amcough solution

patient information leaflet

SCHEDULING STATUS: S2

COMPOSITION:
Each 5 ml contains:

Diphenhydramine hydrochloride	14 mg
Ammonium chloride	136 mg
Sodium Citrate	56 mg
Preservative: Nipastat	0,02 % *m/v*
Contains Sugar: Sucrose	1,3 g

PHARMACOLOGICAL CLASSIFICATION:
A 10.1 Antitussives and expectorants.

INDICATIONS:
The alleviation of cough.

CONTRAINDICATIONS:
Hypersensitivity to any of the ingredients.
AMCOUGH is contraindicated in the presence of impaired hepatic or renal function and during an attack of asthma. Safety in pregnancy and lactation has not been established.

WARNINGS:
The use of **AMCOUGH** leads to drowsiness and impaired concentration which is aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents. it is unsafe to drive a vehicle or be in charge of machinery while using this medicine, where a loss of concentration could lead to accidents.

DOSAGE AND DIRECTIONS FOR USE:
A maximum of four dosages per day should not be exceeded.

Adults:	One to two medicine measures (5 to 10 ml), every three to four hours.
Children 6 to 12 years:	Half to one medicine measure (2,5 to 5 ml) every four hours.

Should not be given to children under 6 years.

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 incoordination. 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 hands, constipation, diarrhoea, epigastric pain, nausea, vomiting, allergic (hypersensitivity) reactions, epileptiform seizures, euphoria, extrapyramidal effects, haemolytic anaemia, leucopenia and photo- sensitisation of the skin. Symptoms of stimulation such as insomnia, nervousness, tachycardia, tremors, muscle twitching and convulsions may also occur.
AMCOUGH should be used cautiously in patients with cardiac failure, hypertension, impaired renal function, peripheral and pulmonary oedema and toxaemia of pregnancy. it should also be used with caution in patients with cardiovascular disease, glaucoma, liver impairment, prostatic hypertrophy and patients with urinary retention.
Elderly patients are more susceptible to the central nervous system depressant and hypotensive effects.
The posiiive results of skin allergy tests may be suppressed.
Side-effects that may arise from large doses of ammonium chloride are nausea, vomiting, thirst, headache, hyperventilation, progressive drowsiness, mental confusion, hyperchloraemic acidosis and hypokalaemia.
Extreme caution should be exercised by patients taking **AMCOUGH** in conjunction with nervous system depressants such as alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives, tranquilisers, anticholinergic agents and tricyclic antidepressants as their effects may be enhanced by diphenhydramine.
Monoamine-oxidase inhibitors may enhance the anticholinergic effects of diphenhydramine hydrochloride.
The warning signs of damage caused by ototoxic medicines may be masked by diphenhydramine hydrochloride.

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.

Diphenhydramine hydrochloride
Overdosage may be fatal, especially in children in whom main symptoms are central nervous system stimulation and antimuscarinic effects, including ataxia, excitement, hypotension, drowsiness, hallucinations, muscle tremor, convulsions, dilated pupils, dry mouth, flushed face and hyperpyrexia, respiratory collapse, death may occur from respiratory failure.
Treatment is symptomatic and supportive.

IDENTIFICATION:
A clear brown syrupy liquid.

PRESENTATION:
100 ml, 200 ml and 2,5 litre containers.

STORAGE INSTRUCTIONS:
Store below 25°C. Protect from light.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
A 27/10.1/0013

NAME AND BUSINESS ADDRESS OF THE APPLICANT:
Innovata Pharmaceuticals (Pty) Ltd
Crownwood Office Park, Block D,
100 Northern Parkway, Ormonde, Johannesburg, 2091 South Africa

MARKETED BY:
United Pharma Marketing (Pty) Ltd

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amcough solution

pasiëntinligtingsblad

SKEDULERING STATUS: S2

SAMESTELLING:
Elke 5 ml stroop bevat:

Difenhidramienhidrochloried	14 mg
Ammoniumchloried	136 mg
Natriumsitraat	56 mg
Preserveermiddel: Nipastat	0,02 % *m/v*
Bevat Suiker: Sukrose	1,3 g

FARMAKOLOGIESE KLASSIFIKASIE:
A 10.1 Hoesonderdrukkers en ekspektorante.

