PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S0

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

UMTHUTHUZELI

Sodium bicarbonate 131,37 mg per 5 ml mixture

Read all of this leaflet carefully because it contains important information for you.

UMTHUTHUZELI is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use UMTHUTHUZELI carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share UMTHUTHUZELI with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if symptoms worsen or do not improve after a few days.

1. WHAT UMTHUTHUZELI CONTAINS

- The active substance is 131,36 mg sodium bicarbonate per 5 ml mixture
- The other ingredients are aniseed oil, caramel, EFM compound rhubarb tincture, ethyl alcohol (96 %) 5,22 % *v/v,* glycerol, methylhydroxybenzoate 0,1 % *m/v,* sucrose 2,96 g / 5 ml and purified water.

2. WHAT UMTHUTHUZELI IS USED FOR

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

3. BEFORE YOU ADMINISTER UMTHUTHUZELI

Do not administer UMTHUTHUZELI:

- If your infant has:
  - blood pH higher than normal,
  - low calcium levels,
  - low stomach acid.
- If your infant is hypersensitive (allergic) to sodium bicarbonate or any of the ingredients of UMTHUTHUZELI.

Take special care with UMTHUTHUZELI:

- If your infant has heart failure, high blood pressure, reduced kidney function, swelling, or high levels of aldosterone (steroid hormone) extreme caution is advised.
- Avoid excessive use in infants.
- UMTHUTHUZELI contains a high percentage of alcohol.
- Special care must be taken when administering UMTHUTHUZELI with other medicines, and in particular with salicylates, tetracyclines, barbiturates and lithium.

Using UMTHUTHUZELI with food and drink:

Alcohol should not be consumed during treatment with UMTHUTHUZELI as it contains a high percentage of alcohol.

Pregnancy and breastfeeding:

Not applicable since UMTHUTHUZELI is not intended for use by women of child-bearing age.

Important information about some of the ingredients of UMTHUTHUZELI:

- UMTHUTHUZELI mixture contains sugar and alcohol.

Using other medicines with UMTHUTHUZELI:

Always tell your healthcare professional if you are administering any other medicine. (This includes complementary or traditional medicines.)

UMTHUTHUZELI may interact with a number of medicines.

UMTHUTHUZELI may:

- decrease or increase the absorption of other medicines due to raising stomach pH
- increase excretion through the kidneys of lithium and acidic medicines such as salicylates, tetracyclines and barbiturates
- delay the excretion of certain medicines and result in toxicity.

4. HOW TO ADMINISTER UMTHUTHUZELI

Do not share medicines prescribed for your infant with any other person.

Shake the bottle well before use.

The usual dose for infants is one medicine measure (5 ml) given after meals or as required.

The mixture should not be given for longer than a few days without medical advice.

If you administer more UMTHUTHUZELI than you should:

Symptoms of overdosage may include mood changes, tiredness, slow breathing, muscle weakness or muscle twitching (especially in patients with low calcium levels), irregular heartbeat, fever or sweating.

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you missed administering a dose of UMTHUTHUZELI:

Do not double the dose. Skip the missed dose and continue with the next dose as directed.

5. POSSIBLE SIDE EFFECTS

UMTHUTHUZELI can have side effects.

Not all side effects reported for UMTHUTHUZELI are included in this leaflet. Should your infants general health worsen or if your infant experiences any untoward effects while taking UMTHUTHUZELI, please consult your doctor, pharmacist or other health care professional for advice.

The following side effects may occur:

Frequency unknown: Stomach cramps, burping, flatulence (gassiness).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF UMTHUTHUZELI

- Store at or below 25 °C.
- Keep the bottle tightly closed and protect from light.
- Keep bottle in unit carton until prior to use.
- Do not use after the expiry date stated on the label.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems. (e.g. toilets)

7. PRESENTATION OF UMTHUTHUZELI

UMTHUTHUZELI mixture is supplied in plastic amber bottles of 50 ml and 100 ml with a white cap, contained in an outer carton.

8. IDENTIFICATION OF UMTHUTHUZELI

UMTHUTHUZELI is a bright, dark brown mixture.

9. REGISTRATION NUMBER

E/11.4.3/1542

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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

11. DATE OF PUBLICATION

17 February 2017

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS S0

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM

UMTHUTHUZELI

Natriumbikarbonaat 31,37 mg per 5 ml mengsel

Lees die hele pamflet noukeurig omdat dit belangrike inligting vir u bevat.
UMTHUTHUZELI is beskikbaar sonder 'n dokter se voorskrif vir u om 'n geringe siekte te behandel. Nietemin, moet u steeds UMTHUTHUZELI versigtig gebruik om die beste resultate daaruit te verkry.
- Hou hierdie pamflet. U mag dit weer wil lees.
- Moenie UMTHUTHUZELI deel met enige ander persoon nie.
- Vra u apteker indien u meer inligting of advies benodig.
- U moet 'n dokter sien indien u simptome vererger, of indien dit nie verbeter binne 'n paar dae nie

1. WAT UMTHUTHUZELI BEVAT
- Die aktiewe bestanddeel is 131,36 mg natriumbikarbonaat per 5 ml mengsel.
- Die ander bestanddele is anysolie, karamel, EFM saamgestelde rabarber tinktuur, etielalkohol (96 %) 5,22 % *v/v,* gliserol, metielhidroksibensoaat 0,1 % *m/v*, sukrose 2,96 g / 5 ml en gesuiwerde water.

