AMENDED PACKAGE INSERT

SUNTUSS SYRUP

Each 5ml contains:-

Diphenhydramine HCl	10mg
Dextromethorphan HBr	5mg

Product Description:
A clear, brown syrup with cherry flavour.

Pharmacodynamics:
Dextromethorphan is a cough suppressant. It acts centrally to elevate the threshold for coughing. It has no analgesic effect or sedative effect on the nervous system, nor any other established pharmacological action. Diphenhydramine hydrochloride is an antihistamine with anticholinergic (drying) and sedative side-effects. Antihistamines appear to compete with histamine for cell receptor sites on effector cells.

Pharmacokinetics:
Dextromethorphan is well absorbed from the gastro-intestinal tract. It is metabolised in the liver and excreted as unchanged dextromethorphan and demethylated morphinan compounds.
Diphenhydramine is readily absorbed from the gastrointestinal tract. It is extensively metabolised in the liver and excreted in the urine. Maximum plasma diphenhydramine concentrations ranging from 81 to 159 mg per ml were obtained 2 to 4 hours after administration of diphenhydramine hydrochloride 100 mg by mouth to 4 healthy subjects. The plasma half-life calculated over the period 4 to 24 hours after administration ranged from 5 to 8 hours. Urinary excretion of diphenhydramine metabolites was about 64% of the dose after 96 hours.

Indication:
It is indicated for the treatment of dry unproductive cough.

Recommended Dosage:
Adults: Two teaspoonfuls (10ml) every four hours not to exceed twelve teaspoonfuls (60ml) in twenty-four hours.
Children (6 to under 12 years): One teaspoonful (5ml) every four hours not to exceed six teaspoonfuls (30ml) in twenty-four hours.

Route of Administration: Oral

Contraindications:
It is contraindicated in asthmatic patients, newborn or premature infants and nursing mothers.
Antihistamines should not be used to treat lower respiratory tract symptoms, including asthma.
Antihistamines are also contraindicated in the following conditions:
Hypersensitivity to diphenhydramine HCl and other antihistamines of similar chemical structure.
Monoamine oxidase inhibitor therapy.

Warnings and Precautions:
It should be administered with caution to patients with liver disease. This product should not be given to children under 2 years of age except under the advice and supervision of a physician. This product is not to be administered for persistent or chronic cough such as occurs with smoking, asthma or emphysema, or where cough is accompanied by excessive secretions, or if the patient has epilepsy, glaucoma, or difficulty in urination due to enlargement of the prostate gland except under the advice and supervision of physician. Antihistamines should be used with considerable caution in patients with narrow-angle glaucoma, stenosing peptic ulcer, pyloroduodenal, obstruction, symptomatic prostatic hypertrophy or bladder neck obstruction. In infants and children, especially antihistamines in overdosage may cause hallucinations, convulsions or death. As in adults, antihistamines may diminish mental alertness in children. In the young child, particularly, they may produce excitation. This product should not be taken for persistent chronic cough such as occurs with smoking, asthma, emphysema, or when cough is accompanied by excessive secretions, or if the patient has epilepsy, glaucoma or difficulty in urinations due to enlargement of the prostate gland except under the advice and supervision of physician. Diphenhydramine hydrochloride has additive effects with alcohol and other CNS depressants (hypnotics, sedative, tranquilizers). Patients should be warned about engaging in activities requiring mental alertness, such as driving a car or operating appliances, machinery, etc. Antihistamines are more likely to cause dizziness, sedation and hypotension in elderly patients. Diphenhydramine hydrochloride has an atropine-like action and, therefore, should be used with caution in patients with a history of bronchial asthma, increased intraocular pressure, hyperthyroidism, cardiovascular disease or hypertension. Not recommended for children below 2 years. Use with caution and on doctor's/pharmacist's advice in children 2 to 6 years of age.

Interactions with Other Medicaments:
Administration of dextromethorphan to patients receiving MAO inhibitors may produce severe reactions; hyperpyrexia and fatalities have been reported.
Antihistamine may enhance the sedative effects of CNS depressants. MAO inhibitors may enhance the antimuscarinic effects of antihistamines, and antihistamines have an additive antimuscarinic action with other antimuscarinic drugs, such as atropine and tricyclic antidepressants.

Pregnancy and Lactation:
This product should be used only if clearly needed. Experience with this drug in pregnant women is inadequate to determine whether exists a potential for harm to the developing foetus.

Side Effects:
Dextromethorphan HBr occasionally causes drowsiness, dizziness, excitation, mental confusion and gastro-intestinal disturbances. Very high doses may produce respiratory depression.
Other adverse reactions are:-

General	: Urticaria, drug rash, anaphylactic shock, photosensitivity, excessive perspiration, chills, dryness of mouth, nose and throat.
Cardiovascular system	: Hypertension, headache, palpitations, tachycardia, extrasystoles.
Hematologic system	: Hemolytic anaemia, thrombocytopenia, agranulocytosis.
Nervous system	: Sedation, sleepiness, dizziness, disturbed co-ordination, fatigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, euphoria, paresthesia, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, hysteria, neuritis, convulsions.
G.I. system	: Epigastric distress, anorexia, nausea, vomiting, diarrhoea, constipation.
G.U. system	: Urinary frequency, difficult urination, urinary retention, early menses.
Respiratory system	: Thickening of bronchial secretions, tightness of chest, wheezing and nasal stuffiness.

Symptoms and Treatment of Overdose:
Antihistamine overdosage reactions may vary from CNS depression to stimulation. Atropine-like signs and symptoms such as dry mouth; fixed, dilated pupils; flushing and gastrointestinal symptoms may also occur.
If vomiting has not occurred spontaneously, the patient should be induced to vomit. Precautions against aspiration must be taken especially in infants and children. If vomiting is unsuccessful, gastric lavage is indicated within 3 hours of ingestion and even later if large amounts of milk or cream has been given before hand. Isotonic or ½ isotonic saline is the lavage solution of choice. Vasopressors may be used to treat hypotension.

Effects on Ability to Drive and Use Machine:
This product may cause drowsiness; if affected, individuals should not drive or operate machinery.

Storage Conditions: Store below 30ºC. Protect from light.

Pack Sizes: A bottle of 60ml, 90ml, 100ml and 120ml.
Pack Sizes (export only): A bottle of 3.6 litres and 3.8 litres.

Shelf-life: 3 years

FURTHER INFORMATION CONCERNING THIS DRUG CAN BE OBTAINED FROM YOUR FAMILY PHYSICIAN / LOCAL GENERAL PRACTITIONER / PHARMACIST.

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