BRUNACOD

PROFESSIONAL INFORMATION

SCHEDULING STATUS
S2

PROPRIETARY NAME (AND DOSAGE FORM)
BRUNACOD, Syrup

COMPOSITION
Each 5 mℓ syrup contains:

Promethazine hydrochloride	3,0 mg
Ephedrine hydrochloride	7,0 mg
Codeine phosphate	9,2 mg
Contains sugar	3,76 g/5 mℓ

Preservatives:

Methylhydroxybenzoate	0,1 % *m/v*
Propyl hydroxybenzoate	0,01 % *m/v*
Alcohol	5,0 % *v/v*

PHARMACOLOGICAL CLASSIFICATION
A10.1 Antitussives and expectorants

INDICATIONS
For the alleviation of cough.

CONTRA-INDICATIONS
Hypersensitivity to any of the ingredients.
Respiratory depression, acute alcoholism, diabetes, head injuries or raised intracranial pressure.
Acute asthma, emphysema or heart failure secondary to chronic lung disease.
Severe hypertension.
Should not be taken simultaneously with mono-amino oxidase inhibitors or within 14 days of stopping such treatment.
Safety for use in pregnancy has not been established.
Should not be given to premature infants or neonates under two years, as promethazine has been associated with the sudden infant death syndrome.
Not recommended in lactation.

WARNINGS AND SPECIAL PRECAUTIONS
This medicine may cause marked sedation, drowsiness and impaired concentration which may be aggravated by the simultaneous intake of alcohol, or any other central nervous system depressant agents.
Patients should be warned not to drive a motor vehicle, operate dangerous machinery or climb dangerous heights, as impaired decision making could lead to accidents.
Exceeding the prescribed dose together with prolonged and continuous use of this medication may lead to dependence.
NOT FOR USE IN ASTHMA, EMPHYSEMA OR CHRONIC BRONCHITIS.
Promethazine hydrochloride should be used with care in patients with cardiovascular and hepatic diseases, narrow angle glaucoma, pyloroduodenal obstruction, urinary retention and prostatic hypertrophy. Promethazine may potentiate the hypotensive effect of some anti-hypertensives.
Ephedrine hydrochloride should be used with care in patients with hyperthyroidism, *diabetes mellitus* or closed-angle glaucoma, cardiovascular disease, hypertension, occlusive vascular disorders, and aneurisms. Anginal pain may be precipitated in patients with angina pectoris.
Codeine phosphate should be given with caution or in reduced doses to patients with hypothyroidism, adrenocortical insufficiency, impaired kidney or liver function, prostatic hypertrophy or shock. Patients with obstructive bowel disorders and myasthenia gravis also need to be cautious when taking codeine phosphate.

INTERACTIONS
Avoid or use with caution in patients undergoing anaesthesia with cyclopropane, halothane, or other halogenated anaesthetics, as they may induce ventricular fibrillation. An increase of arrhythmias may occur in patients receiving cardiac glycosides, quinidine, or tricyclic antidepressants. Complex interactions occur with alpha- and beta-blocking drugs. Codeine may delay the absorption of other medicines.
Promethazine may potentiate the action of sedatives and tranquillisers. False negative or positive pregnancy test results have been reported with promethazine. Antihistamines may suppress positive skin test results and should be stopped several days before the test.
MAO inhibitors: See "**WARNINGS AND SPECIAL PRECAUTIONS**". Sedative effects are enhanced by alcohol, anaesthetics, hypnotics and sedatives, tricyclic antidepressants, and phenothiazines.

PREGNANCY AND LACTATION
Safe use in pregnancy has not been established. Should not be given to premature infants or neonates under two years, as promethazine has been associated with the sudden infant death syndrome.
Not recommended in lactation.

DOSAGE AND DIRECTIONS FOR USE
Adults: 5 mℓ to 10 mℓ three times a day.
Not recommended for children.
Shake bottle before use.

