PACKAGE INSERT

SCHEDULING STATUS: S2.

PROPRIETARY NAME (AND DOSAGE FORM):

PHENORANT WITH CODEINE (SYRUP)

COMPOSITION:

Each 5ml contains:	Codeine Phosphate	8.33	mg
	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 a cough suppressant, as an expectorant in the relief of cough, aids in drying up excess mucous secretions.

INDICATIONS:
Relief of coughs.

CONTRA-INDICATIONS:
Sensitivity to the components. Patients with impaired renal or hepatic function. Patients with respiratory depression, especially in the presence of cyanosis and excessive bronchial secretion, after operations on the biliary tract, acute alcoholism, head injuries and conditions in which intracranial pressure is raised. It should not be given during an attack of bronchial asthma or in heart failure secondary to chronic lung disease.

WARNINGS:
The use of this medicine may lead to drowsiness and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents. Patients should be warned against performing potentially hazardous tasks where loss of concentration may lead to accidents. Exceeding the prescribed dose, together with prolonged and continuous use of this medication may lead to dependency and addiction.

DOSAGE AND DIRECTIONS FOR USE:
Every four hours.
Adults: One to two 5 ml medicine measures.
Children 6-12 years: One 5 ml medicine measure.
Children 1-6 years: Half a 5 ml medicine measure.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
Codeine may cause vomiting, constipation, drowsiness, confusion, dry mouth, sweating, facial flushing, vertigo, bradycardia, palpitations, orthostatic hypotension, hypothermia, restlessness, changes of mood and miosis. Micturition may be difficult and there may be ureteric or biliary spasm. Raised intracranial pressure may occur.
Codeine should be given with caution to patients with hypothyroidism, adrenocortical insufficiency, impaired liver function, prostatic hypertrophy or shock. It should be used with caution in patients with inflammatory or obstructive bowel disorders. The dosage should be reduced in elderly and debilitated patients.
The depressant effects of codeine are enhanced by depressants of the central nervous system such as alcohol, anaesthetics, hypnotics and sedatives, and phenothiazines. Larger doses produce respiratory depression and hypotension, with circulatory failure and deepening coma. Convulsions may occur in children.
Prolonged use of high doses of codeine has produced dependence of the morphine type.
Diphenhydramine HCL may give rise to the following side-effects: sedation, varying from slight drowsiness to deep sleep and including inability to concentrate, lassitude, dizziness, hypotension, muscular weakness and inco-ordination.
Other side-effects include gastro-intestinal disturbances such as nausea, vomiting, diarrhoea or constipation, and epigastric pain.
Diphenhydramine HCL may also cause headache, blurred vision, tinnitus, elation or depression, irritability, nightmares, anorexia, difficulty in micturition, dryness of the mouth, tightness of the chest and tingling, heaviness and weakness of the hands. Symptoms of cerebral stimulation may arise in some adults and they include insomnia, nervousness, tachycardia, tremors, muscle twitching and convulsions.
Large doses of diphenhydramine HCL may precipitate fits in epileptics.
Diphenhydramine HCL may enhance the sedative effect of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers. It should be used with care in conditions which can be exacerbated or otherwise adversely affected by atropine, such as glaucoma and prostatic hypertrophy. The effects of anticholinergic drugs such as atropine and tricyclic antidepressants may be enhanced by concomitant administration.
Ammonium chloride – large doses may cause nausea, vomiting, thirst, headache, hyperventilation, and progressive drowsiness, and lead to profound acidosis and hypokalaemia.
Sodium citrate – hypernatraemia may occur and the symptoms include restlessness, weakness, thirst, reduced salivation and tear production, swollen tongue, flushing of the skin, pyrexia, dizziness, headache, oliguria, hypotension, tachycardia, delirium, hyperpnoea and respiratory arrest. Sodium citrate should be used cautiously in patients with cardiac failure, hypertension, impaired renal function, peripheral and pulmonary oedema, and in toxaemia of pregnancy.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Symptoms as under side-effects. In addition, symptoms of codeine overdosage are the development of coma, respiratory depression, cyanosis and hypotension together with pin-point non-reactive pupils.
Symptoms of overdosage in infants and children may include convulsions and hyperpyrexia. Treatment is supportive and symptomatic.

IDENTIFICATION:
A clear brown sweet syrupy liquid.

PRESENTATION:
Bottles with 100 ml and 200 ml
HDPE Polycans with 2,5L

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

REFERENCE NUMBER:
G 1053 (Act 101 of 1965)

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

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
16 March 1992

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VOUBILJET

SKEDULERINGSTATUS: S2.

EIENDOMSNAAM (EN DOSEERVORM):

PHENORANT WITH CODEINE (STROOP)

SAMESTELLING:

Elke 5 ml bevat:	Kodeienfosfaat	8.33	mg
	Difenhidramienhidrochloried	13.33	mg
	Ammoniumchloried	130	mg
	Natriumsitraat	54.166	mg
Preserveermiddel:	Nipastat	0.02	%m/v

FARMAKOLOGIESE KLASSIFIKASIE:
A.10.1 Hoesonderdrukkers en slymmiddels (Voorkom/verminder hoes en medisynes wat hoes en mukus uitdrywing bevorder).

FARMAKOLOGIESE WERKING:
Die middel is werksaam as 'n hoesonderdrukker en as 'n hoesdryfmiddel in die verligting van hoes, is van hulp in die opdroging van oortollige slymafskeiding.

INDIKASIES:
Verligting van hoes.

KONTRA-INDIKASIES:
Gevoeligheid vir die bestanddele. Pasiënte met verswakte lewer- of niewerking. Pasiënte met asemhalingonderdrukking, veral in die teenwoordigheid van blousug en oormatige brongiale afskeiding, na operasies op die galbaan, akute alkoholisme, hoofbeserings en in toestande waar die binneskedeldruk verhoog is. Dit behoort nie gegee te word gedeurende 'n brongiale
asma aanval nie of in hartversaking bykomstig tot langdurige longsiekte.

