UMTHUTHUZELI® MIXTURE

SCHEDULING STATUS: S0

PROPRIETARY NAME AND DOSAGE FORM

UMTHUTHUZELI (Mixture)

COMPOSITION

Each 5 ml contains:

Sodium bicarbonate	131,37 mg
Ethyl alcohol (96 %)	5,22 % *v/v*
Preservative:	
Methylhydroxybenzoate	0,1 % *m/v*

Excipients: aniseed oil, caramel, EFM compound rhubarb tincture, glycerol and purified water.

Contains sugar: Sucrose	2,96 g / 5 ml

CATEGORY AND CLASS:

A 11.4.3 Medicines acting on the gastro-intestinal tract: Others.

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties

Sodium bicarbonate is an antacid that neutralises acid secretions in the gastrointestinal tract.

Pharmacokinetic properties

Sodium bicarbonate neutralises gastric acid secretions with the production of carbon dioxide. Bicarbonate not involved in neutralising gastric acid is absorbed and in the absence of a deficit of bicarbonate in the plasma, the bicarbonate ions are then excreted in the urine rendering it alkaline, and there is an accompanying diuresis.

INDICATIONS:

UMTHUTHUZELI is indicated for winds, gripes, colic and upset stomach associated with excess acid in infants.

CONTRAINDICATIONS:

UMTHUTHUZELI is contraindicated in:

- patients with metabolic or respiratory alkalosis, hypocalcaemia or hypochlorhydria
- patients who are hypersensitive to sodium bicarbonate or to any of the ingredients of UMTHUTHUZELI. (see COMPOSITION)

WARNINGS AND SPECIAL PRECAUTIONS:

UMTHUTHUZELI should be used extremely cautiously in patients with cardiac failure, hypertension, impaired renal function, peripheral or pulmonary oedema, or aldosteronism.

Care should be taken to avoid excessive use in infants.

Special care must be taken when administering UMTHUTHUZELI with other medicines, and in particular with salicylates, tetracyclines, barbiturates and lithium. (Refer to INTERACTIONS)

UMTHUTHUZELI contains a high percentage of alcohol.

INTERACTIONS:

Bicarbonate may reduce or increase the rate and/or extent of absorption of a number of medicines due to raising intra-gastric pH. Alkalinisation of the urine leads to increased renal clearance of acidic medicine such as salicylates, tetracyclines and barbiturates. Conversely; it may prolong the half-life of alkaline medicines and result in toxicity.

Sodium bicarbonate enhances the excretion of lithium.

(Refer to Warnings and Special Precautions)

HUMAN REPRODUCTION:

Not applicable. UMTHUTHUZELI is not intended for administration to women of child-bearing age.

DOSAGE AND DIRECTIONS FOR USE:

SHAKE THE BOTTLE BEFORE USE.

Infants: 5 ml (one medicine measure) after meals or as required.

UMTHUTHUZELI should not be taken for longer than a few days without medical advice.

SIDE EFFECTS:

The following side effects may occur:

Gastrointestinal disorders

Frequency unknown: Stomach cramps, belching, flatulence

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Excessive use of UMTHUTHUZELI may lead to hypokalaemia and metabolic alkalosis, especially in patients with impaired renal function. Symptoms include mood changes, tiredness, slow breathing, muscle weakness, and irregular heartbeat. Muscle hypertonicity, twitching, and tetany may develop, especially in hypocalcaemic patients. Treatment of metabolic alkalosis and hypernatraemia associated with sodium bicarbonate overdose consists mainly of appropriate correction of fluid and electrolyte balance. Replacement of calcium, chloride and potassium ions may be of particular importance.

Excessive doses of sodium salts may also lead to sodium overloading and hyperosmolality.

Sodium "excess" may take two forms. The first is a rise in extracellular concentration (hypernatraemia) and the second form is too much sodium and water in the body without change in extracellular concentration. 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. Symptoms of hyponatraemia may include anorexia, fatigue, muscle weakness, diarrhoea, abdominal cramps, confusion, hypotension, tachycardia, weakened pulse, cyanosis, hypothermia, pitting oedema, oliguria and convulsions. Treat symptomatically.

IDENTIFICATION:

Bright, dark brown mixture.

PRESENTATION:

50 ml and 100 ml plastic amber bottles with a white aluminium cap, contained in an outer carton.

STORAGE INSTRUCTIONS:

Keep bottle tightly closed and protect from light.

Keep bottle in outer carton until prior to use.

Store at or below 25 °C.

KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER:

E/11.4.3/1542

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

Avid Brands (Pty) Ltd
Suite 9, Hillcrest Office Park
2 Old Main Road
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17 February 2017

UMTHUTHUZELI® MENGSEL

SKEDULERINGSTATUS S0

EIENDOMSNAAM EN DOSEERVORM
UMTHUTHUZELI (Mengsel)

SAMESTELLING:
Elke 5 ml bevat:

Natriumbikarbonaat	131,37 mg
Etielalkohol (96 %)	5,22 % *v/v*
Preserveermiddel:	
Metielhidroksibensoaat	0,1 % *m/v*

Onaktiewe bestanddele: anysolie, karamel, EFM saamgestelde rabarber tinktuur, gliserol en gesuiwerde water.
Bevat suiker: Sukrose 2,96 g / 5 ml

KATEGORIE EN KLAS:
A 11.4.3 Medisyne wat op die gastroïntestinale stelsel inwerk: Ander.