INDIKASIES:
Die verligting van hoes.

KONTRA-INDIKASIES:
Hipersensitiwiteit tot enige van die bestaandele.
AMCOUGH is teenaangedui in die teenwoordigheid van verswakte lewer of nierfunksie en gedurende 'n asma aanval. Veiligheid in swangerskap en gedurende borsvoeding is nie bevestig nie.

WAARSKUWINGS:
Die gebruik van **AMCOUGH** kan tot lomerigheid en verswakte konsentrasie lei, wat deur die gelyktydige inname van alkohol of ander sentrale senuweestelsel- onderdrukkers vererger kan word. Dit is ook onveilig om 'n voertuig te bestuur, of in beheer van masjiene te wees, waar 'n verlies aan konsentrasie tot ongelukke kan lei.

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.
Moet nie aan kinders onder ses jaar oud toegedien word nie.

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, konstipasie, diaree, epigastriese pyn, naarheid, vomeering, allergiese (hipersensitiwiteit) reaksies, epileptiese aanvalle, uitgelatenheid, extrapirimidale effekte, hemolitiese anemie, leukopenie, en fotosensitiwiteit van die vel.
Simptome van stimulering soos slaaploosheid, senuweeagtigheid, tagikardie, tremore, spiertrekkings en konvulsies kan ook voorkom.
AMCOUGH moet versigtig gebruike word in pasiënte met hartversaking, hipertensie, verswakte nierfunksie, perifêre en pulmonale edeem en by swangerskapstoksemie. Dit moet versigtig gebruik word by pasiënte met hart-kwale, gloukoom, hepatiese benadele, prostaathipertrofie en pasiënte met urinêre retensie.
Bejaarde pasiënte is meer vatbaar aan die sentrale senuweestelsel onderdrukkende en hipotensiewe effekte.
Die positiewe effekte van vel allergiese toetse kan onderdruk word.
Newe-effekte wat kan voorkom na groot dosisse ammoniumchloried, is naarheid, vomering, dors, hoofpyn, hiperventilasie, progressiewe lomerigheid, geestelike verwaring, hiperchloremiese asidose en hipokalemie.
Uiterste versigtigheid moet beoefen word by pasiënte wat **AMCOUGH** gebruik in verbinding met sentrale senuweestelselonderdrukkers soos alkohol, barbiturate, hipnotika, narkotiese analgetika, kalmeermiddels, susmiddels, anticholinergiese middels en trisikliese antidepressante, omdat hulle effekte kan vergroot word deur difenhidramien.
Monoamine-oxidase inhibeerdes mag die anticholinergiese effekte van difenhidramien vergroot.
Die waarskuwingstekens van skade wat deur ototoksiese medisyne veroorsaak kan deur difenhidramien gemaskeerd word.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Natrium retensie lei tot die ophoping van vloeistof, serebrale edeem en perifêre en pulmonale edeem. Simptome van hipernatremie kan rusteloosheid, swakheid, dors, verlaagde speeksel - en traanafskeiding, geswelde tong, velgloede, pireksie, duiseligheid, hoofpyn, oligurie, hipotensie, tagikadie, delirium, hiperpnee en asemhalingstilstand. Ander simptome van oordosering is maagdermkanaalsteurnisse, lomerigheid, hipochloremieseasidose en hipokalemie.

Difenhidramienhidrochloried
Oordosering mag dodelik wees, besonderd in kinders waar die hoof simptome, sentralsenuwestelsel stimulasie en antimuskariniese effekte, ingesluit en ataxia, opwinding, hipotensie, lomerigheid, sinsbedrog, spiertremore, konvulsies, dilateerde pupil, droë mond, velgloed en hiperpireksie, asemhalingsstilstand kan tot die dood veroorsaak.
Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:
'n Helder bruin stroperige vloeistof.

AANBIEDING:
100 ml, 200 ml en 2,5 liter houers.

BERGINGSAANWYSINGS:
Bêre benede 25ºC. Beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIE NOMMER:
A 27/10.1/0013

NAAM EN BESIGHEIDSADRES VAN DIE APPLIKANT:
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BEMARK DEUR:
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