SIDE-EFFECTS
Promethazine hydrochloride
The most common side-effect is sedation, drowsiness, including lassitude, dizziness and incoordination. Other side effects include gastro-intestinal disturbances such as nausea, vomiting, diarrhoea or constipation, anorexia or increased appetite and epigastric pain. Thickened respiratory tract secretion, blurred vision, difficulty in micturition, dysuria, dryness of the mouth, tightness of the chest, hypotension, bradycardia, tachycardia, transient minor hypertension, muscular weakness, tinnitus, euphoria, photosensitivity, jaundice, thrombocytopenia, purpura, skin rash, angioedema and occasionally headache may also occur. Paradoxical central nervous system stimulation may occur, especially in children. Agranulocytosis, leucopenia and hemolytic anaemia have been reported, though rare.
Ephedrine hydrochloride
Side-effects may include fear, anxiety, restlessness, tremors, insomnia, confusion, irritability, weakness, psychotic states, decrease in appetite, nausea and vomiting. Vasoconstriction with resultant hypertension, reflex bradycardia, tachycardia, cardiac arrhythmia, anginal pain, palpitations, cardiac arrest, hypotension with dizziness and fainting and flushing have also been reported. Anginal pain may be precipitated in patients with angina pectoris. Jaundice and blood dyscrasias have been reported and extrapyramidal effects at high doses. Other effects that may occur with sympathomimetic agents include difficulty in micturition and urinary retention, dyspnea, altered metabolism including disturbances of glucose metabolism, sweating and hyper salivation. Headache is also common.
Codeine phosphate
The most common side effects are nausea, vomiting, constipation, drowsiness and confusion. Difficulty in micturition, urethral or biliary spasm, antidiuretic effect, dry mouth, sweating, facial flushing, pruritus and urticaria, vertigo, bradycardia, palpitations, orthostatic hypotension, hypothermia. Restlessness, changes of mood and meiosis may also occur. Raised intracranial pressure, euphoria, urticaria and pruritus occur in some patients. Psychological and physical dependence may occur with repeated use, and withdrawal symptoms appear upon discontinuation after long term misuse.

KNOWN SYMPTOMS OF OVER-DOSAGE AND PARTICULARS OF ITS TREATMENT
Overdose may be fatal, especially in children. In the event of an overdose, immediate attention should be given to maintaining adequate respiration.
Drowsiness to deep sleep, dizziness, muscular weakness and incoordination may occur. In infants and children the antihistamines often act as cerebral stimulant and may cause hyperpyrexia and convulsions.
Large doses of ephedrine may cause excitation, vomiting, nausea, tachycardia, extrasystoles, convulsions, respiratory depression, hypertension, circulatory failure and deepening coma may occur.
Codeine phosphate: Constipation, respiratory depression, histamine release, pinpoint pupils, hypotension and hypothermia, excitement and convulsions, especially in children, and non-cardiogenic pulmonary oedema occur.
In the event of overdosage the stomach should be emptied by aspiration and lavage. Activated charcoal and laxative may also be used.
Intensive supportive therapy may be required to treat respiratory failure and shock. Naloxone hydrochloride is used as an antagonist to codeine phosphate in dosages of 0,4 mg to 2 mg intravenously which may be treated at intervals of 2 to 3 minutes if necessary, up to 10 mg.

IDENTIFICATION
Pale amber clear liquid with a blackcurrant odour and taste.

PRESENTATION
100 mℓ, 200 mℓ and 2,5 litre amber bottles.

STORAGE INSTRUCTIONS
Store at or below 25 ºC. Protect from light and moisture. Keep bottle tightly closed.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
G 1064 (Act 101/1965)

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A5820

BRUNACOD

PROFESSIONELE INLIGTING

SKEDULERINGSTATUS
S2

EIENDOMSNAAM (EN DOSEERVORM)
BRUNACOD, Stroop

SAMESTELLING

Elke 5 mℓ stroop bevat:	
Prometasienhidrochloried	3,0 mg
Efedrienhidrochloried	7,0 mg
Kodeïenfosfaat	9,2 mg
Bevat suiker	3,76 g/5 mℓ
Preserveermiddels:	
Metielhidroksiebensoaat	0,1 % *m/v*
Propielhidroksiebensoaat	0,01 % *m/v*
Totale alkoholinhoud	5,0 % *v/v*

FARMAKOLOGIESE KLASSIFIKASIE
A.10.1 Hoesmiddels en ekspektorante

INDIKASIES
Vir die verligting van hoes.