WAARSKUWINGS:
Die gebruik van hierdie medisyne kan lei tot lomerigheid en verswakte konsentrasie wat vererger kan word deur die gelyktydige inname van alkohol of ander sentrale senuweestelsel onderdrukkermiddels. Pasiënte moet gewaarsku word teen die verrigting van moontlike
gevaarlike werk waar 'n verlies van konsentrasie kan lei tot ongelukke. Oorskreiding van die voorgeskrewe dosis tesame met langurige en voortdurende gebruik van hierdie medisyne mag tot afhanklikheid en verslawing lei.

DOSIS EN GEBRUIKSAANWYSINGS:
Elke vier uur.
Volwassenes: Een tot twee 5 ml medisynemate.
Kinders 6 – 12 jaar: Een 5 ml medisynemaat.
Kinders 1 – 6 jaar: 'n Halwe 5 ml medisynemaat.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Kodeien kan braking, hardlywigheid, lomerigheid, verwarring, droë mond, gesweet, gloede in die gesig, duiseligheid, stadige hartklop, hartkloppings, ortostatiese lae bloeddruk, ligaamshittegebrek, rusteloosheid, verandering van bui en kykervernouing veroorsaak. Urinering kan moeilik wees en urienleier- en galspasma kan voorkom. Verhoogde binneskedeldruk kan voorkom.
Kodeien behoort met sorg aan pasiënte met skildkliertekort, bynierskorsontoereikendheid, verswakte lewerfunksie, voorstanderkliervergroting of skok gegee te word. Dit behoort met sorg geneem te word by pasiënte met inflammatoriese- of versperrende dermafwykings. Die dosis behoort verminder te word by bejaarde en verswakte pasiënte.
Die onderdrukkende uitwerking van kodeien word verhoog deur sentrale senuweestelsel onderdrukkers soos alkohol, narkosemiddels, slaapmiddels en kalmeermiddels, en fenotiasiene. Groter dosisse bring asemhalingonderdrukking en lae bloeddruk met omloopversaking en verdiepte koma voort. Stuipe kan voorkom in kinders.
Langdurige gebruik van hoë dosisse kodeien het afhanklikheid van die morfien sort, teweeggebring.
Difenhidramien-HCL kan aanleiding gee tot die volgende newe-effekte: kalmering wat wissel van 'n ligte slaperigheid tot 'n diep slaap, insluitende die onvermoë om te konsentreer, lusteloosheid, duiseligheid, lae bloeddruk, spierswakheid en inkoördinasie.
Ander newe-effekte sluit versteurings van die spysverteringskanaal soos naarheid, braking, diaree of hardlywigheid, en maagkroppyn in.
Difenhidramien-HCL kan ook hoofpyn, wasige gesigsvermoë, oorsuising, uitgelatenheid of neerslagtigheid, prikkelbaarheid nagmerries, eetlusverlies, moeilikheid by urinering, droogheid van die mond, benoudheid van die bors en prikkelgevoel, swaarheid en swakheid van die hande insluit.
Simptome van breinstimulering kan ook onstaan in sommige volwassenes en dit sluit in: slaaploosheid, senuagtigheid, hartslagversnelling, bewings, spiertrekking en stuipe.
Groot dosisse van difenhidramien-HCL kan aanvalle in vallendesiektelyers ontketen. Difenhidramien-HCL kan die kalmerende uitwerking van sentrale senuweestelsel onderdrukkers insluitende alkohol, barbiturate, slaapmiddels, narkotiese pynstillers, kalmeermiddels en bedaarmiddels versterk. Dit moet versigtig gebruik word in toestande wat vererger of andersins ongunstig geaffekteer word deur atropien, soos gloukom en voorstanderkliervergroting. Die uitwerking van anticholinergiese middels soos atropien en trisikliese gemoedsverligters kan versterk word deur bykomstige toediening.
Ammoniumchloried – groot dosisse kan naarheid, braking, dors, hoofpyn, ooraseming en toenemende slaperigheid veroorsak wat lei tot diepgaande asidose en bloedkaliumgebrek.
Natriumsitraat – oormaatbloednatrium kan voorkom en die simptome sluit rusteloosheid, swakheid, dors, verminderde speeksel en traanafskeiding, opgeswelde tong, blosing van die vel, koors, duiseligheid, hoofpyn, urienafname, lae bloeddruk, hartslagversnelling, ylhoofdigheid, hygasemhaling en asemhalingstilstand in.
Natriumsitraat moet versigtig gebruik word deur pasiënte met hartversaking, hoë bloeddruk, verswakte nierwerking, perifere en longwatersug, en in swangerskapstuipe.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Simptome soos onder newe-effekte. Ter byvoeging is simptome van kodeien-oordosering die ontwikkeling kan koma, asemhalingsonderdrukking, blousug en lae bloeddruk tesame met speldepunt-nie-reagerende kykers. Simptome van oordosering by babas en kinders kan stuipe en hiperpireksie insluit. Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:
'n Soet bruin stroperige vloeistof.

AANBIEDING:
Bottles met 100 ml en 200 ml
HDPE Polycans met 2,5L

BERGINGSINSTRUKSIES:
Bewaar op 'n koel plek benede 25°C, beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS

REGISTRASIENOMMER:
G 1053 (Act 101 of 1965)

NAAM EN BESIGHEIDSADRES VAN DIE APPLIKANT:
GULF DRUG COMPANY
22 BURNSIDE DRIVE
OLD MILL INDUSTRIAL PARK
MOUNT EDGECOMBE
4300

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:
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