FARMAKOLOGIESE AKSIE:
Farmakodinamiese eienskappe
Natriumbikarbonaat is 'n teensuurmiddel wat suur sekresies in die gastroïntestinale stelsel neutraliseer.
Farmakokinetiese eienskappe
Natriumbikarbonaat neutraliseer maagsuursekresies deur die produksie van koolstofdioksied. Bikarbonaat wat nie betrokke is by die neutralisasie van maagsuur nie, word geabsorbeer en in die afwesigheid van 'n bikarbonaattekort in die plasma, word die bikarbonaatione dan in die uriene uitgeskei, wat dit alkalies maak, met meegaande diurese.

INDIKASIES:
UMTHUTHUZELI is aangedui vir winde, krampe, koliek en ongestelde maag geassosieer met oormatige suur by babas.

KONTRA INDIKASIES:
UMTHUTHUZELI is teenaangedui by:
- pasiënte met metaboliese of respiratoriese alkalose, hipokalsemie of hipochloorhidrie
- pasiënte wat hipersensitief is vir natriumbikarbonaat of enige van die bestanddele van UMTHUTHUZELI. (sien SAMESTELLING)

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
UMTHUTHUZELI moet met uiterste omsigtigheid gebruik word by pasiënte met hartversaking, hipertensie, ingekorte nierfunksie, perifere of pulmonale edeem, of aldosteronisme. Sorg moet geneem word om oormatige gebruik by babas te voorkom.
Spesiale sorg moet geneem word wanneer UMTHUTHUZELI toegedien word met ander medisynes, veral met salisilate, tetrasikliene, barbiturate en litium. (Verwys na INTERAKSIES)
UMTHUTHUZELI bevat 'n hoë persentasie van alkohol.

INTERAKSIES:
Bikarbonaat kan die tempo en/of mate van absorpsie van 'n aantal medisynes vermeerder of verminder weens 'n toename in intragastriese pH. Alkalinisering van die urine lei tot 'n toename in renale opruiming van medisyne wat sure is, soos salisilate, tetrasikliene en barbiturate.
Aan die ander kant; kan dit die halfleeftyd van alkaliese medisynes verleng, en tot toksisiteit lei.
Natriumbikarbonaat veroorsaak 'n toename in die ekskresie van litium. (Verwys na Waarskuwings en Spesiale Voorsorgmaatreëls)

MENSLIKE REPRODUKSIE:
Nie van toepassing nie. UMTHUTHUZELI is nie bedoel vir toediening aan vroue van vrugbare ouderdom nie.

DOSIS EN GEBRUIKSAANWYSINGS:
SKUD DIE BOTTEL VOOR GEBRUIK.
Babas: 5 ml (een medisynemaat) na maaltye of soos benodig.
UMTHUTHUZELI moet nie vir langer as 'n paar dae geneem word sonder mediese advies nie.

NEWE EFFEKTE:
Die volgende newe effekte kan voorkom:
Gastroïntestinale versteurings
Frekwensie onbekend: Maagkrampe, windopbraak, winderigheid

BEKENDE SIMPTOME VAN OORDOSERING EN DIE BEHANDELING DAARVAN
Oormatige gebruik van UMTHUTHUZELI kan lei tot hipokalemie en metaboliese alkalose, veral by pasiënte met ingekorte nierfunksie. Simptome sluit buierigheid, moegheid, stadige asemhaling, spierswakheid, en onreëlmatige hartklop, in. Hipertoniese spiere, senuweetrekkings, en tetanie kan ontwikkel, veral by hipokalsemiese pasiënte. Behandeling van metaboliese alkalose en hipernatremie geassosieer met natriumbikarbonaat oordosis bestaan hoofsaaklik uit toepaslike korreksie van vloeistof- en elektroliet balans. Vervanging van kalsium-, chloried- en kaliumione kan van besondere belang wees.
Oormatige dosisse van natriumsoute kan ook lei tot natriumoorlading en hiperosmolaliteit. Natrium "oormaat" kan twee vorms inneem. Die eerste is 'n toename in ekstrasellulêre konsentrasie (hipernatremie), en die tweede vorm is te veel natrium en water in die liggaam sonder 'n verandering in ekstrasellulêre konsentrasie. Simptome van hipernatremie kan rusteloosheid, swakheid, dors, verminderde speekselafskeiding en traanafskeiding, geswelde tong, blosing van die vel, koors, duiseligheid, hoofpyn, oligurie, hipotensie, tagikardie, delirium, hiperpnee en respiratoriese arres, insluit. Simptome van hiponatremie kan anoreksie, moegheid, spierswakheid, diarree, maagkrampe, verwarring, hipotensie, tagikardie, verswakte pols, sianose, hipotermie, puttende edeem, oligurie en konvulsies. Behandel simptomaties.

IDENTIFIKASIE:
Helder, donkerbruin mengsel.

AANBIEDING:
50 ml en 100 ml plastiese amber bottels met 'n wit aluminium dop, bevat in 'n buitenste karton.

BERGINGSINSTRUKSIES:
Hou die bottel dig toe en beskerm teen lig.
Hou die bottel in die buitenste karton tot voor gebruik.
Berg by of benede 25 °C.
HOU ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS

REGISTRASIENOMMER:
E/11.4.3/1542

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
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