A: S/10.2/126

200ml

S2 NUELIN LIQUID

A10.2 Bronchodilator/brongodilator

CUT ALONG DOTTED LINE

ZIMBABWE
Scheduling status:
Prescription preparation (PP10)
Pharmacological classification:
22.1.1 Systemic bronchodilators
Registration number:
98/22.1.1/3446

NAMIBIA
Scheduling status: NS1
Registration Number: 04/10.2/0957

Farmakologiese werking
Teofillien is 'n gemetileerde xantien en is dus verwant aan kaffeien en teo-bromien. Die farmakologiese werking van teofillien veroorsaak verslapping van gladde spiere.

Indikasies
NUELIN LIQUID word aangedui vir die instandhoudings-behandeling van brongospasma by asmatiese kinders.

Kontra-indikasies
Met die uitsondering van hipersensitiwiteit vir teofillien is daar geen bekende kontra-indikasie vir die gebruik van **NUELIN LIQUID** nie.

Waarskuwings en speciale vorgsorgmaatreels
Bevat sukrose wat 'n effek op die glukemiese beheer van pasiënte met diabetes mellitus mag hê.
Pasiënte met seldsame oorerflike toestande soos fruktose intoleransie, glukose-galaktose wanabsorpsie of sukrase-isomaltase ontoereikendheid moenie **NUELIN LIQUID** neem nie.
Pasiënte met die seldsame oorerflike toestand van sorbitol / maltitol / lactitol intoleransie moenie **NUELIN LIQUID** neem nie.
Teofillien moet nie toegedien word aan kinders jonger as twee jaar nie, aangesien hulle nie teofillien voldoende kan metabiliseer nie. Nadat hulle **NUELIN LIQUID** geneem het moet pasiënte hul monde sorgvuldig uitspoel met baie water. **NUELIN LIQUID** is nie geskik vir kinders met diabetes mellitus nie.

Wisselwerkings
Die gebruik van simpatomimetiese aerosols moet vermy word by pasiënte wat met **NUELIN LIQUID** behandel word aangesien dit aanleiding kan gee tot 'n verhoging van newe-effekte.
'n Verlaging van die dosis van mondelinge teofillien word aanbeveel gedurende gelyktydige simetidienterapie. Simetidien verlaag opruiming van teofillien wat kan lei tot toksiese plasmavlakke.

Swangerskap en laktasie:
Veiligheid gedurende swangerskap is nog nie bepaal nie.

Dosis en Gebruiksaanwysings
2-8 jaar:
24 mg/kg per 24 uur, toegedien in 4 verdeelde dosisse, dws elke 6 ure
9-12 jaar:
20 mg/kg per 24 uur, toegedien in 4 verdeelde dosisse, dws elke 6 ure
13-16 jaar:
18 mg/kg per 24 uur, toegedien in 4 verdeelde dosisse, dws elke 6 ure

Newe-effekte
Newe-effekte hou verband met teofillienplasmavlakke: naarheid en braking, prikkeling, senuagtigheid en slaaploosheid kom voor met plasmakonsen-trasies van 20 tot 30 mg/l, histerie met 30 mg/l, kardiale aritmieë en koma met konsentrasies van hoër as 40 mg/l. Hierdie toksiese verskynsels word verhoog deur hipoksie en asidose. Die behandeling van toksiese effekte is simptomaties: (tydelik al dan nie) staking van teofillientoediening, herstel van die asidose of hipoksie, en sorgvuldige toesig oor enige terapeutiese toe-trede wat onderliggende hart - of longaandoenings kan vererger, soos oor-lading met water en sout, suurstof, kalmeermiddels, braakteenmiddels en betablokkers.

Bekende simptome van oordosering en besonderhede van die behandeling daarvan
Simptome:
Gekenmerk deur naarheid, braking en irritasie van die maagdermkanaal. Tagi kardie en hipotensie kan voorkom.
Behandeling:
Maagspoeling en algemene onder steunende maatreëls word aanbeveel.

Identifikasie
NUELIN LIQUID is 'n helder, kleurlose tot naas-kleurlose, stroopagtige vloeistof met 'n kenmerkende reuk en smaak.

Aanbieding
NUELIN LIQUID is beskikbaar in 200 ml en 500 ml bottels.

Bergingsaanwysings
NUELIN LIQUID moet teen of benede 25°C gehou word en teen lig beskerm word. Hou buite die bereik van kinders.

Registrasienommer
S/10.2/126

Naam en besigheidsadres van die houer van die sertifikaat van registrasie
iNova Pharmaceuticals (Pty) Ltd.
Rileyweg 15e, Bedfordview,
Suid-Afrika.

