PACKAGE INSERT

SCHEDULING STATUS: S2.

PROPRIETARY NAME (AND DOSAGE FORM):

PHENORANT (SYRUP)

COMPOSITION:

Each 5ml contains:	Diphenhydramine Hydrochloride	13.33 mg
	Ammonium Chloride	130 mg
	Sodium Citrate	54.166 mg
Preservative:	Nipastat	0.02 $\%^{m}/_{v}$

PHARMACOLOGICAL CLASSIFICATION:
A.10.1 Antitussives and expectorants.
(Prevents/reduces coughing and medicines that promote coughing and expulsion of mucous).

PHARMACOLOGICAL ACTION:
Acts as an expectorant in the relief of simple uncomplicated cough, as a result of colds. The antihistamine is an aid to drying up excess mucous secretions.

INDICATIONS:
Relief of coughs.

CONTRA-INDICATIONS:
Hypersensitivity (allergy) to any of the ingredients.
PHENORANT is contra-indicated in the presence of impaired hepatic function (decrease in liver function) or impaired renal function (decrease in kidney function).
During an attack of asthma. Safety in pregnancy and lactation has not been established.

WARNING:
The use of Phenorant may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants. Patients should be warned against driving a vehicle or being in charge of machinery or performing potentially hazardous tasks while using this medicine, as impaired decision making could lead to an accident.

DOSAGE AND DIRECTIONS FOR USE:

Adults:	One to two 5ml medicine measures every four hours.	
Children:	(6 - 12 years)	One 5ml medicine measure every four hours.
	(1 - 6 years)	Half a 5ml medicine measure every four hours.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
The most common side-effect caused by diphenhydramine is sedation (sedative effect) which includes drowsiness, inability to concentrate, lassitude (lack of energy/fatigue), dizziness, hypotension (low blood pressure), muscular weakness and incoordination. Other side-effects include gastro-intestinal (affecting the stomach and intestines) disturbances, headache, blurred vision, tinnitus (ringing in the ears), elation (high spirits) or depression, irritability, nightmares, anorexia (lack of appetite), difficulty in micturition (passing of urine), dryness of mouth and tightness of chest, tingling, heaviness and weakness of the hands. Constipation (infrequent bowel movement), diarrhoea (frequent or loose watery stools), epigastric pain (pain in upper, middle region of stomach), nausea (feeling that one is about to be sick), vomiting (to be sick), allergic (hypersensitivity) reactions, epilepitform seizures (resembling certain types of fits), euphoria (unrealistic feeling of well-being), extrapyramidal effects (effects of the brain), haemolytic anaemia (lack of red blood cells due to destruction of circulating cells), leucopenia (too few white blood cells) and photosensitisation (sensitisation of the skin to sunlight). Symptoms of stimulation such as insomnia (inability to sleep), nervousness, tachycardia (increased rate of heart beat), tremors (shakes), muscle twitching and convulsions (fits) may also occur.
Side-effects that may arise from large doses of ammonium chloride are nausea (feeling that one is about to vomit), vomiting (to be sick), thirst, headache, hyperventilation (abnormally deep and rapid breathing), progressive drowsiness, mental confusion, hyperchloraemic acidosis (abnormally high levels of chloride in the blood causing the blood to be acidic) and hypokalaemia (low blood levels of potassium). Extreme caution should be exercised by patients taking PHENORANT in conjunction with nervous system depressants such as alcohol, barbiturates, hypnotics (causes sleep), narcotic analgesics (dependence producing substances used for the relief of pain), sedatives (for calming) and tranquillizers (agent used for calming nerves) and anticholinergic agents (a substance to stop the release of certain nerve impulses involving acetylcholine) and tricyclic antidepressants as their effects may be enhanced by diphenhydramine. Monoamine-oxidase inhibitors may enhance the anticholinergic effects of diphenhydramine. The warning signs of damage caused by ototoxic medicines may be masked by diphenhydramine. PHENORANT should be used cautiously in patients with cardiac (heart) failure, hypertension (high blood pressure), impaired renal function (decrease in kidney function), peripheral oedema (swelling of hands and feet due to retained fluid) and pulmonary oedema (excessive fluid accumulation in the lungs) and in toxaemia of pregnancy (serious metabolic abnormalities during pregnancy associated with increased blood pressure).

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
In infants and children symptoms of overdosage may include convulsions and hyperpyrexia. In adults symptoms include those mentioned under side-effects.
Treatment is symptomatic and supportive.

IDENTIFICATION:
A sweet brown syrupy liquid.

PRESENTATION:
50 ml, 100 ml and 200 ml glass and plastic bottles
HDPE polycans with 2,5 litre

STORAGE INSTRUCTIONS:
Store in a cool place below 25°C, protect from light.
KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER:
G 1054 (Act 101 of 1965)

NAME AND BUSINESS ADDRESS OF APPLICANT:
GULF DRUG COMPANY
22 BURNSIDE DRIVE
OLD MILL INDUSTRIAL PARK
MOUNT EDGECOMBE
4300

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