PACKAGE INSERT

SCHEDULING STATUS: S0

PROPRIETARY NAME AND DOSAGE FORM: GO-KOFF COUGH MIXTURE (Liquid)

COMPOSITION:

Each 5 ml liquid contains:

Ammonium chloride	137 mg
Contains Sugar: Caramel	37,30 mg
Invert sugar	2,50 ml
Ethanol 96 %	9,04 % *v/v*
Preservative: Sodium benzoate	0,2 % *m/v*

Excipients: Caramel, caraway oil, chloroform, ethanol 96 %, glycerol, invert sugar, purified water, sodium benzoate, sodium citrate

CATEGORY AND CLASS: A 10.1 Antitussives and expectorants

INDICATIONS: For the alleviation of cough.

CONTRAINDICATIONS:

Go-Koff Cough Mixture is contraindicated in patients who have impaired hepatic or renal function and hypersensitivity to any of the ingredients.

Safety in pregnancy and lactation has not been established (see Human Reproduction)

WARNINGS AND SPECIAL PRECAUTIONS:

Do not exceed the recommended dosage unless prescribed by a doctor.

Use with caution in patients with heart disease.

Contains caramel and invert sugar which may have an effect on the glycaemic control of patients with diabetes mellitus.

HUMAN REPRODUCTION: Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Adults and children over 12 years: 10 ml (2 medicine measures) four times a day, with an adequate amount of water (half to one glass).

SIDE EFFECTS:

Ammonium salts are irritant to the gastric mucosa and may produce nausea and vomiting, acidosis and hypokalemia.

Sodium citrate should be administered cautiously to patients with heart failure, oedema, renal impairment, hypertension and aldosteronism.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS:

Large doses of ammonium chloride may cause gastric irritation, a profound acidosis and hypokalemia. These should be treated symptomatically. If the capacity of the liver to convert ammonium ions to urea is exceeded, hepatic encephalopathy may ensue. Excessive doses of sodium salts may lead to sodium overloading and hyperosmolality. General adverse effects of excess sodium in the body include nausea, vomiting, diarrhoea, abdominal cramps, thirst, reduced salivation and lachrymation, sweating, fever, tachycardia, hypertension, renal failure, peripheral and pulmonary oedema, respiratory arrest, headache, dizziness, restlessness, irritability, weakness, muscular twitching and rigidity, convulsions, coma and death. Treatment involves emesis or gastric lavage and is otherwise symptomatic and supportive.

IDENTIFICATION:

A dark brown to black clear liquid with an aromatic odour and a sweetish taste.

PRESENTATION:

100 ml PVC clear flat bottles with white snap-on caps.

STORAGE INSTRUCTIONS:

Store in a cool, dry place at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

G1049 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THECERTIFICATE OF REGISTRATION:

Avid Brands S.A. (Pty) Ltd
Suite 9, Hillcrest Office Park
2 Old Main Road, Hillcrest, 3610

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION: 25 May 1995

SKEDULERINGSTATUS: S0

EIENDOMSNAAM EN DOSEERVORM: GO-KOFF COUGH MIXTURE (Vloeistof)

SAMESTELLING:

Elke 5 ml vloeistof bevat:

Ammoniumchloried	137 mg
Bevat Suiker: Karamel	37,30 mg
Inverssuiker	2,50 ml
Etanol 96 %	9,04 % *v/v*
Preserveermiddel: Natriumbensoaat	0,2 % *m/m*

Onaktiewe bestanddele: Karamel, karwy-olie, chloroform, etanol 96 %, gliserol, inverssuiker, gesuiwerde water, natriumbensoaat, natriumsitraat.

KATEGORIE EN KLAS: A 10. 1 Hoesonderdrukkers en ekspektorante

INDIKASIES: Vir die verligtig van hoes.

KONTRA INDIKASIES:

Go-Koff Cough Mixture is teenaangedui by pasiënte met ingekorte lewer of nierfunksie, en met hipersensitiwiteit vir enige van die bestanddele.

Veiligheid tydens swangerskap en laktasie is nog nie vasgestel nie (sien Menslike Reproduksie).

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:

Moenie die aanbevole dosis oorskry nie, tensy voorgeskryf deur 'n dokter.

Gebruik met omsig by pasiënte met hartsiekte.

Bevat karamel en inverssuiker, wat 'n effek op die glisemiese beheer van pasiënte met diabetes mellitus kan hê.

MENSLIKE REPRODUKSIE: Veiligheid tydens swangerskap en met laktasie is nog nie vasgestel nie.

DOSIS EN GEBRUIKSAANWYSINGS:

Volwassenes en kinders bo 12 jarige ouderdom: 10 ml (2 medisynemate) vier keer 'n dag, met 'n voldoende hoeveelheid water ('n half tot een glas).

NEWE EFFEKTE:

Ammoniumsoute irriteer die gastriese mukosa en kan naarheid en braking-, asidose-, en hipokalemie veroorsaak.

Natriumsitraat moet met omsigtigheid toegedien word aan pasiënte met hartversaking, edeem, nierinkorting, hipertensie en aldosteronisme.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Groot dosisse van ammoniumchloried kan gastriese irritasie en aansienlike asidose en hipokalemie veroorsaak. Dit moet simptomaties behandel word. Indien die kapasiteit van die lewer om ammoniumione om te skakel na ureum oorskry word, kan hepatiese enkefalopatie ontstaan. Oormatige dosisse van natriumsoute kan lei tot natriumoorlading en hiperosmolaliteit. Algemene newe effekte van oormatige natrium in die liggaam sluit in naarheid, braking, diarree, maagkrampe, dorsheid, afname in salivasie en lakrimasie, sweet, koors, tagikardie, hipertensie, nierversaking, perifere en pulmonêre edeem, respiratoriese arres, hoofpyn, duiseligheid, rustelooosheid, irriteerbaarheid, swakheid, spiertrekkings en rigiditeit, konvulsies, koma en die dood. Behandeling sluit in emese of gastriese spoeling, en is andersins simptomaties en ondersteunend.

IDENTIFIKASIE:

'n Donkerbruin tot swart helder vloeistof met 'n aromatiese reuk en 'n soeterige smaak.

AANBIEDING: 100 ml PVC helder plat bottels met wit aan-klik doppe.

BERGINGSINSTRUKSIES:

Berg op 'n koel, droë plek by of benede 25 °C.

HOU BUITE DIE BEREIK VAN KINDERS.

REGISTRASIENOMMER: G1049 (Act 101/1965)

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:

Avid Brands S.A. (Edms) Bpk
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