Datum van publikasie van hierdie voubiljet
22 September 1986

Scheduling status [S2]

Proprietary name and dosage form
NUELIN LIQUID, liquid

Composition
Each 5 ml Liquid contains:
Theophylline 25 mg
Preservatives:
Methyl hydroxybenzoate 0,2%
Propyl hydroxybenzoate 0,03%

Other ingredients include: Berry citrus blend, purified water, sorbitol 70 % solution and sucrose.
Contains sugar (sucrose)

Pharmacological classification
A.10.2 Bronchodilators

Pharmacological action
Theophylline is a methylated xanthine and is therefore related to caffeine and theobromine. The pharmacological action of theophylline results in the relaxation of smooth muscle.

Indications
NUELIN LIQUID is indicated for maintenance treatment of bronchospasm in asthmatic children.

Contra-indications
With the exception of hypersensitivity to theophylline, there are no known contra-indications to the use of **NUELIN LIQUID**.

Warnings and special precautions
Contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.
Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase in-sufficiency should not take **NUELIN LIQUID**.
Patients with the rare hereditary condition of sorbitol / maltitol / lactitol intolerance should not take **NUELIN LIQUID**.
Theophylline should not be administered to children younger than two years of age, as they cannot metabolize theophylline sufficiently.
After taking **NUELIN LIQUID**, patients should carefully rinse out their mouths with plenty of water. **NUELIN LIQUID** is unsuitable for children suffering from diabetes mellitus.

Interactions:
The use of sympathomimetic aerosols should be avoided in patients being treated with **NUELIN LIQUID**, as this could lead to an increase in side effects.
A reduction in the dose of oral theophylline is recommended during concurrent cimetidine therapy. Cimetidine delays theophylline clearance which could give rise to toxic plasma levels.

Pregnancy and Lactation:
Safety in pregnancy has not been established.

Dosage and directions for use
2-8 years:
24 mg/kg per 24 hours, given in 4 divided doses, ie every 6 hours
9-12 years:
20 mg/kg per 24 hours, given in 4 divided doses, ie every 6 hours
13-16 years:
18 mg/kg per 24 hours, given in 4 divided doses, ie every 6 hours

Side effects
Side-effects are related to theophylline plasma levels: nausea and vomiting, excitation, nervousness and insomnia occur at plasma concentrations of 20 to 30 mg/l, hysteria at 30 mg/l, cardiac arrhythmias and coma at concentrations greater than 40 mg/l. These toxic phenomena are enhanced by hypoxia and acidosis. The treatment of toxic effects is symptomatic: (whether or not temporary) discontinuance of the administration of theophylline, correction of the acidosis and hypoxia, and careful supervision of any therapeutic intervention that may aggravate underlying heart or lung diseases, such as overloading with water and salt, oxygen, sedatives, anti-emetics and beta blockers.

Known symptoms of overdosage and particulars of its treatment
Symptoms:
Characterised by nausea, vomiting and gastro-intestinal irritation. Tachycardia and hypotension may occur.
Treatment:
Gastric lavage and general supportive measures are recommended.

Identification
NUELIN LIQUID is a clear, colourless to almost colourless, syrupy liquid with a characteristic odour and taste.

Presentation
NUELIN LIQUID is available in bottles of 200 ml and 500 ml.

Storage instructions
NUELIN LIQUID should be stored at or below 25 °C, and be protected from light.
KEEP OUT OF REACH OF CHILDREN

Registration number
S/10.2/126

Name and business address of the holder of the certificate of registration
iNova Pharmaceuticals (Pty) Ltd
15e Riley Road
Bedfordview
South Africa

Date of publication of the package insert
22 September 1986

ZIMBABWE
Scheduling status:
Prescription preparation (PP10)
Pharmacological classification:
22.1.1 Systemic bronchodilators
Registration number:
98/22.1.1/3446

NAMIBIA
Scheduling status: NS1
Registration Number: 04/10.2/0957

Skeduleringstatus [S2]

Eiendomsnaam en doseervorm
NUELIN LIQUID, vloeistof

Samestelling
Elke 5 ml Vloeistof bevat:
Teofillien 25 mg
Preserveermiddel:
Metielhidroksibensoaat 0.2%
Propielhidroksibensoaat 0.03%

Ander onaktiwe bestandele: Bessie sitrus mengsel, gesuiwerde water, sorbitol 70% oplossing en sukrose.
Bevat suiker (sukrose).

Farmakologiese klassifikasie
A.10.2 (Brongodilators)