SmPC (Summary of Product Characteristics)

1. NAME OF THE MEDICINAL PRODUCT

Kriskold Tablets (Paracetamol, Phenylephrine HCL, Chlorpheniramine Maleate & Caffeine Tablets).

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:
Paracetamol BP ----------.-325mg.
Phenylephrine Hydrochloride BP ----- 2.5 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 tablets embossed with KRISHAT one side & the other side plain.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Kriskold 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.

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-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 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, Kriscold Tablets should be discontinued. Kriscold Tablets contains Paracetamol and therefore should not be used in conjunction with other Paracetamol containing products.
Kriscold 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 Kriscold Tablets.

4.5 Interaction with other medicinal products and other forms of interaction

Clinically significant drug interactions may occur on concomitant administration of Kriscold 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 Kriscold 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.

Phenylephrine Hcl:
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

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

NA

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch BP
Povidone 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

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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