

1.3.2 CURRENT APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S0**

UMTHUTHUZELI, Mixture

Sodium bicarbonate 131,37 mg per 5 ml mixture.

Contains sugar: Sucrose 2,96 g

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 healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if symptoms worsen or do not improve after a few days.

What is in this leaflet

1. What UMTHUTHUZELI is and what it is used for
2. What you need to know before you give UMTHUTHUZELI
3. How to administer UMTHUTHUZELI
4. Possible side effects
5. How to store UMTHUTHUZELI
6. Contents of the pack and other information

1. What UMTHUTHUZELI is and what it is used for

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

2. What you need to know before you give 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 (listed in section 6).

Warnings and precautions

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.

Other medicines and UMTHUTHUZELI

Always tell your health care provider if you are administering any other medicine.

(This includes all 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.

Using UMTHUTHUZELI with food, drink and alcohol:

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.

Driving and using machines

Not applicable as UMTHUTHUZELI is intended for use by infants only.

UMTHUTHUZELI contains sugar and alcohol.

UMTHUTHUZELI contains a high percentage of alcohol.

3. How to administer UMTHUTHUZELI

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

Always give UMTHUTHUZELI exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

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.

4. Possible side effects

UMTHUTHUZELI can have side effects.

Not all side effects reported for UMTHUTHUZELI are included in this leaflet.

Should your infant's general health worsen or if your infant experiences any untoward effects while taking UMTHUTHUZELI, please consult your health provider 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.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of UMTHUTHUZELI.

5. How to store 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)

6. Contents of the pack and other information

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, methyl hydroxybenzoate 0,1 % *m/v*, sucrose 2,96 g / 5 ml and purified water.

What UMTHUTHUZELI looks like and contents of the pack

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

Holder of Certificate of Registration

Avid Brands S.A. (Pty) Ltd

Suite 9, Hillcrest Office Park

2 Old Main Road

Hillcrest

3610

This leaflet was last revised in

05 September 2022

Applicant: Avid Brands S.A. (Pty) Ltd

Product Name: **Umthuthuzeli**

Dosage form and strength: Each 5 ml mixture contains Sodium bicarbonate 131,37 mg

Module 1.3.2

Registration number

E/11.4.3/1542

Access to the corresponding Professional Information

<https://www.avidbrands.co.za>

Contact information:

Email: info@avidbrands.com

Telephone: 0860 104 061