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CUSTOMER	: IDAMAN PHARMA MANUFACTURING SDN BHD	SHEET SIZE	: NIL	COLOUR :	Black
DESCRIPTION	: DIPHENHYDRAMINE	PROCESS	: NIL		
MEASUREMENT	: W:210mm X H:148mm	FINISHING	: UNFOLD		
MATERIAL	: SMPO 060	BOARD OUTING	: NIL		

MATERIAL CODE: Lt-312.00

MOULD NO : -

Attn : MS. ZAKIAH
From : MALA
I hereby verify & confirm that this draft is the final copy. Any subsequence changes of the design and content of the end product will not be borne by THUNDER PRINT SDN. BHD.

Customer Signature & Date

27.10.2022

pharmaniaga®

Diphenhydramine

Expectorant

DESCRIPTION
Brown syrup.

COMPOSITION
Each 5 mL contains:
Ammonium chloride 135 mg.
Diphenhydramine hydrochloride 12.5 mg.

Preservative:
Sodium benzoate 0.10 % w/v.

PHARMACODYNAMICS
Ammonium chloride is used as an expectorant.

Diphenhydramine is an ethanolamine derivative with the actions and uses of the histamine H_1-receptor antagonist.

PHARMACOKINETICS
Ammonium chloride is absorbed from the gastro-intestinal tract. The ammonium ion is converted into urea in the liver, the anion thus liberated into the blood stream and extracellular fluid causes a metabolic acidosis and decreases the pH of the urine; this is followed by transient diuresis.

Diphenhydramine is well absorbed from the gastro-intestinal tract, though high first-pass metabolism appears to affect systemic availability. Peak plasma concentrations are achieved about 1 to 4 hours after administration by mouth. Diphenhydramine is widely distributed throughout the body including the CNS.

It crosses the placenta and has been detected in breast milk. Diphenhydramine is highly bound to plasma proteins. Metabolism is extensive. Diphenhydramine is excreted mainly in the urine as metabolites, little is excreted as unchanged drug. Excretion is almost complete within 24 hours of administration. The elimination half-life has been reported to range from 2.4 to 9.3 hours.

INDICATIONS
Cough, nasal and bronchial congestion.

CONTRAINDICATIONS
This medication is contraindicated for use in patients with:
- known hypersensitivity or idiosyncratic reaction to diphenhydramine (or substances of similar chemical structure) or ammonium chloride or any of the other ingredients in the product;
- narrow-angle glaucoma;
- asthma;
- symptomatic prostatic hypertrophy;
- presence of impaired hepatic/renal function;
- monoamine oxidase inhibitors (MAOIs) therapy;
- stenosing peptic ulcer;
- bladder neck obstruction;
- pyloroduodenal obstruction;
- porphyria.

This medication is also contraindicated for use in:
- premature infants or neonates;
- children under the age of 2 years.

ADVERSE REACTIONS
Headache, photosensitivity, ataxia, chills, fatigue, diaphoresis, menstrual disease, hypotension, palpitations, tachycardia, constipation, diarrhoea, anorexia, dry mouth, dry throat, dyspepsia, nausea, vomiting, stomach discomfort, agitation/ excitation, anxiety, confusion, euphoria, excitement, convulsions, psychosis (mental disorder), disturbed coordination, dizziness, hallucinations, insomnia, irritability, nervousness, paresthesia, somnolence/ sedation, tremor, neuritis, seizure, vertigo, impaired performance (impaired driving performance, poor work performance, incoordination, reduced motor skills and impaired information processing), appetite stimulation, muscle dyskinesias and activation of epileptogenic foci, dryness of nose, thickening of bronchial secretions, tightness of chest or throat, wheezing, shortness of breath, breathing difficulty, nasal congestion, constriction of pharynx, acute labyrinthitis, pruritis, rash, itching, urticaria, anaphylactic shock, swelling of the face, lips, tongue or other parts of the body, agranulocytosis, haemolytic anaemia, thrombocytopenia, dryness of the eyes, blurred vision, tinnitus, diplopia, urinary hesitancy and retention. Somnolence was the most frequently reported adverse effect.

Nausea and vomiting have been reported with high doses of ammonium chloride.

WARNINGS AND PRECAUTIONS
This medication may cause drowsiness and may increase the effects of alcohol. Drowsiness may continue the following day. Patients should avoid alcoholic drinks.

Caution is advised in conditions such as urinary retention, pyloroduodenal obstruction, epilepsy or seizure disorder, severe cardiovascular disorder, myasthenia gravis and thyroid dysfunction.