2. WAARVOOR UMTHUTHUZELI GEBRUIK WORD
UMTHUTHUZELI word gebruik vir winde, krampe, koliek en ongestelde maag geassosieer met oormatige suur by babas.

3. VOORDAT U UMTHUTHUZELI TOEDIEN
Moenie UMTHUTHUZELI toedien:
- Indien u baba die volgende het nie:
  * hoër as normale bloed pH,
  * lae kalsiumvlakke,
  * lae maagsuur.
- Indien u baba hipersensitief (allergies) is vir natriumbikarbonaat of enige van die bestanddele van UMTHUTHUZELI nie.

Neem spesiale sorg met UMTHUTHUZELI:
- Indien u baba hartversaking, hoë bloeddruk, verminderde nierfunksie, swelling, of hoë vlakke van aldosteroon (steroïedhor moon) het, word uiterste versigtigheid aanbeveel.
- Vermy oormatige gebruik by babas.
- UMTHUTHUZELI bevat 'n hoë persentasie van alkohol.
- Spesiale sorg moet geneem word wanneer UMTHUTHUZELI toegedien word met ander medisynes, en veral met salisilate, tetrasikliene, barbiturate en litium.

Gebruik van UMTHUTHUZELI met kos en drank:
Alkohol moet nie ingeneem word gedurende behandeling met UMTHUTHUZELI nie, aangesien dit 'n hoë persentasie van alkohol.

Swangerskap en Laktasie:
Nie toepaslik, aangesien UMTHUTHUZELI nie bedoel is vir gebruik deur vroue van vrugbare ouderdom nie.

Belangrike inligting oor sommige van die bestanddele van UMTHUTHUZELI:
- UMTHUTHUZELI mengsel bevat suiker en alkohol.

Neem van ander medisynes met UMTHUTHUZELI:
Vertel altyd u professionele gesondheidsorgpraktisyn indien u enige ander medisyne toedien. (Dit sluit in komplementêre- of tradisionele medisynes in.)
UMTHUTHUZELI kan lei tot interaksies met 'n aantal medisynes.
UMTHUTHUZELI kan:
- die absorpsie van ander medisynes verhoog of verlaag weens 'n toename in maag pH
- lei tot toename in ekskresie deur die niere van litium, asook medisyne wat sure is soos salisilate, tetrasikliene en barbiturate
- die ekskresie van sekere medisynes vertraag en tot toksisiteit lei.

4. HOE OM UMTHUTHUZELI TOE TE DIEN
Moenie medisynes wat vir u voorgeskryf is deel met enige ander persoon nie.
Skud die bottel goed voor gebruik.
Die normale dosis vir babas is een medisynemaat (5 ml) gegee na maaltye of soos benodig. Die mengsel moet nie vir langer as 'n paar dae gegee word sonder mediese advies nie.

Indien u meer UMTHUTHUZELI gee as wat u moet:
Simptome van oordosering kan buierigheid, moegheid, stadige asemhaling, spierswakheid of spiersametrekkings (veral by pasiënte met lae kalsium vlakke), onreëlmatige hartklop, koors, of sweet insluit.
In die geval van 'n oordosis, konsulteer u dokter of apteker. Indien beide nie beskikbaar is nie, kontak die naaste hospitaal of gifstofbeheersentrum.

Indien u 'n dosis van UMTHUTHUZELI toediening gemis het:
Moenie die dosis verdubbel nie. Slaan die gemiste dosis oor en gaan voort met die volgende dosis soos aangedui.

5. MOONTLIKE NEWE EFFEKTE
UMTHUTHUZELI kan newe effekte hê. Nie alle newe effekte wat aangemeld is vir UMTHUTHUZELI is in hierdie pamflet ingesluit nie. Indien u baba se algemene gesondheid versleg of indien u baba enige ongewenste effekte ervaar tydens die gebruik van UMTHUTHUZELI, raadpleeg asseblief u dokter, apteker or ander professionele gesondheidsorgpraktisyn vir advies.
Die volgende newe effekte kan voorkom:
Frekwensie onbekend: Maagkrampe, windopbraak,winderigheid (gasagtigheid).
Indien u enige newe effekte waarneem wat nie in hierdie pamflet genoem is nie, lig asseblief u dokter of apteker in.

6. BERGING EN VERNIETIGING VAN UMTHUTHUZELI
- Bewaar by of benede 25 ˚C.
- Hou die bottel dig toe en beskerm teen lig.
- Hou die bottel in die buitenste karton tot voor gebruik.
- Moenie gebruik na die vervaldatum wat op die etiket aangedui is nie.

Hou alle medisynes buite die bereik van kinders.
Gee alle ongebruikte medisyne terug aan u apteker.
Moenie van ongebruikte medisyne ontslae raak in dreine of rioolstelsels (b.v. toilette) nie.

7. AANBIEDING VAN UMTHUTHUZELI
UMTHUTHUZELI mengsel word verskaf in plastiese amber bottels van 50 ml en 100 ml met 'n wit dop, en is verpak in 'n buitenste karton.

8. IDENTIFIKASIE VAN UMTHUTHUZELI
UMTHUTHUZELI is 'n helder, donkerbruin mengsel.

9. REGISTRASIENOMMER
E/11.4.3/1542

10. NAAM EN ADRES VAN REGISTRASIEHOUER
Avid Brands S.A. (Edms) Bpk
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