SM PHARMACEUTICALS SDN BHD

CUREKUF W COUGH SYRUP

DESCRIPTION:
A brown colored, syrupy liquid with honey and pleasantly flavored with peach and raspberry flavour.

COMPOSITION:
Each 5 ml contains:
1. Diphenhydramine Hydrochloride 14.0 mg
2. Ammonium Chloride 135.0 mg

Preservative:
Sodium Benzoate 7.5mg

PHARMACODYNAMICS:
Diphenhydramine suppresses the cough reflex by a direct effect on the cough centre in the medulla of the brain. Its antihistaminic action is by competing with histamine for H1-receptor sites on effector cells. The antimuscarinic actions of antihistamine provides a drying effect on the nasal mucosa. It diminishes vestibular stimulation and depress labyrinthine function. An action on the medullary chemoreceptive trigger zone may also be involved in the antiemetic effect.
Ammonium Chloride has irritant action on the gastric mucous membrane and may contribute expectorant action.

PHARMACOKINETICS:
Diphenhydramine is readily absorbed from the GIT. It is metabolised in the liver and excreted mainly as metabolites in the urine. After an oral dose of 50 mg of Diphenhydramine HCl, plasma concentrations of 50 to 54 ng/ml are attained at 1 hour; at 2 hours, plasma concentration is 64 to 70 ng/ml. The plasma half-life after an oral dose is 13 to 21 hours. 98% is bound to plasma proteins. About 50% of an oral dose is metabolised in the liver before reaching the general circulation. Reactions include N-deakylation and deamination. In the urine, up to 3% of a dose is excreted unchanged, up to 13% as basic amines and up to 65% as diphenylmethane metabolites. The major urinary metabolite appears to be diphenylmethoxyacetic acid in free or conjugated form.
Ammonium Chloride is rapidly absorbed from the GIT. The Ammonium is converted into urea in the liver. The anion thus is liberated into the blood stream and extracellular fluids causes a metabolic acidosis and decreases the pH of the urine. This is followed by transient diuresis.

INDICATIONS:
It is indicated as an expectorant for control of coughs due to colds or allergy.

CONTRAINDICATIONS:
This preparation should not be used in newborn or premature infants and in nursing mother. It should not be used to treat lower respiratory tract symptoms including asthma. It is also contraindicated in cases of hypersensitivity to Diphenhydramine and other antihistamine of similar chemical structure.

SIDE EFFECTS:
The overall percentage of treated patients expected to experience adverse reactions is unknown.
Common side effects include:
CNS effects such as nervous drowsiness (usually diminishes within a few days), paradoxical stimulation, nervous headache, nervous psychomotor impairment.
Anti-muscarinic effects such as urinary retention, dry mouth, blurred vision, gastrointestinal disturbances and thickened respiratory tract secretions.
Rare side effects include:
Hypotension, extrapyramidal effects, dizziness, confusion, depression, sleep disturbances, tremor, convulsions, palpitation, arrhythmia, hypersensitivity reactions, blood disorders and liver dysfunction.

WARNINGS/ PRECAUTIONS:
Diphenhydramine has an atropine-like action and thus it should be used with caution in patients with a history of bronchial asthma, increased intraocular pressure, hyperthyroidism, cardiovascular disease, or hypertension, patients with narrow-angle glaucoma, urinary retention, prostatic hypertrophy and respiratory depression.
This preparation may cause drowsiness. If affected, patient should not drive or operate machinery. Patients should avoid alcoholic beverages.
When used for treatment of cough and cold:
1. Not to be used in children less than 2 years of age.
2. To be used with caution and doctor's/ pharmacist's advice in children 2 to 6 years of age.

PREGNANCY AND LACTATION:
Although there is no evidence to suggest that exposure to Diphenhydramine during pregnancy is related to major malformations, there were slight suggestions of an association between Diphenhydramine use and inguinal hernia or genitourinary malformations. Accordingly, Diphenhydramine is considered to be contraindicated during pregnancy.

Diphenhydramine is excreted into human breast milk but levels have not been reported. Although the levels are not thought to be high, the drug is considered to be contraindicated during lactation.

DRUG INTERACTIONS:
Alcohol, tranquilizers, sedative-hypnotics and CNS depressants increases CNS depression.
MAO Inhibitors: Increases anticholinergic effects.

RECOMMENDED DOSAGE, DOSAGE SCHEDULE AND ROUTE OF ADMINISTRATION:
Unless otherwise prescribed by the physician:
Adults and children over 12 years: 5 to 10 ml every 4 or 6 hours (not to exceed 60 ml in 24 hours).
Children 6 to 12 years: 2.5 to 5 ml every 4 to 6 hours (not to exceed 30 ml in 24 hours).
Children 2 to 5 years: 2.5 ml every 4 to 6 hours (not to exceed 20 ml in 24 hours).
Take medication with a full glass of water. Do not exceed the stated dose.

DOSAGE FORM: Oral liquid

ROUTE OF ADMINISTRATION: Oral Use.

SYMPTOMS AND TREATMENT OF OVERDOSE:
Overdosage reactions may vary from CNS depression to stimulation. Stimulation is particularly likely in children. Atropine-like signs and symptoms - dry mouth, dilated pupils, flushing, gastrointestinal symptoms may occur.
Treatment: If vomiting has not occurred spontaneously, the patient should be induced to vomit. This is best done by having the patient to drink a glass of water or milk, after which the patients should be made to gag.
Precautions against aspiration must be taken, especially in infants and children. If vomiting is unsuccessful, gastric lavage is indicated within 3 hours after given beforehand. Isotonic or ½ isotonic saline is the lavage solution of choice. Saline cathartics, as milk of magnesia, by osmosis drew water into the bowel and therefore are valuable for their action in rapid dilution of bowel content. Stimulants should not be used. Vasopressors may be used to treat hypotension.

EFFECT ON ABILITY TO DRIVE AND USE MACHINE:
This product may cause drowsiness. If affected, the patient should not drive or operate machinery.

PACKING / PACK SIZES:
Packed in 100 ml amber colored glass bottle (USP Type III) with ROPP cap.

STORAGE CONDITIONS, USER INSTRUCTIONS AND PHARMACEUTICAL PRECAUTIONS:
Store in a dry place below 30°C.
Protect from Light.
Keep container tightly closed.

JAUHI UBAT DARIPADA KANAK-KANAK
KEEP OUT OF REACH OF CHILDREN

For further information, consult your doctor or pharmacist.

For oral use. Take medication with a full glass of water. Do not exceed the stated dose.

SHELF LIFE: 3 years.

MANUFACTURER/ PRODUCT REGISTRATION HOLDER:
SM PHARMACEUTICALS SDN BHD (218620-M)
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MALAYSIA

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