SmPC (Summary of Product Characteristics)

1. NAME OF THE MEDICINAL PRODUCT

Kold Go Tablets (Paracetamol, Pseudoephedrine HCL, Chlorpheniramine Maleate & Caffeine Tablets).

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains:

Paracetamol BP ----------325mg.

Pseudoephedrine Hydrochloride BP ----- 15 mg.

Chlorpheniramine Maleate BP…….... 2 mg.

Caffeine Anhydrous BP…….. 15 mg.

Excipients----------q.s.

Excipients with known effect:

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Flat, white Colour, round shaped uncoated tablet, embossed with KRISHAT one side & the break-line on other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Kold Go Tablets is 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 3-4 tablets per a Day
Children (6-12 Years): Maximum Recommended 2 tablets per a day.
Maximum Recommended 1 tablets per a day children under 6 years of age.
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.

Pseudoephedrine HCl: contraindicated in patients with diabetes mellitus, cardiovascular disease, severe or uncontrolled hypertension, severe coronary artery disease, prostatic hypertrophy, hyperthyroidism, closed angle glaucoma, or by pregnant women. The safety and effectiveness of nasal decongestant use in children is unclear.

Chlorpheniramine Maleate: Contraindicated to hypersensitivity to antihistamines; narrow-angle glaucoma; stenosing peptic ulcer; symptomatic porostatic hypertrophy; asthmatic attack; bladder neck obstruction; 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 Pseudoephedrine HCl 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, Kold Go Tablets should be discontinued. Kold Go Tablets contains Paracetamol and therefore should not be used in conjunction with other Paracetamol containing products.
Kold Go Tablets 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 Kold Go Tablets.

4.5 Interaction with other medicinal products and other forms of interaction

Clinically significant drug interactions may occur on concomitant administration of Kold Go Tablets 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

Don’t drive or use machine while taking Kold Go Tablets.

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.

Pseudoephedrine HCl:
Prolonged use of Pseudoephedrine HCl, especially at short intervals, may reduce the effectiveness of the drug (tachyphylaxis) and increase the risk of toxic effects. As the result of an overdose, the symptoms of a sympathomimetic effect may vary. Sometimes there is a depressive effect on the CNS (sedative effect, apnoea, decreased ability to concentrate, cyanosis, coma and circulatory collapse), other times a stimulating effect (insomnia, hallucinations, tremors and convulsions). In extreme cases, death may occur. Symptoms of overdose also include headache, dizziness, anxiety, euphoria, tinnitus, blurred vision, ataxia, chest pain, tachycardia, palpitations, increased or decreased blood pressure, increased thirst, sweating, difficulty urinating, nausea and vomiting. In children, more frequently observed symptoms are dry mouth, wide and rigid pupils, hot flushes, fever, and digestive tract dysfunctions.

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

Paracetamol is an analgesic and antipyretic compound.

Pseudoephedrine HCL is a drug with a long history of medical use; it is helpful in treating symptoms of the common cold and flu, sinusitis, asthma, and bronchitis. Due to its central nervous system (CNS) stimulant properties and structural similarity to amphetamine, it is also used for non-medical purposes. The substance is taken as an appetite reducer, an agent which eliminates drowsiness and fatigue, to improve concentration and as a doping agent. Due to its easier availability, it is sometimes used as a substitute for amphetamine or methamphetamine.

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.

Pseudoephedrine is active after oral administration and is easily absorbed from the gastrointestinal tract. The onset of action occurs after 30 min and after 1–4 h the drug reaches its maximum concentration in the blood. When using the extended-release formulation, this time is twice as long. Pseudoephedrine is mainly excreted unchanged in the urine (43–96%); only a small amount, approximately 1–6%, is metabolised in the liver by N-demethylation to the active metabolite norpseudoephedrine (cathine). The time the drug remains in the body depends on the pH of the urine; the value of the biological half-life ($t_{0.5}$) decreases when the urine is acidic, and increases when the urine is alkaline. Selected pharmacokinetic properties of pseudoephedrine are presented in Pseudoephedrine pharmacokinetics presented in below table:

Pharmacokinetic Parameters of Pseudoephedrine	
Onset of action	30 min
Time to reach C_{max}	1–4 h
Time to reach C_{max} after administration of the extended-release formulation	2–6 h
Duration of action	4–12 h
Distribution coefficient	2.64–3.51 l/kg
Biological half-life	3–16 h
Renal clearance	0.44–0.46 l/h/kg, 7.3–7.7 mL/min/kg

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

NA

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch BP
PVPK-90 BP
Di basic calcium phosphate BP
Propyl paraben BP
Methyl paraben BP
Purified Talc BP
Purified Water BP
Magnesium Steratre BP
Sodium Starch Glycolate BP

Croscarmellose Sodium BP
Colloidal Silicon Dioxide BP

6.2 Incompatibilities
NA

6.3 Shelf life
36 Months

6.4 Special precautions for storage
Store below 30 °C , protect from light and moisture.
KEEP OUT OF REACH OF CHILDREN

6.5 Nature and contents of container
1 X 4 PVC/ALU blister Pack

6.6 Special precautions for disposal and other handling
No special requirements.

7. MARKETING AUTHORISATION HOLDER

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