KONTRA-INDIKASIES
Hipersensitiwiteit vir enige van die bestanddele.
Asemhalings-onderdrukking, akute alkoholisme, diabetes, kopbeserings of verhoogde kraniale druk.
Akute asma, emfiseem of hartversaking sekondêr tot chroniese longsiekte.
Erge hipertensie.
Moenie saam met monoamienoksidaseremmers geneem word of binne 14 dae na staking daarvan nie.
Veiligheid van gebruik in swangerskap is nie vasgestel nie.
Moenie aan prematuur babas of neonate onder twee jaar gegee word nie aangesien prometasien met die skielike babadoodsindroom geassosieer is.
Nie aanbeveel tydens laktasie nie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS
Hierdie medisyne kan lei tot merkbare sedasie, lomerigheid en verswakte konsentrasie wat vererger kan word deur die gelyktydige inname van alkohol, of enige ander sentrale senuweestelsel onderdrukkende middels.
Pasiënte moet gewaarsku word om nie 'n motorvoertuig te bestuur, met gevaarlike masjinerie te werk of gevaarlike hoogtes te klim nie aangesien benadeelde besluitneming tot ongelukke kan lei. Oorskryding van die voorgeskrewe dosis saam met verlengde, volgehoue gebruik kan tot afhanklikheid lei.
NIE VIR GEBRUIK IN ASMA, EMFISEEM OF CHRONIESE BRONGITIS NIE.
Prometasienhidrochloried moet met sorg gebruik word in pasiënte met kardiovaskulêre en lewersiekte, nouhoekgloukoom, piloroduodenale obstruksie, urienretensie en hipertrofie van die prostaat.
Prometasien kan die hipotensiewe effek van sommige antihipertensiemiddels versterk.
Efedrienhidrochloried moet met sorg gebruik word in pasiënte met hipertireose, *diabetes mellitus* of nouhoekgloukoom, kardiovaskulêre siekte, hipertensie, okklusiewe vaskulêre siekte, aneurismes.
Anginale pyn kan veroorsaak word in pasiënte met angina pectoris.
Kodeïenfosfaat moet met sorg of in verlaagde doserings gegee word aan pasiënte met hipotireose, adreno-kortikale ontoereikendheid, verswakte nier- of lewerfunksie, prostaat-hipertrofie of skok.
Pasiënte met obstruktiewe maagtoestande en myastinie gravis moet ook versigtig wees wanneer kodeïenfosfaat geneem word.

INTERAKSIES
Vermy of gebruik met omsigtigheid in pasiënte wat narkose ondergaan met siklopropaan, halotaan, of ander gehalogeneerde narkosemiddels, aangesien hulle ventrikulêre fibrillasie kan veroorsaak. 'n Toename in aritmieë kan voorkom in pasiënte wat hartglikosiede, kinidien, of trisikliese antidepressante ontvang. Gekompliseerde interaksies vind plaas met alfa- en betablokkers. Kodeïen kan absorpsie van ander medisyne vertraag. Prometasien kan die werking van kalmeermiddels en susmiddels versterk. Vals negatiewe of positiewe swangerskaptoetse is aangemeld met prometasien. Antihistamiene kan uitslae van positiewe veltoetse onderdruk en moet 'n paar dae voor die toets gedoen word, gestaak word. MAO onderdrukkers: Sien "**WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**". Kalmerende effekte word versterk deur alkohol, narkose, slaapmiddels en kalmeermiddels, trisikliese antidepressante en fenotiasiene.

SWANGERSKAP EN LAKTASIE
Veilige gebruik tydens swangerskap is nie vasgestel nie. Moenie aan premature babas of neonate onder twee jaar gegee word nie, aangesien prometasien met die skielike babadoodsindroom geassosieer is. Nie aanbeveel tydens laktasie nie.

DOSIS EN GEBRUIKSAANWYSINGS
Volwassenes: 5 mℓ tot 10 mℓ drie maal per dag.
Nie aanbeveel vir kinders nie.
Skud bottel voor gebruik.

