

PROFESSIONAL INFORMATION

Complementary Medicine: Health Supplement

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

LOCAL HEALTH L. REUTERI chewable tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Lactobacillus reuteri 200 Million CFU (Colony Forming Units)

Contains sugar: sorbitol (75 mg) and xylitol (35 mg) per chewable tablet.

Contains sweetener: sodium cyclamate and acesulfame-K blend (0,7 mg) per chewable tablet.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablets.

Small, round, white speckled chewable tablets with a strawberry flavouring.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

When ingested on a regular basis, LOCAL HEALTH L. REUTERI should improve or normalise the microbial balance in the human intestines and thereby improve the function of the digestive tract and gut.

4.2 Posology and method of administration

Children 3 years and older:

One chewable tablet daily. Can be increased to two chewable tablets daily while taking antibiotics, continued for a minimum of 3 days afterwards.

Adults 18 years and older:

One chewable tablet daily. Can be increased to two chewable tablets daily while taking antibiotics, continued for a minimum of 3 days afterwards.

Elderly:

One chewable tablet daily. Can be increased to two chewable tablets daily while taking antibiotics, continued for a minimum of 3 days afterwards.

4.3 Contraindications

- Hypersensitivity to *Lactobacillus reuteri* or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

- Rare cases of bacteremia have been reported in patients taking lactobacillus-containing products with indwelling or central venous catheters.
- Lactobacillus preparations may cause pathogenic colonization in patients with liver cirrhosis, immunodeficiency or severe gastrointestinal disorders (e.g. short bowel syndrome, inflammatory bowel disease). Caution is advised for such patients.
- Lactobacillus preparations may cause pathogenic colonization in patients with valvular heart disease. Use should be avoided prior to dental surgery or other invasive gastrointestinal procedures.

4.5 Interaction with other medicines and other forms of interaction

- Administration of antibiotics and lactobacillus preparations must be separated by a minimum of two hours, as antibiotic medications may decrease the effectiveness of lactobacillus when taken simultaneously.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or use of machinery have been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that LOCAL HEALTH L. REUTERI does not adversely affect their performance.

4.8 Undesirable effects

Gastrointestinal disorders

Less frequent: epigastric discomfort, abdominal pain, dyspepsia, rumbling, bloating, diarrhoea, belching.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity.

Treatment of overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

Category and class: D 34.9 Probiotics.

5.1 Pharmacodynamic properties

When ingested on a regular basis, LOCAL HEALTH L. REUTERI should improve or normalise the microbial balance in the human intestines and thereby improve the function of the digestive tract and gut.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on LOCAL HEALTH L. REUTERI.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol
Xylitol
Sodium cyclamate and acesulfame-K blend
Citric acid anhydrous
Flavouring
Isomalt
Magnesium stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

24 months

6.4 Special precautions for storage

Store at or below 25 °C.

Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

PVC / aluminium blister strips containing 10 chewable tablets, packed into an outer carton.

Pack size: 10 tablets.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Manufactured for CJ Distribution

23 Stag Road, Glen Austin, Johannesburg, South Africa

careline@cjsa.com

011 589 2729

www.localhealth.com

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

**PATIENT INFORMATION LEAFLET
SCHEDULING STATUS**

50

LOCAL HEALTH L. REUTERI (chewable tablets)

Each chewable tablet contains:

Lactobacillus reuteri 200 Million CFU (Colony Forming Units)
Contains sugar: sorbitol (75 mg) and xylitol (35 mg) per chewable tablet.
Contains sweetener: sodium cyclamate and acesulfame-K blend (0,7 mg) per chewable tablet.

Complementary Medicine: Probiotics (Health Supplement)

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

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

LOCAL HEALTH L. REUTERI is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use LOCAL HEALTH L. REUTERI carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LOCAL HEALTH L. REUTERI with any other person.
- Ask your healthcare practitioner or pharmacist if you need more information or advice.

What is in this leaflet

1. What LOCAL HEALTH L. REUTERI is and what it is used for.
2. What you need to know before you use LOCAL HEALTH L. REUTERI.
3. How to use LOCAL HEALTH L. REUTERI.
4. Possible side effects.

5. How to store LOCAL HEALTH L. REUTERI.

6. Contents of the pack and other information.

1. What LOCAL HEALTH L. REUTERI is and what it is used for

When ingested on a regular basis, LOCAL HEALTH L. REUTERI should improve or normalise the microbial balance in the human intestines and thereby improve the function of the digestive tract and gut.

2. What you need to know before you use LOCAL HEALTH L. REUTERI

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance.

Do not use LOCAL HEALTH L. REUTERI:

- If you are hypersensitive (allergic) to *Lactobacillus reuteri* or to any of the ingredients listed in section 6.

Warnings and precautions

Consult with a healthcare practitioner prior to using LOCAL HEALTH L. REUTERI, especially if you have a medical condition.

