SKEDULERINGSTATUS S2

NS1 (Namibië)

EIENDOMSNAAM (EN DOSEERVORM)

Coryx Pediatriese Stroop

SAMESTELLING

Elke 5 ml bevat:

Triprolidienhidrochloried	1,25 mg
Pseudoefedrien-hidrochloried	25,00 mg
Vitamien C	75,00 mg

Preserveermiddels:

Natriumbensoaat	0,2 % *m/v*
Kaliumsorbaat	0,2 % *m/v*

FARMAKOLOGIESE KLASSIFIKASIE

A.5.8 Verkouemiddels, insluitende neusontstoppingsmiddels en antihistaminika.

FARMAKOLOGIESE WERKING

CORYX PEDIATRIESE STROOP het antihistaminiese en dekongestiewe eienskappe.

INDIKASIES

CORYX PEDIATRIESE STROOP is aangedui vir die behandeling van simptome wat gepaard gaan met verkoue en griep, soos neuskongestie.

KONTRA-INDIKASIES

Bekende hipersensitiwiteit of onverdraagsaamheid vir enige van die bestanddele.
CORYX PEDIATRIESE STROOP is teenaangedui by pasiënte wat tans, of binne die voorafgaande twee weke, behandeling met monoamienoksidase inhibeerders ontvang het.
Die veiligheid van CORYX PEDIATRIESE STROOP tydens swangerskap en laktasie is nog nie vasgestel nie.
CORYX PEDIATRIESE STROOP moet nie toegedien word aan kinders onder die ouderdom van 2 jaar nie.

WAARSKUWINGS

Die gebruik van CORYX PEDIATRIESE STROOP kan tot lomerigheid lei wat deur die gelyktydige inname van alkohol of ander sentrale senuweestelsel onderdrukkers vererger kan word. Pasiënte behoort gewaarsku te word om nie te bestuur of gevaarlike masjinerie te beheer nie. Gebruik met sorg by pasiënte met kardiovaskulêre siektes soos iskemiese hart siekte, aritmie of tagikardie, okklusiewe vaskulêre versteurings, insluitende arteriosklerose, hipotensie of aneurismes.

DOSIS EN GEBRUIKSAANWYSINGS

Volwassenes en kinders ouer as 12 jaar:	2 medisynemate (10,0 ml) drie maal per dag
Kinders van 6 tot 12 jaar:	1 medisynemaat (5,0 ml) drie maal per dag
Kinders van 2 tot 5 jaar:	½ medisynemaat (2,5 ml) drie maal per dag
Kinders jonger as 2 jaar*:	Nie aanbeveel nie

*'n Geneesheer moet geraadpleeg word voordat CORYX PEDIATRIESE STROOP aand kinders jonger as 2 jaar gegee word. Moet nie die voorgeskrewe dosis oorskry nie en raadpleeg u geneesheer indien simptome voortduur.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS

Pseudoefedrien-hidrochloried:

Sentrale effekte van pseudoefedrien sluit vrees, angstigheid, rusteloosheid, bewing, slapeloosheid, verwarring, prikkelbaarheid, swakheid en psigotiese toestande in. Eetlus kan verminder word en naarheid en braking kan voorkom. Anginapyn kan ontketen word by pasiënte met angina pektoris. Pseudoefedrien veroorsaak vasokonstriksie wat 'n gevolglike styging in bloeddruk en moontlike serebrale bloeding en pulmonêre edeem tot gevolg kan hê. Pseudoefedrien kan ook tagikardie, kardiale aritmieë, anginapyn, hartkloppings, hartstilstand, hipotensie met duiseligheid en floutes en blosing veroorsaak.

'n Verhoogde risiko van aritmieë kan voorkom indien dit aan pasiënte wat hartglikosiede, kinidien of trisikliese antidepressante neem, gegee word.

Gebruik met sorg wanneer pseudoefedrien toegedien word aan pasiënte met hipertiroïdisme, diabetes mellitus, toehoek gloukoom of prostaat vergroting. Wees versigtig indien ernstige nier of lewer inkorting voorkom. Simptome van sentrale senuweestelsel stimulering kan voorkom, insluitend slaapversteurings en hallusinasies. Urienretensie is gerapporteer by mans wat pseudoefedrien ontvang. Moeite met mikturisie kan ook ondervind word. Dispnee, veranderde metabolisme, insluitend stoornisse van glukose metabolisme, sweet en hipersalivering is moontlik. Hoofpyn is ook algemeen.

