SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

COL-COL
Paracetamol, Phenylephrine HCL, Chlorpheniramine Maleate & Caffeine Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains:

Paracetamol BP	: 500 mg
Phenylephrine Hydrochloride BP	: 5 mg
Chlorpheniramine Maleate USP	: 2 mg
Caffeine Anhydrous BP	: 15 mg
Excipients	: Q.S.
Colour	: Ponceau 4R

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Tablet
For oral administration

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

COL-COL are indicated for the relief of symptoms associated with Colds and Flu such as Fever, Nasal Decongestants, Headache and Minor Aches and Pains.

4.2 Posology and method of administration

Adults : Maximum Recommended 4 tablets per a Day.
Children (6-12 Years): Maximum Recommended 2 tablets per a day.
Not recommended for children under 6 years of age.
Repeat three times daily.
Do not use continuously for more than ten (10) days without consulting your doctor

Method of Administration
Oral

4.3 Contraindications

Paracetamol:
Contraindicated to hypersensitivity to any of the ingredients. Severe liver disease.
Phenylephrine HCl:
Contra-indicated in patients hypersensitive to any of the ingredients. Contra-indicated in most types of cardiovascular disease, including angina and hypertension, and also in

hyperthyroidism, hyperexcitability, phaeochromocytoma and closed angle glaucoma.

Chlorpheniramine Maleate:
Contraindicated to hypersensitivity to antihistamines; narrow-angleglaucoma; stenosing peptic ulcer; symptomatic porostatic hypertrophy; asthmatic attack; bladder neckobstruction; pyloroduodenal obstruction.

Caffeine: Contraindicated to patients with Porphyria

4.4 Special warnings and precautions for use

WARNINGS:
Severe hypertensive episodes leading to intracranial haemorrhage have followed phenylephrine ingestion. Patients should be informed of the dangers of exceeding the recommended dose; in particular the increased risk of serious adverse effects such as hypertensive crisis. This medicine may lead to drowsiness and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents. Patients should be warned not to drive a motor vehicle, operate dangerous machinery or perform potentially dangerous tasks, as impaired decision making could lead to accidents. Dosages in excess of those recommended may cause severe liver damage.

PRECAUTION:
In case a hypersensitivity reaction occurs which is rare, COL-COL Tablet should be discontinued. COL-COL Tablet contains Paracetamol and therefore should not be used in conjunction with otherParacetamol containing products.
COL-COL Tablet should be used with caution in patients with renal or hepatic dysfunction, diabetes mellitus, hyperthyroidism, cardiovascular problems, epilepsy and closed angle glaucoma.
It is advisable not to drive or operate machinery when on treatment with COL-COL Tablet.

4.5 Interaction with other medicinal products and other forms of interaction

Clinically significant drug interactions may occur on concomitant administration of COL-COL Tablet with monoamine oxidase inhibitors, tricyclic antidepressants, beta-adrenergic agents, methyldopa, reserpine and veratrum alkaloids.

4.6 Pregnancy and lactation
Not recommended in pregnancy and lactating mothers.

4.7 Effects on ability to drive and use machines
It is advisable not to drive or operate machinery when on treatment with COL-COL Tablet.

4.8 Undesirable effects
Prolonged excessive use may cause irreversible kidney damage, anxiety, fear, restlessness, tremor, irritability, confusion, weakness, sedation varying from slight drowsiness to deep

sleep. Tachycardia, cardiac arrhythmias, angina pectoris, palpitations, hypertension, hypotension with dizziness, dyspnoea, upset stomach, dizziness, drowsiness, nausea, vomiting and cramps.

4.9 Overdose

Paracetamol:
Symptoms of overdosage include nausea and vomiting. Liver damage which may be foetal may only appear after a few days. Kidney failure has been described following acute intoxication. Specific therapy with an antidote such as acetylcysteine or methionine is necessary. Any patient who has ingested about 7.5 g of paracetamol in the proceeding four hours undergo gastric lavage.