Consult a healthcare practitioner prior to use:

- If you have an indwelling or central venous catheter.
- If you have liver cirrhosis, immunodeficiency or a severe gastrointestinal disorder.
- If you have valvular heart disease and are scheduled to undergo dental surgery or other invasive gastrointestinal procedures.

Children and adolescents

LOCAL HEALTH L. REUTERI is not recommended for individuals below the age of 3 years.

Other medicines and LOCAL HEALTH L. REUTERI

Always tell your healthcare practitioner if you are taking any other medicine (this includes complementary or traditional medicines). Not all possible interactions with other medicines may be included in this leaflet. Consult with a healthcare practitioner prior to use if you are taking any other medication.

Consult a healthcare practitioner if you are taking antibiotics. Antibiotics and LOCAL HEALTH L. REUTERI should be taken at least 2 hours apart, or as directed by your healthcare practitioner.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare practitioner for advice before using LOCAL HEALTH L. REUTERI.

Driving and using machinery

No studies on the effects on the ability to drive or use of machinery have been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that LOCAL HEALTH L. REUTERI does not adversely affect their performance.

3. How to use LOCAL HEALTH L. REUTERI

Do not share medicines prescribed to you with any other person. Do not exceed the daily recommended dosage. Always use LOCAL HEALTH L. REUTERI exactly as described in this leaflet or as your healthcare practitioner has instructed. Check with your healthcare practitioner if you are not sure. Adults and children 3 years and older

Chew one tablet daily. Can be increased to two chewable tablets daily while taking antibiotics, continued for a minimum of 3 days afterwards, or as recommended by a healthcare practitioner. Doses of antibiotics and LOCAL HEALTH L. REUTERI should be separated by a minimum of two hours.

4. Possible side effects

LOCAL HEALTH L. REUTERI can have side effects. Not all side effects reported for LOCAL HEALTH L. REUTERI are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LOCAL HEALTH L. REUTERI, please consult your doctor, pharmacist or other healthcare practitioner for advice. If any of the following happens, stop using LOCAL HEALTH L. REUTERI and tell your doctor or pharmacist immediately, or go to the casualty department at your nearest hospital: swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching, fainting. These are very serious side effects. If you have them, you may have had a serious reaction to LOCAL HEALTH L. REUTERI. You may need urgent medical attention or hospitalisation.

Less frequent: epigastric discomfort, abdominal pain, dyspepsia, rumbling, bloating, diarrhoea, belching.

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

Reporting of side effects

If you experience side effects, inform your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of LOCAL HEALTH L. REUTERI.

5. How to store LOCAL HEALTH L. REUTERI

- Protect from moisture and store at or below 25 °C.
- KEEP OUT OF REACH OF CHILDREN.
- Store the blister strips in the outer carton.
- Do not use after the expiry date stated on the label.
- Return all unused LOCAL HEALTH L. REUTERI to your pharmacist.
- Do not dispose of unused LOCAL HEALTH L. REUTERI in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LOCAL HEALTH L. REUTERI contains

Each chewable tablet contains:

Lactobacillus reuteri 200 Million CFU (Colony Forming Units)
Other ingredients: sorbitol, xylitol, sodium cyclamate and acesulfame-K blend, citric acid anhydrous, flavouring, isomalt, magnesium stearate.

Contains sugar: sorbitol (75 mg) and xylitol (35 mg) per chewable tablet.
Contains sweetener: sodium cyclamate and acesulfame-K blend (0,7 mg) per chewable tablet.

Presentation and identification of LOCAL HEALTH L. REUTERI

Small, round, white speckled chewable tablets with a strawberry flavouring, in PCV / aluminium blister strips of 10, packed into an outer carton.

Pack size: 10 tablets.

Holder of Certificate of Registration

Manufactured for: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, South Africa, 1685
Careline: 011 589 2729; careline@cjdsa.com; www.localhealth.co.za

This pamphlet was last revised in

Will be allocated by SAHPRA upon registration.

Registration number

Will be allocated by SAHPRA upon registration.

**PASIËNTINLIGTINGSBLAD
SKEDULERINGSSTATUS**

50

LOCAL HEALTH L. REUTERI (koubare tablette)

Elke koubare tablet bevat:

Lactobacillus reuteri 200 Miljoen KVE (Kolonievormende Eenhede)
Bevat suiker: sorbitol (75 mg) en xylitol (35 mg) per koubare tablet.
Bevat versoeter: natriumsiklamaat en acesulfame-K mengsel (0,7 mg) per koubare tablet.

Komplementêre Medisyne: Probiotika (Gesondheidsaanvulling)

Hierdie ongeregistreerde medisyne is nie deur SAHPRA vir gehalte, veiligheid of beoogde gebruik geëvalueer nie. Gesondheidsaanvullings dien slegs as aanvulling tot gesondheid of dieet.

Lees hierdie inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir u.

