestinal tract and is widely distributed throughout the body. It is almost completely metabolized in the liver by oxidation and demethylation to various xanthine derivatives, which are excreted in the urine. The mean plasma half life is about 4.9 hours.

Phenylephrine hydrochloride: Phenylephrine is completely absorbed following oral administration and is believed to undergo high first-pass metabolism in the intestinal wall and liver. The bioavailability of Phenylephrine following oral administration and is approximately 38%. Peak serum concentrations occur at 0.75 to 2 hours and nasal decongestion may occur within 15-20 minutes and may persist for 2-4 hours. Phenylephrine and its metabolites are excreted mainly in urine. The elimination half-life of Phenylephrine is 2-3 hours.

5.3 Preclinical Safety Data

No foetal toxicity or fertility studies have been carried out in animals. No other relevant preclinical data is available.

6. Pharmaceutical Particulars

6.1 List of Excipients

Lactose

Potassium Dihydrogen Phosphate

Povidone (PVPK-30)

Magnesium Stearate

Purified Talc

Sodium Starch Glycolate (Type-A)

Colour Ponceau 4R (Supra)

Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

Store under normal storage conditions (l5°C- 30°C). Protect from light

6.5 Nature and Contents of Container

4 Tablets are packed in a strip Pack. Such 1 strip is packed in a printed catch cover. Such 50 catch covers are packed in a printed carton with a packing insert.

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, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062
E-mail: hiren@lincolnpharma.com;
Web site: www.lincolnpharma.com

7.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062

E-mail: hiren@lincolnpharma.com;

Web site: www.lincolnpharma.com

8. Marketing Authorization Number

To be included after obtaining first registration.

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

13th Febraury,2023

11. Dosimetry (If Applicable)

Not Applicale

12. Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable

13. Document Revision History

Date of Revision	Revision Number	Document No.	Change Made
24/05/2019	Rev_0	DAR/GDL/010A	First Issue
13/02/2023	Rev_1	DAR/GDL/010A	Changed format as per Rwanda FDA Guideline and added visual description of product in point 3