Phenylephrine Hydrochloride:
Psychotic states, cardiac arrest. Overdose may be foetal especially in children in whom the main symptoms are central nervous system stimulation, ataxia, excitement, hallucinations, muscle tremor, convulsions, dilated pupils, dry mouth, flushed face and hyperpyrexia. Deepening coma, cardio- respiratory collapse and death may occur within 18 hours. In adults, the usual symptom of central nervous depression with drowsiness, coma and convulsions. Hypotension may also occur. In the event of overdosage consult a doctor or take the patient to the nearest hospital immediately. Specialized treatment is essential as soon as possible.

Chlorpheniramine Maleate:
Symptoms of overdosage may include convulsions and hyperpyrexia. : overdosage may lead to maniacal behaviour, diuresis and repeated vomiting with extreme thirst, tremor, delirium, hyperthermia, tachycardia, tachypnoea, electrolyte disturbances, convulsions and death. In the event of overdosage consult a doctor or take the patient to the nearest hospital immediately. Specialised treatment is essential as soon as possible. Toxic effects are treated symptomatically as required. The latest information regarding the treatment of overdosage can be obtained from the nearest poison centre.

Caffeine:
An acute overdose of caffeine, usually in excess dose, dependent on body weight and level of caffeine tolerance, can result in a state of central nervous system over-stimulation called caffeine intoxication. It may include restlessness, nervousness, excitement, insomnia, flushing of the face, increased urination, gastrointestinal disturbance, muscle twitching, a rambling flow of thought and speech, irritability, irregular or rapid heart beat, and psychomotor agitation. Treatment of severe caffeine intoxication is generally supportive, providing treatment of the immediate symptoms, but if the patient has very high serum levels of caffeine then peritoneal dialysis, hemodialysis, or hemofiltration may be required.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other analgesics and antipyretics & Other cold combination preparations

Paracetamol is an analgesic and antipyretic compound.

Phenylephrine HCL is a decongestant of the mucous membrane of the respiratory tract. Chlorpheniramine is an antihistamine for cases in which allergic symptoms are a factor may due to inhibition of nasal discharge.
Caffeine is a bitter, white crystalline xanthine alkaloid that is a CNS stimulant drug.

5.2 Pharmacokinetic properties

Paracetamol is metabolised by the hepatic microsomal enzymes. It is rapidly and completely absorbed from the gastro-intestinal tract. Plasma concentration reaches a peak in half to one hour, the plasma half-life is one to three hours and it is uniformly distributed throughout the body.
Phenylephrine hydrochloride is irregularly absorbed from the gastro-intestinal tract. When injected intramuscularly it takes 10- 15 minutes to act and subcutaneous and intramuscular injections are effective for about one hour. Intravenous injections are effective for about 20 minutes.
Chlorpheniramine Maleate is well absorbed when administered orally. Maximum concentration to the plasma is seen about 2 hours from the intake. The metabolism of Chlorpheniramine Maleate to the liver is made by the hepatic P-450 system.
Caffeine is readily absorbed from the gastro-intestinal tract.

5.3 Preclinical Safety Data

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Name of Material	Specification
Maize Starch	BP
Microcrystalline Cellulose	BP
Colloidal Anhydrous silica	BP
Povidone	BP
Colour Ponceau 4R	IHS
Purified Water	BP
Magnesium Stearate	BP
Purified Talc	BP
Croscarmellose Sodium	BP

6.2 Incompatibilities

NA

6.3 Shelf life

48 Months

6.4 Special precautions for storage

Store below 30°C. Protected from light.
KEEP OUT OF REACH OF CHILDREN

6.5 Nature and contents of container

5 x 4 Tablets in Alu-Alu pack is packed in a printed carton along with a package insert.

6.6 Instructions for use and handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

SAGA LIFESCIENCES LIMITED

Ahmedabad
Gujarat, India.
E-mail: info@sagalabs.com
URL: www.sagalabs.com

8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

06944/08158/NMR/2020

9. DATE OF FIRSHT AUTHORISATION/RENEWAL OF THE AUTHORISATION

09/02/2021

10. DATE OF REVISION OF THE TEXT

01 April 2026