Pseudoefedrien moet vermy word of met oorleg gebruik word by pasiënte wat narkose met siklopropaan, halotaan of ander gehalogeneerde narkotika ondergaan omdat dit ventrikulêre fibrillasie kan induseer.

Triprolidien:

Triprolidien is 'n antihistamien en kan sedering veroorsaak wat wissel van ligte lomerigheid tot diep slaap, en sluit lusteloosheid, duiseligheid en wankoördinasie in. Verswakte visie, disurie, droogheid van die mond en benoude bors kan voorkom. Gastro-intestinale stoornisse soos naarheid, braking, diarree of hardlywigheid, epigastriese pyn, anoreksie of verhoogde eetlus kan voorkom. Ander sentrale effekte kan hipotensie, spierswakheid, tinnitus, euforie en hoofpyn insluit. Teenstrydige sentrale senuweestelsel stimulasie kan veral in kinders voorkom, met slapeloosheid, senuagtigheid, tagikardie, bewings en konvulsies. Allergiese reaksies en kruis-sensitiwiteit teenoor verwante medisyne is moontlik met sistemiese triprolidien toediening. Bloedafwykings insluitend agranulositose, leukopenie, trombositopenie en hemolitiese bloedarmoede is al aangemeld. Gebruik met sorg as trisikliese antidepressante, guanetidien, reserpien, metieldopa of atropien gelyktydig geneem word, omdat die antimuskariniese effek versterk kan word.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Verwys na "NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS".

Oordosering mag fataal wees, veral in kinders by wie die hoofsimptome sentrale senuweestelsel stimulasie en antimuskariniese effekte is: ataksie, opwinding, hallusinasies, spiertremore, konvulsies, gedilateerde pupille, droë mond en blosing en hiperpireksie. Verdiepte koma, kardiorespiratoriese ineenstorting en die dood kan binne 18 uur intree. In volwassenes is die gewone simptome van oordosering lomerigheid, koma en konvulsies. Swakheid, duiseligheid, wankoördinasie, moeite met urinering, respiratoriese depressie, hipotensie, agitasie, prikkelbaarheid, hipertensie, hartkloppings, rusteloosheid en tagikardie kan voorkom.

Behandeling is simptomaties en ondersteunend – die pasiënt moet onmiddellik na 'n dokter of hospitaal geneem word omdat gespesialiseerde behandeling nodig mag wees.

IDENTIFIKASIE

'n Helder blou stroop met 'n swartbessie reuk, smaak en geur.

AANBIEDING

Bruin glasbottels van 100 ml.

BERGINGSAANWYSINGS

Bewaar benede 25 °C in 'n dig geslote houer.
Beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER

31/5.8/0056
04/17.5.8/1652 (Namibië)

NAAM EN BESIGHEIDSADRES VAN DIE APPLIKANT

Mirren (Edms) Bpk
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SCHEDULING STATUS S2

NS1 (Namibia)

PROPRIETARY NAME (AND DOSAGE FORM)

Coryx Paediatric Syrup

COMPOSITION

Each 5 ml contains:

Triprolidine hydrochloride	1,25 mg
Pseudoephedrine hydrochloride	25,00 mg
Vitamin C	75,00 mg

Preservatives:

Sodium benzoate	0,2 % *m/v*
Potassium sorbate	0,2 % *m/v*

PHARMACOLOGICAL CLASSIFICATION

A.5.8 Preparations for the common cold including nasal decongestants and antihistaminics.

PHARMACOLOGICAL ACTION

CORYX PAEDIATRIC SYRUP has antihistaminic and decongestant properties.

INDICATIONS

CORYX PAEDIATRIC SYRUP is indicated for the relief of symptoms associated with colds and influenza, such as nasal congestion.

CONTRA-INDICATIONS

Known hypersensitivity or intolerance to any of the ingredients.

CORYX PAEDIATRIC SYRUP is contra-indicated in patients who are taking or have taken monoamine oxidase inhibitors within the preceding two weeks.

The safety of CORYX PAEDIATRIC SYRUP during pregnancy and lactation has not been established.

CORYX PAEDIATRIC SYRUP should not be administered to infants under the age of 2 years.

