KOOSIL® 4 FLU SYRUP

Composition
Each 5 ml of the syrup contains: Triprolidine HCl 1.25 mg, Paracetamol 125 mg, Promethazine HCl 4 mg and Pseudoephedrine HCl 25 mg.
Pharmacology
Promethazine, a phenothiazine derivative, is a sedating antihistamine with antimuscarinic, significant sedative, and some serotonin-antagonist properties.
Paracetamol is believed to exert its antipyretic effect by direct action on the hypothalamic heat-regulating center to block the effects of endogenous pyrogens. This results in increased heat dissipation through sweating and vasodilation. Its analgesic effect may be related to an elevation of the pain threshold probably by inhibition of prostaglandin synthesis in the CNS.
Pseudoephedrine is a direct- and indirect-acting sympathomimetic. It is a stereoisomer of ephedrine and has a similar action, but has been stated to have less pressor activity and fewer CNS effects. It facilitates the vasodilation of bronchial smooth muscles, an action that causes relief of lung congestion.
Triprolidine is an alkyl amine sedating antihistamine with antimuscarinic and mild sedative effects.
Pharmacokinetics
Promethazine is well absorbed after oral administration. Peak plasma concentrations are obtained 2 to 3 hours after administration. It crosses the blood-brain barrier and the placenta, and is distributed into breast milk. Values ranging from 76 to 93% have been reported for plasma-protein binding. Elimination half-lives of 5 to 14 hours have been reported.
Triprolidine is metabolized; a carboxylated derivative accounts for about half the dose excreted in the urine. Reported half-lives vary from 3 to 5 hours or more. **Triprolidine** is distributed into breast milk.
Paracetamol is completely and rapidly absorbed via gastrointestinal tract after oral administration with a peak serum levels occurring in 15 – 45 minutes with a bioavailability of 96% ± 10%. It is 25% protein-bound. Plasma concentrations do not correlate well with analgesic effect, but do correlate with toxicity. Approximately 90% to 95% is metabolized by hepatic microsomal enzymes. It is excreted in the urine. The average elimination half-life ranges from 1 to 4 hours.
Pseudoephedrine is readily absorbed from the gastrointestinal tract. It is largely excreted unchanged in the urine together with small amounts of its hepatic metabolites. It has a half-life of about 5 to 8 hours; elimination is enhanced and half-life is accordingly shorter in acid urine. Small amounts are distributed into breast milk.
Indications
Koosil® 4 Flu is indicated for the symptomatic treatment of flu, rhinitis, coughs and the common cold.
Dosage and Administration
To be taken 3-4 times a day. Adults and children over 12 years: Two 5 ml spoonfuls. Children 6 – 12 years: One 5 ml spoonful.
Children 2 – 5 years: Half 5ml spoonful.
Children under 2 years: Not recommended.
Adverse reactions
The most common side-effect of the sedating antihistamines are CNS depression, with effects varying from slight drowsiness to deep sleep, and including lassitude, dizziness, and incoordination. Others include headache, psychomotor impairment, and antimuscarinic effects, such as dry mouth, thickened respiratory-tract secretions, blurred vision, urinary difficulty or retention, constipation, and increased gastric reflux. Occasional ones include nausea, vomiting, diarrhoea, or epigastric pain, palpitations and arrhythmias.
Promethazine may sometimes cause rashes and hypersensitivity reactions (including bronchospasm, angioedema, and anaphylaxis) and cross-sensitivity to related drugs may occur. Photosensitivity can be a problem with promethazine.
Interactions
Sedating antihistamines may enhance the sedative effects of CNS depressants including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives, and antipsychotics. Promethazine has addictive antimuscarinic action with other antimuscarinic drugs, such as atropine and some antidepressants (both tricyclics and MAOIs). It has been suggested that some sedating antihistamines could mask the warning signs of damage caused by ototoxic drugs such as aminoglycoside antibiotics.
Precautions
Promethazine is considered to be unsafe in patients with porphyria because it has been shown to be porphyrinogenic in animals or in-vitro systems. Phenothiazine-induced toxic psychosis occurred in a patient with chronic renal failure who had been given promethazine.
Presentation
100 ml amber coloured bottles.
Storage
Store in a dry place, below 30°C, protected from light.
Keep all medicines out of reach of children.
Manufactured By:

DAWA Limited, Plot No. 7879/8, Baba Dogo Road, Ruaraka
P. O. Box 16633 - 00620, Nairobi, Kenya.

Ref: Lf /DL/ Koosil for flu /03
Date of issue: August 2014