

## KOOSIL EXPECTORANT

### Composition

Each 5 ml of the syrup contains: Bromhexine 2 mg, Promethazine hcl 4 mg and Ammonium Chloride 100 mg.

### Pharmacology

**Promethazine**, a phenothiazine derivative, is a sedating antihistamine with antimuscarinic, significant sedative, and some serotonin-antagonist properties.

**Bromhexine** is a mucolytic used in the treatment of respiratory disorders associated with productive cough.

**Ammonium chloride** acts as an expectorant by reflex stimulation of bronchial mucous glands resulting from irritation of gastric mucosa following oral administration of the drug.

### 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.

**Bromhexine hydrochloride** is rapidly absorbed from the gastrointestinal tract and undergoes extensive first-pass metabolism in the liver: its oral bioavailability is stated to be only about 20%. It is widely distributed to body tissues. About 85 to 90% of a dose is excreted in the urine mainly as metabolites. Bromhexine is highly bound to plasma proteins. It has a terminal elimination half-life of up to about 12 hours. Bromhexine crosses the blood-brain barrier and small amounts cross the placenta. Administration of bromhexine hydrochloride by mouth to healthy subjects produced peak plasma concentrations after about 1 hour. Only small amounts were excreted unchanged in the urine with a half-life of about 6.5 hours.

**Ammonium chloride** is rapidly absorbed from the GI tract, complete absorption occurring within 3–6 hours. The drug is metabolized in the liver to form urea and hydrochloric acid.

### Indications

**Koosil Expectorant** is indicated for the relief of productive coughs in adults.

### Dosage and Administration

To be taken 3-4 times a day.

Adults and children over 12 years: Two 5 ml spoonfuls.

Children 2 to 12 years –One 5ml spoonful.

### Side Effects

The side effects that may be experienced following administration of Koosil Expectorant Syrup include: immune system disorders, skin disorders and respiratory disorders. In some rare cases skin lesions have been linked with this medication. Also, nausea, vomiting, thirst, hyperventilation and progressive drowsiness may be experienced. Other side effects include; blurred vision and gastrointestinal disturbance.

### Interactions

Sedating antihistamines may enhance the sedative effects of CNS depressants including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives, and antipsychotics. Promethazine has additive 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.

For Bromhexine; no clinically relevant unfavourable interactions with other medications have been reported.

### Special warnings and Precautions for use:

May cause drowsiness; if affected do not drive or operate machinery.

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.

### Pregnancy and lactation:

**Koosil Expectorant** should be avoided during pregnancy & breast feeding.

### 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,  
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