WARNINGS

The use of CORYX PAEDIATRIC SYRUP may lead to drowsiness which is aggravated by the simultaneous intake of alcohol or other central nervous system depressants. Patients should be warned not to drive or operate dangerous machinery. Great care is needed in patients with cardiovascular disease such as ischaemic heart disease, arrhythmia or tachycardia, occlusive vascular disorders, including arteriosclerosis, hypertension or aneurysms.

DOSAGE AND DIRECTIONS FOR USE

Adults and children over 12 years:	2 medicine measures (10,0 ml) three times a day
Children 6 to 12 years:	1 medicine measure (5,0 ml) three times a day
Children 2 to 5 years:	½ medicine measure (2,5 ml) three times a day
Children younger than 2 years*:	Not recommended

*A doctor's advice should be obtained before administering CORYX PAEDIATRIC SYRUP to children aged less than 2 years. Do not exceed the stated dose and if symptoms persist consult a doctor.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS

Pseudoephedrine hydrochloride:

Central effects of pseudoephedrine include fear, anxiety, restlessness, tremor, insomnia, confusion, irritability, weakness and psychotic states. Appetite may be reduced and nausea and vomiting may occur. Anginal pain may be precipitated in patients with angina pectoris. Pseudoephedrine causes vasoconstriction which may lead to a resultant rise in blood pressure and possibly to cerebral haemorrhage or pulmonary oedema. Pseudoephedrine may also produce tachycardia, cardiac arrhythmias, anginal pain, palpitations, cardiac arrest, hypotension with dizziness and fainting and flushing.

An increased risk of arrhythmias may occur when given to patients receiving cardiac glycosides, quinidine or tricyclic antidepressants.

Care is required when pseudoephedrine is given to patients with hyperthyroidism, diabetes mellitus, closed-angle glaucoma or prostatic enlargement. Caution should be exercised in the presence of severe renal or hepatic impairment. Symptoms of central nervous system excitation may occur, including sleep disturbances and hallucinations. Urinary retention has been reported in men receiving pseudoephedrine. Difficulty with micturition may also be experienced. Dyspnoea, altered metabolism including disturbances of glucose metabolism, sweating and hypersalivation are possible. Headaches are also common.

Pseudoephedrine should be avoided or used with caution in patients undergoing anaesthesia with cyclopropane, halothane, or other halogenated anaesthetics, as they may induce ventricular fibrillation.

Triprolidine:

Triprolidine is an antihistamine and may cause sedation, varying from slight drowsiness to deep sleep, and including lassitude, dizziness and incoordination. Blurred vision, dysuria, dryness of the mouth and tightness of the chest may occur. Gastrointestinal disturbances such as nausea, vomiting, diarrhoea or constipation, epigastric pain, anorexia or appetite increase may occur. Other central effects may include hypotension, muscular weakness, tinnitus, euphoria and headache. Paradoxical central nervous system stimulation may occur particularly in children, with insomnia, nervousness, tachycardia, tremors and convulsions. Allergic reactions and cross-sensitivity to related medicines are possible with systemic triprolidine administration. Blood disorders including agranulocytosis, leucopaenia, thrombocytopaenia and haemolytic anaemia have been reported. Care should be observed when tricyclic antidepressants, guanethidine, reserpine, methyldopa or atropine are taken concomitantly, as the anti-muscarinic effect may be enhanced.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See "SIDE-EFFECTS AND SPECIAL PRECAUTIONS".

Overdosage may be fatal, especially in children in whom the main symptoms are central nervous system stimulation and anti-muscarinic effects: ataxia, excitement, hallucinations, muscle tremor, convulsions, dilated pupils, dry mouth, flushed face and hyperpyrexia. Deepening coma, cardio-respiratory collapse and death may occur within 18 hours. In adults, the usual symptoms of overdosage are drowsiness, coma and convulsions. Weakness, dizziness, incoordination, difficulty with micturition, respiratory depression, hypotension, agitation, irritability, hypertension, palpitations, restlessness and tachycardia may occur.

Treatment is symptomatic and supportive - the patient must be taken to a doctor or hospital immediately as specialised treatment may be necessary.

IDENTIFICATION

A clear blue coloured syrup with a blackcurrant smell and taste.

PRESENTATION

Amber glass bottles of 100 ml.

STORAGE INSTRUCTIONS

Store below 25 °C in a well-closed container.
Protect from light.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

31/5.8/0056
04/17.5.8/1652 (Namibia)

NAME AND BUSINESS ADDRESS OF THE APPLICANT

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