1. Summary of Product Characteristics

1.1 Proprietary name of the medicinal product
FLUCOMOL

1.2 Approved Generic Name(s)
Anticold Capsules

1.3 Qualitative & Quantitative Composition

Sr. No.	Ingredients	Specification	Standard Quantity/Capsule (mg)
1	Blend Of Paracetamol, Dextromethorphan Hydrobromide, Chlorpheniramine Maleate and Phenylephrine Hydrochloride **(As Pellets)**	In-House	710.0
2	Transparent/Transparent Size “00” Hard Gelatin Capsule Shell	In-House	1 Unit

1.4 Dosage Form
Oral Capsules

1.5 Clinical Particulars

(i) Therapeutic Indication(s)

Relieves of cold and flu symptoms like minor aches and pains, headache, cough, sneezing and runny nose, nasal congestion, sinus congestion and pressure, sore throat.

(ii) Route of Administration

Oral

(iii) Contra-indications

Hypersensitivity to any ingredients of product.

It is contraindicate in severe hypertension, ventricular tachycardia, severe coronary artery disease, narrow-angle glaucoma, urinary retention, peptic ulcer, emphysema, chronic bronchitis, as treatment for lower respiratory tract conditions including asthma and during an asthma attack.

Concomitant MAOI therapy or for 2 weeks after stopping MAOI therapy.

(iv) Special warning & Precautions for use

CNS depression: It may cause CNS depression, which may impair physical or mental abilities; patients must be cautioned about performing tasks which require mental alertness (e.g., operating machinery or driving).

Debilitated patients: Use with caution in patients who are sedated, debilitated or confined to a supine position.

Pregnancy: Category C.

Lactation: Caution should be exercised when used in lactating mother.

Hepatic impairment: It may cause severe hepatic toxicity on acute overdose.

(v) Drug Interactions

It may interact with alcohol, barbiturates (e.g. phenobarbital), tricyclic antidepressants (e.g. amitriptyline), other CNS depressants, anesthesia (e.g. halothane), antihypertensives (e.g. methyldopa, reserpine, veratrum alkaloids), Cholestyramine resin, Isoniazid, anticonvulsants (Hydantoin), Anticoagulant (e.g. Warfarin), Quinidine, selective Serotonin reuptake inhibitors, Beta-adrenergic blockers, MAOIs (e.g. isocarboxazid), Opioid antitussives (e.g. codeine).

(vi) Adverse effects :

Cardiovascular: Cardiac arrhythmias, extrasystoles, hypertension, reflux bradycardia, palpitations, decrease cardiac output.

CNS: Sedation, dizziness, drowsiness (most common); anxiety, confusion, excitement, irritability, convulsions, disturbed coordination, dysphoria, euphoria, excitation, fatigue, hallucinations, hysteria, insomnia, nervousness, neuritis, paresthesia, restlessness, trembling, tremor, vertigo, weakness.

Dermatologic: Pruritus, rash, urticaria.

GI: Dryness of mouth (most common); anorexia, epigastric discomfort, nausea, vomiting.

Genitourinary: Difficult urination, polyuria.

Endocrine and metabolic: metabolic acidosis.

Hematologic: Agranulocytosis, hemolytic anemia, hypoplastic anemia, thrombocytopenia.

Respiratory: Thickening of bronchial secretions (most common); nasal stuffiness, respiratory difficulty, shortness of breath, tightness of chest, wheezing.

(vii) 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.

1.6 Pharmacological Properties

(i) Pharmacodynamic Properties

Paracetamol: Paracetamol inhibits the synthesis of prostaglandins in the central nervous system and peripherally blocks pain impulse generation; produces antipyresis from inhibition of hypothalamic heat-regulating center.

Dextromethorphan Hydrobromide: Decreases the sensitivity of cough receptors and interrupts cough impulse transmission by depressing the medullary cough center through sigma receptor stimulation; structurally related to codeine.

Chlorpheniramine maleate: Chlorpheniramine Maleate is a potent histamine antagonist (antihistamine) acting specifically on H_1 receptors. It competes with histamine for the receptor site and reversibly inhibits interaction of histamine with H_1 receptors. It exerts anti-allergic effects by antagonizing the allergic response (vasodilatation, increased capillary permeability and increased secretion). Besides, it reduces secretions (drying effect) due to its anticholinergic actions and it also has sedative effects.

Phenylephrine hydrochloride: Phenylephrine is a potent, direct-acting alpha-adrenergic stimulator with weak beta-adrenergic activity; which causes vasoconstriction of the arterioles of the nasal mucosa and allows the air passages to open up.

(ii) Pharmacokinetics 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.

Dextromethorphan Hydrobromide: Dextromethorphan is well absorbed from the gastrointestinal tract after oral administration. It is metabolised in the liver, exhibiting polymorphic metabolism involving the cytochrome P450 isoenzyme (CYP 2D6). It is excreted in the urine as unchanged dextromethorphan and demethylated metabolites, including dextrorphan, which has some cough suppressant activity. The plasma

elimination half-life of dextromethorphan is 1.2 to 3.9 hours. However, the rate of metabolism varies between individuals according to phenotype (extensive v poor metabolisers), with half-life being as long as 45 hours in patients who are poor metabolisers.

Chlorpheniramine maleate: Chlorpheniramine 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.

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 mins 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.

1.7 Pharmaceutical Particulars

(i) List of Excipients
Transparent/Transparent Size “00” Hard Gelatin Capsule Shell

(ii) Incompatibilities
Not Applicable

(iii) Shelf Life
36 Months

(iv) Special Precaution for Storage
Store under normal storage conditions (15°C - 30°C). Protect from light and moisture.

(v) Nature & Composition of Containers
Blister pack

(vi) Special Instruction for use
Not Applicable

(vii) Restriction on sale/distribution
POM

1.8 Administrative Data

(i) Name & Address of the product Licence Holder

LINCOLN PHARMACEUTICALS LTD.
Lincoln House, Behind Satyam Complex,
Science City Road, Sola,
Ahmedabad-380 062**,** Gujarat- India.
Phone : +91-79-30018000,30018062
Fax : +91-79-30018062
Web Site : www.lincolnpharma.com

(ii) Registation number

(iii) Date of first registration/renewal of a product Licence

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(iv) Date of revision of the Text

1.9 Registration in a SADC member state

(Not Applicable)