ME GRAPHICS

BRAND DESIGN & PRINT

PROOF SHEET

Provisional Proof 2

DATE: 28 April 2015

CLIENT: Ranbaxy Pharmaceuticals (Pty) Ltd

DESCRIPTION: Clear Cough Syrup PI

CODE: 5115454

BARCODE:

SIZE: 120mm(W) x 255mm(H)

DESIGNER: Ashton Buckley

COLOURS USED:

BLACK

PRINT AREA:

DATE: _____ **SIGNATURE:** _____

ENGLISH

120mm

255mm

SCHEDULING STATUS: S2
PROPRIETARY NAME: (and dosage form):

CLEAR COUGH® SYRUP

COMPOSITION:
Each 5 ml of syrup contains:

Diphenhydramine Hydrochloride	14,1 mg
Ammonium Chloride	135,0 mg
Sodium Citrate	55,0 mg
Sugar	1,5 g
Alcohol	0,1 % *v/v*
Preservative: Nipastat	0,02 % *m/v*

PHARMACOLOGICAL CLASSIFICATION:
A 10.1. Antitussives and Expectorants.
PHARMACOLOGICAL ACTION: Has been formulated to alleviate cough.
INDICATION:
The alleviation of cough.
CONTRA-INDICATIONS:
Ammonium Chloride is contra-indicated in the presence of impaired hepatic or renal function. Preparations containing sodium salts should be used cautiously in patients with cardiac failure, hypertension, impaired renal function, peripheral and pulmonary oedema and in toxaemia of pregnancy.
Clear Cough® is not recommended for children under the age of 6 years.
WARNING:
This medicine may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressant agents. Patients should be warned against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration may lead to accidents.
INTERACTIONS:
The anticholinergic effects of atropine and tricyclic antidepressants may be enhanced by diphenhydramine.
Diphenhydramine may mask the warning symptoms of damage caused by ototoxic medicines and may effect the metabolism of other medicines in the liver. It may enhance the sedative affect of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers.
DOSAGE AND DIRECTIONS FOR USE:
A maximum of four doses per day should not be exceeded.
ADULTS: One to two medicine measure (5 - 10 ml) every three to four hours.
CHILDREN 6 to 12 years: Half to one medicine measure (2,5 - 5 ml) every four hours.
SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
The most common side-effect caused by diphenhydramine is sedation which includes drowsiness, inability to concentrate, lassitude, dizziness, hypotension, muscular weakness and inco-ordination. Other side effects include gastro-intestinal disturbances, headache, blurred vision, tinnitus, elation or depression, irritability, nightmares, anorexia, difficulty in micturition, dryness of mouth and tightness of chest, tingling, heaviness and weakness of the hand. Symptoms of stimulation such as insomnia, nervousness, tachycardia, tremors, muscle twitching and convulsions may also occur. Allergic reactions and anaphylaxis may occur. Blood dyscrasias including agranulocytosis and haemolytic anaemia may occur.
Diphenhydramine has anticholinergic properties and should be used with care in conditions such as glaucoma and prostatic hypertrophy. Side-effects that may arise from large doses of ammonium chloride are nausea, vomiting, thirst, headache, hyperventilation, progressive drowsiness, and leads to profound acidosis and hypokalaemia. Large doses of antihistamines may precipitate fits in epileptics.
KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Retention of sodium leads to the accumulation of fluid, with cerebral oedema and peripheral and pulmonary oedema. Symptoms of hypernatraemia may include restlessness, weakness, thirst, reduced salivation and lachrymation, swollen tongue, flushing of the skin, pyrexia, dizziness, headache, oliguria, hypotension, tachycardia, delirium, hyperpnoea and respiratory arrest. Other symptoms of overdosage are gastro-intestinal upset, drowsiness, hypochloraemic acidosis and hypokalaemia. Treatment is symptomatic and supportive.
IDENTIFICATION:
A brown syrupy liquid.
PRESENTATION:
100 ml, 200 ml, 2,5 litres and 25 litres containers.
STORAGE INSTRUCTION: Store in a cool place at or below 25 ^{0}C, protect from light.
KEEP OUT OF REACH OF CHILDREN.
REGISTRATION NUMBER:
W/10.1/367 (S.A.)

(S3) BOT 0500758 (Botswana) (100 ml)
P168/005 (Zambia) (100 ml)
NS1 90/10.1/00372 (Namibia) (100 ml, 200 ml, 2,5 litres)
PMPB/PL4/9 (Malawi) (100 ml, 200 ml, 2,5 litres)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
RANBAXY PHARMACEUTICALS (PTY) LTD.
14 LAUTRE ROAD
STORMILL EXT. 1
ROODEPOORT
1724
SOUTH AFRICA
DATE OF PUBLICATION OF THIS PACKAGE INSERT: 28 FEBRUARY 1990
CODE: 5115454

AFRIKAANS

120mm

255mm

SKEDULERINGSTATUS: S2
EIENDOMSNAAM: (en doseervorm):

CLEAR COUGH® STROOP

SAMESTELLING:
Elke 5 ml stroop bevat:

Difenhidramienhidrochloried	14,1 mg
Ammoniumchloried	135,0 mg
Natriumsitraat	55,0 mg
Suiker	1,5 g
Alkohol	0,1 % *v/v*
Preserveermiddel: Nipastat	0,02 % *m/v*

FARMAKOLOGIESE KLASSIFIKASIE:
A 10.1 Hoesonderdrukkers en slymmiddels.
FARMAKOLOGIESE WERKING: Is geformuleer om hoes te verlig.
INDIKASIES:
Die verligting van hoes.
KONTRA-INDIKASIES:
Ammoniumchloried word teenaangedui in die teenwoordigheid van verswakte lewer of nierfunksie. Preparate wat natriumsoute bevat moet versigtig gebruik word by pasiënte met hartversaking, hipertensie, verswakte nierfunksie, perifere en pulmonale edeem en by swangerskapstoksemie.
Clear Cough® word teenaangewys vir kinders onder die ouderdom van 6 jaar.
WAARSKUWINGS:
Hierdie medisyne kan tot lomerigheid en verswakte konsentrasie lei, wat deur die gelyktydige inname van alkohol of ander sentrale senuweestelselonderdrukkers vererger kan word. Pasiënte moet gewaarsku word om nie beheer te neem van voertuie of masjinerie nie en om nie moontlike gevaarlike take uit te voer waar 'n verlies aan konsentrasie tot ongelukke kan lei nie.
INTERAKSIES:
Die anticholinerge effekte van atropien en trisikliese antidepressante kan verhoog word deur difenhidramien.
Difenhidramien kan die waarskuwingstekens maskeer van skade wat deur ototoksiese medisyne veroorsaak word en dit kan die metabolisme van ander medisyne in die lewer beïnvloed. Dit kan die sederende uitwerking van sentrale senuweestelselonderdrukkers, insluitende alkohol, barbiturate, hipnotika, narkotiese analgetika, kalmeermiddels en susmiddels vergroot.
DOSIS EN GEBRUIKSAANWYSINGS:
'n Maksimum van vier dosisse per dag moet nie oorskry word nie.
VOLWASSENES: Een tot twee medisynemate (5 - 10 ml) elke drie tot vier uur.
KINDERS 6 tot 12 jaar: 'n Halwe tot een medisynemaat (2,5 - 5 ml) elke vier uur.
NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Die algemeenste newe-effekte wat veroorsaak word deur difenhidramien is sedering wat lomerigheid, 'n onvermoë om te konsentreer, lusteloosheid, duiseligheid, hipotensie, spierswakheid en inkoordinasie insluit. Ander newe-effekte sluit in maagdermkanaalsteurnisse, hoofpyn, belemmerde sig, tinnitus, uitgelatenheid of neerslagtigheid, prikkelbaarheid, nagmerries, anoreksie, moeite om te urineer, monddroogheid en benoude bors, 'n prikkelgevoel, swaarheid en swakheid van die hande. Simptome van stimulering soos slaaploosheid, senuagtigheid, tagikardie, tremore, spiertrekkings en konvulsies kan ook voorkom.
Allergiese reaksies en anafilakse kan voorkom. Bloedafwykings, insluitende agranulositose en hemolitiese anemie kan voorkom.
Difenhidramien het anticholinergiese eienskappe en moet versigtig gebruik word by toestande soos gloukoom en prostaathipertrofie. Newe-effekte wat kan voorkom na groot dosisse ammoniumchloried is naarheid, vomering, dors, hoofpyn, hiperventilasie, progressiewe lomerigheid en dit kan lei tot erge asidose en hipokalemie. Groot dosisse antihistamiene kan epileptiese aanvalle teweegbring by epileptikers.
BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Natriumretensie lei tot die ophoping van vloeistof, serebrale edeem, en perifere en pulmonale edeem. Simptome van hipernatremie kan insluit rusteloosheid, swakheid, dors, verlaagde speeksel - en traanafskeiding, geswelde tong, velgloede, pireksie, duiseligheid, hoofpyn, oligurie, hipotensie, tagikardie, delirium, hiperpnee en asemhalingstilstand. Ander simptome van oordosering is maagdermkanaalsteurnisse, lomerigheid, hipochloremiese asidose en hipokalemie. Behandeling is simptomaties en ondersteunend.
IDENTIFIKASIE:
'n Bruin stroperige vloeistof.
AANBIEDING:
100 ml, 200 ml, 2,5 liter en 25 liter houers.
BERGINGSAANWYSINGS:
Bewaar op 'n koel plek, by of benede 25 ^{0}C. Beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS.
REGISTRASIENOMMER:
W/10.1/367(S.A.)

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NAAM EN BESIGHEIDSADRES VAN DIE EIENAAR VAN DIE SERTIFIKAAT VAN REGISTRASIE:
RANBAXY PHARMACEUTICALS (EDMS) BPK.
LAUTREWEG 14
STORMILL UITBR. 1
ROODEPOORT
1724
SUID AFRIKA
DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET: 28 FEBRUARIE 1990
KODE: 5115454