This medication should be used with caution in patients with:
- breathing problems such as emphysema or chronic bronchitis or chronic obstructive pulmonary disease (COPD);
- persistent or chronic cough such as with smoking, asthma or emphysema;
- cough accompanied by excessive secretions (mucus);
- renal or hepatic impairment;
- glaucoma;
- other sedating antihistamines.

Consult a physician if symptoms persist for more than 7 days, or if high fever, skin rash or continuing headache is present with cough.

Patients with moderate to severe renal or hepatic dysfunction or urinary retention should exercise caution when using this medication. It may be prudent to increase the dosage intervals in patients with moderate to severe renal failure.

Patients with rare hereditary problems of fructose intolerance,glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medication.

Patients are advised to not exceed the stated dose and to keep this medication out of the reach and sight of children.

Paediatric
This medication should not be given to premature infants or neonates as this group of patients has an increased susceptibility to anticholinergic adverse effects of antihistamines such as CNS excitation and an increased tendency towards convulsions.

A paradoxical reaction characterised by hyperexcitability may occur in older children taking antihistamines.

Geriatrics
The elderly are more susceptible to many adverse effects of antihistamines including the antimuscarinic effects, sedation and hypertension.

When used for treatment of cough and cold:
- Not to be used in children less than 2 years of age.
- To be used with caution and doctor's or pharmacist's advice in children 2 to 6 years of age.

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

PREGNANCY AND LACTATION
Diphenhydramine is known to cross the placenta and has been detected in breast milk. In view of the potential risks versus small benefits, it is recommended that Pharmaniaga Diphenhydramine Expectorant should not be used during pregnancy and lactation particularly as the safety of Pharmaniaga Diphenhydramine Expectorant in human pregnancy and during lactation is not established.

DRUG INTERACTIONS

DRUG	EFFECT
Alcohol Barbiturates Hypnotics Opioid analgesics Anxiolytic sedatives and neuroleptics	Enhanced sedation.
Monoamine oxidase inhibitors	increased anticholinergic adverse effects.
Antimuscarinic drugs	Enhanced antimuscarinic effects.
Aminoglycoside antibiotics	Masked symptoms of ototoxicity.
Diagnostic skin test using Allergen extracts	Produces false-negative result; It is recommended that medication be discontinued at least 72 hours before testing begins.
Tricyclic antidepressants (TCAs)	Increased anticholinergic adverse effects.
Beta Blockers such as metoprolol	Potentiate the effects of diphenhydramine due to inhibition of CYP2D6.
CNS depressants (hypnotics, sedative, transquilisers, TCAs)	Additive effects with other CNS depressants.

DOSAGE AND ADMINISTRATION
Adults: 10 mL every four to six hours. Do not exceed 60 mL in 24 hours.

Children (6 - 12 years): 5 mL every four to six hours. Do not exceed 30 mL in 24 hours.

Children (2-5 years): 2.5 mL every four to six hours. Do not exceed 15 mL in 24 hours.

Take with food or milk to minimise gastric irritation. Drink a glass of water after each dose to help loosen mucous in lungs.

OVERDOSAGE
Overdose of antihistamine may be fatal especially in infants and children.

Symptoms:
For antihistamines
In infants and children, CNS stimulation predominates over CNS depression, causing ataxia, excitement, tremors, psychoses, hallucinations and convulsion; hyperpyrexia may also occur. Deepening coma and cardiorespiratory collapse may follow.

In adults, CNS depression is more common with drowsiness, coma and convulsions, progressing to respiratory failure or possibly cardiovascular collapse. Large doses of ammonium chloride may cause a profound acidosis and hypokalaemia.

Treatment:
There is no specific antidote for overdosage with antihistamines and Ammonium chloride, treatment is symptomatic and supportive until possible utilisation of the following:

- induction of emesis (syrup of ipecac is recommended, however, precaution against respiration is necessary especially in infants and children).
- gastric lavage if patient unable to vomit within 3 hours of ingestion.
- saline carthartics are sometimes used.
- vasopressors to treat hypotension,
- however, epinephrine should not be used since it may further lower blood pressure.
- oxygen and intravenous fluids.
- precaution against use of stimulant because they may cause seizures

ROUTE OF ADMINISTRATION
Oral.

STORAGE CONDITIONS
Store below 30°C.
Protect from light.
Keep container tightly closed.

SHELF LIFE
Product should not be used beyond the expiry date imprinted on the product packaging.

PRESENTATION
In bottles of 90 mL and 120 mL.

Date of revision: 27th Oct 2022

PRODUCT REGISTRATION HOLDER:
Pharmaniaga Manufacturing Berhad
(198001006232)
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