NEWE-EFFEKTE
Prometasienhidrochloried
Die mees algemene newe-effekte is sedasie, lomerigheid, insluitende lusteloosheid, duiseligheid en swak koördinasie. Ander newe-effekte sluit in gastro-intestinale versteurings soos naarheid, braking, diarree of hardlywigheid, anoreksie of verhoogde eetlus en maagpyn. Verdikking van slym in lugwegkanaal, dowwe visie, moeilike urinering, pynlike urinering (disurie), droogheid van die mond, beklemming om die bors, hipotensie, bradikardie, tagikardie, verbygaande geringe hipertensie, spierswakheid, tinnitus, euforie, ligsensitiwiteit, geelsug, trombositopenie, purpura, veluitslag, angio-edeem en hoofpyn af en toe, kan ook voorkom.
Paradoksale sentrale senuweestelsel stimulasie kan voorkom, veral by kinders. Agranulositose, leukopenie en hemolitiese anemie is aangemeld, maar is skaars.
Efedrienhidrochloried
Newe-effekte kan vrees, angs, rusteloosheid, bewing, slaaploosheid en verwarring, geïrriteerdheid, swakheid, psigotiese toestande, afname in eetlus, naarheid en braking insluit. Vasokonstriksie en gevolglike hipertensie, refleks bradikardie, tagikardie, hartaritmieë, angina pyn, hartkloppings, hartstilstand, hipotensie met duiseligheid en floute en gloede is ook aangemeld. Angina pyn kan voorkom in pasiënte met angina pectoris. Geelsug en bloed-afwykings is aangemeld asook ekstrapirimidale simptome by hoë doserings. Ander simptome wat kan voorkom met simpatomimetiese middels sluit moeilike urinering en urienretensie in, dispnee, gewysigde metabolisme insluitende versteuring van glukosemetabolisme, sweet en oormatige speekselafskeiding. Hoofpyn is ook algemeen.
Kodeïenfosfaat
Die mees algemene newe-effekte is naarheid, braking, hardlywigheid, lomerigheid en verwarring. Moeilike urinering, ureter- of bilêre spasma, anti-diuretiese effek, droë mond, sweet, gesigblos, urtikaria en pruritus, vertigo, bradikardie, hartkloppings, ortostatiese hipotensie, hipotermie. Rusteloosheid, verandering van gemoed en meiose kan ook voorkom.
Verhoogde intrakraniale druk, euforie, urtikaria en pruritus kom in sommige pasiënte voor. Psigiese en fisiese afhanklikheid kan met herhaalde gebruik voorkom, en onttrekkingsimptome kan voorkom by staking na langtermyn misbruik.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Oordosis kan dodelik wees, veral by kinders. In die geval van oordosis moet aandag dadelik gegee word aan die handhawing van voldoende asemhaling.
Lomerigheid tot diep slaap, duiseligheid, spierswakheid, en swak koördinasie kan voorkom. By babas en kinders tree antihistamiene dikwels op as sebrale stimulante en kan aanleiding gee tot hoë koors en konvulsies.
Hoë doserings efedrien kan hiperaktiwiteit, braking, naarheid en tagikardie, ekstrasistole, konvulsies, asemhalingsonderdrukking, hipertensie, ineenstorting van sirkulasie en diep koma tot gevolg hê.
Kodeïenfosfaat: Hardlywigheid, asemhalingsonderdrukking, histamienvrystelling, speldepunt pupille, hipotensie en hipotermie, hiperaktiwiteit en konvulsies, veral in kinders en nie-kardiogeniese pulmonêre edeem veroorsaak. In geval van oordosering moet die maag met spoeling en suiging geledig word. Geaktiveerde koolstof en lakseermiddels kan ook gebruik word.
Intensiewe ondersteunende behandeling mag nodig wees om respiratoriese versaking en skok te behandel. Naloksoonhidrochloried word gebruik as 'n antagonis vir kodeïenfosfaat in dosisse van 0,4 mg tot 2 mg binneaars met intervalle van 2 tot 3 minute indien nodig tot en met 10 mg.

IDENTIFIKASIE
Bleek amber helder oplossing met 'n swartbessie reuk en smaak.

AANBIEDING
100 mℓ, 200 mℓ en 2,5 liter amber bottels.

BERGINGSAANWYSINGS
Bewaar teen of benede 25°C. Beskerm teen lig en vog. Hou bottel dig toe.
HOU BUITE DIE BEREIK VAN KINDERS.

REGISTRASIENOMMER
G 1064 (Wet 101/1965)

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