Anprodryl Syrup

NAME AND STRENGTH OF ACTIVE SUBSTANCE:
Each 5ml syrup contains:
Diphenhydramine Hydrochloride …… ……12.5mg
Ammonium Chloride…… 125mg

PRODUCT DESCRIPTION:
A caramel colour liquid with Prune flavour and sweet taste.

PHARMACODYNAMICS :
Diphenhydramine hydrochloride is a monoethanolamine-derivative antihistamine with sedative and antihistamine properties. It also has anti-emetic, anticholinergic and local anaesthethic properties. Antihistamines compete with histamine for cell receptor sites on effector cells. Ammonium chloride encourages productive cough by increasing the volume of bronchial secretion.

PHARMACOKINETICS:
Diphenhydramine hydrochloride is well absorbed from the gastrointestinal tract, although 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 central nervous system. It crosses the placenta and has been detected in breast milk. It is highly bound to plasma proteins. Diphenhydramine is extensively metabolised and is excreted mainly in the urine as metabolites and little is excreted as unchanged drug. The elimination half-life has been reported to range from 2.4 to 9.3 hours. Ammonium chloride is absorbed from the gastrointestinal tract. It is converted to urea by the liver via the ornithine cycle. Its metabolism releases hydrogen ions and bicarbonate, which decreases the pH of the urine and promotes diuresis. Ammonium chloride is excreted renally.

INDICATION:
For the control of cough, nasal congestion, sneezing, lachrymation and bronchial congestion due to common cold and allergic conditions.
Should not be used in children less than 2 years of age.

RECOMMENDED DOSAGE:
Adults : One to two teaspoonfuls (5-10ml), three to four times daily.
Children (2-12 years) : 2.5-5ml three or four times daily or 5mg per kg body –weight in divided doses.
Not to be used in children under 2 years of age.
To be used with caution and on doctor's or pharmacist's advice in children 2 to 6 years of age.

ROUTE OF ADMINISTRATION:
To be taken orally

CONTRAINDICATIONS:
Hypersensitivity to diphenhydramine hydrochloride and other antihistamines of similar chemical structure. Nursing mother, premature infants, full term neonates.

WARNINGS AND PRECAUTIONS:
Not to be used in children under 2 years of age.
To be used with caution and on doctor's or pharmacist's advice in children 2 to 6 years of age.
Diphenhydramine hydrochloride can cause drowsiness. Avoid driving or operating machinery. It should be used with caution in patients with conditions such as angle-closure glaucoma, hepatic disease, hyperthyroidism, cardiovascular disease or hypertension, urinary retention, prostatic hyperplasia, pyloroduodenal obstruction, epilepsy, porphyria and in patients with a history of bronchial asthma. Should be cautiously used in elderly (approximately 60 years or older).

INTERACTIONS WITH OTHER MEDICAMENTS:
Diphenhydramine enhances sedative effects of central nervous system depressants including alcohol, barbiturates, hypnotics, opiod analgesics, anxiolytic sedativs and antipsychotics. Monoamine oxidase inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines.

PREGNANCY AND LACTATION:
If pregnant or nursing, consult your physician before taking Anprodryl Syrup.

SIDE EFFECTS:
Drowsiness, dizziness, sleepiness, disturbed coordination, headache, psychomotor impairment, antimuscarinic effects (dry mouth, thickened respiratory-tract secretions, blurred vision, urinary difficulty and retention, constipation, increased gastric reflux), occasional gastrointestinal disturbances (nausea, vomiting, diarrhoea, epigastric pain).

SYMPTOMS AND TREATMENT OF OVERDOSAGE:
Symptoms: Antihistamine overdosage reactions may vary from central nervous system depression to stimulation. Stimulation is particularly likely in pediatric patients. Atropine-like signs and symptoms, dry mouth; fixed, dilated pupils; flushing, and gastrointestinal symptoms may also occur.

Treatment: Symptomatic and supportive treatment for acute overdose. If a patient is conscious, not having seizure and has not lost the gag reflex, emesis should be induced. Otherwise, gastric lavage and activated charcoal may be used. Saline cathartics (eg. Magnesium sulfate) may be administered. Vasopressors may be used to treat hypotension. Diazepam can be given IV in the management of seizures that do not respond to physostigmine.

EFFECT ON ABILITY TO DRIVE AND USE MACHINE
Do not drive or use machine as the medication can cause drowsiness

PRECLINICAL SAFETY DATA
Not applicable

INSTRUCTION FOR USE
For oral use only

DOSAGE FORMS AND PACKAGING AVAILABLE:
Pack size : 100ml in amber round plastic bottle

NAME AND ADDRESS OF MANUFACTURER / PRODUCT REGISTRATION HOLDER:
MALAYSIAN PHARMACEUTICAL INDUSTRIES SDN BHD (101323-U)
Plot 14, Lebuhraya Kampung Jawa,11900 Bayan Lepas,
Pulau Pinang, Malaysia.

DATE OF REVISION:
15/01/18