LOCAL HEALTH L. REUTERI is beskikbaar sonder 'n dokter se voorskrif, om u gesondheid te handhaaf. Nietemin moet LOCAL HEALTH L. REUTERI versigtig gebruik word ten einde die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer lees.
- Moenie LOCAL HEALTH L. REUTERI met enige ander persoon deel nie.
- Vra u gesondheidsorgpraktisyn of apteker indien u meer inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat LOCAL HEALTH L. REUTERI is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u LOCAL HEALTH L. REUTERI gebruik.
3. Hoe om LOCAL HEALTH L. REUTERI te gebruik.
4. Moontlike nuwe-effekte.

5. Hoe om LOCAL HEALTH L. REUTERI te bêre.

6. Inhoud van die verpakking en ander inligting.

1. Wat LOCAL HEALTH L. REUTERI is en waarvoor dit gebruik word

Wanneer dit op 'n gereelde basis ingeneem word, behoort LOCAL HEALTH L. REUTERI die mikrobiële balans in die menslike ingewande te verbeter of te normaliseer en sodoende die funksie van die spysverteringskanaal en derm te verbeter.

2. Wat u moet weet voordat u LOCAL HEALTH L. REUTERI gebruik

'n Gevarieerde dieet is die doeltreffendste en veiligste manier om goeie voeding, gesondheid, liggaamsamestelling, sowel as geestelike en fisiese prestasie te behaal.

Moet nie LOCAL HEALTH L. REUTERI neem nie:

- Indien u hipersensitief (allergies) is vir *Lactobacillus reuteri* of vir enige van die bestanddele gelys inafdeling 6.

Waarskuwings en voorsorgmaatreëls

Raadpleeg 'n gesondheidsorgpraktisyn voordat u LOCAL HEALTH L. REUTERI gebruik, veral as u 'n mediese toestand het.

Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik:

- Indien u 'n inwonende of sentrale veneuse kateter het.
- Indien u lewersirroze, immuniteitsgebrek of 'n ernstige gastrointestinale versteuring het.
- Indien u hartklepsiekte het en geskeduleer is om tandheelkundige chirurgie of ander indringende gastrointestinale prosedures te ondergaan.

Kinders en adollesente

LOCAL HEALTH L. REUTERI word nie aanbeveel vir individue onder die ouderdom van 3 jaar nie.

Die neem van LOCAL HEALTH L. REUTERI en ander medisyne

Lig altyd u gesondheidsorgpraktisyn in indien u enige ander medisyne neem (dit sluit aanvullende of tradisionele medisyne in). Nie alle moontlike interaksies met ander medisyne word in hierdie pamflet ingesluit nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik indien u enige ander medikasie gebruik.

Raadpleeg 'n gesondheidsorgpraktisyn indien u antibiotika neem. Antibiotika en LOCAL HEALTH L. REUTERI moet ten minste 2 uur uitmekaar geneem word, of soos aanbeveel deur u gesondheidsorgpraktisyn.

Swangerskap, borsvoeding en vrugbaarheid

Indien u swanger is of borsvoed, vermoed dat u swanger is of beplan om 'n baba te hê, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies voordat u LOCAL HEALTH L. REUTERI gebruik.

Bestuur en die gebruik van masjinerie

Geen studies is uitgevoer oor die effekte op die vermoë om te bestuur of die gebruik van masjinerie nie. Pasiënte moet versigtig wees voordat hulle bestuur of masjinerie gebruik, totdat hulle redelik seker is dat LOCAL HEALTH L. REUTERI nie hul werkverrigting nadelig beïnvloed nie.

3. Hoe om LOCAL HEALTH L. REUTERI te gebruik

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie. Moenie die aanbeveelde daaglikse dosis oorskry nie. Gebruik LOCAL HEALTH L. REUTERI presies soos aanbeveel in hierdie inligtingsblad, of soos aanbeveel deur u gesondheidsorgpraktisyn. Raadpleeg u gesondheidsorgpraktisyn indien u nie seker is nie.

Volwassenes en kinders 3 jaar en ouer

Kou een tablet daaglik. Kan verhoog word na twee koubare tablette daaglik terwyl u antibiotika neem, vir 'n minimum van 3 dae na antibiotika voltooi is, of soos aanbeveel deur u gesondheidsorgpraktisyn. Dosis antibiotika en LOCAL HEALTH L. REUTERI moet 'n minimum van twee uur geskei word.

4. Moontlike nuwe-effekte

LOCAL HEALTH L. REUTERI kan nuwe-effekte hê. Nie alle nuwe-effekte vir LOCAL HEALTH L. REUTERI is ingesluit in hierdie inligtingsblad nie. Indien u algemene gesondheid vererger, of as u enige ongewenste reaksies ervaar tydens die gebruik van LOCAL HEALTH L. REUTERI, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies. As een van die volgende gebeur, hou op met die gebruik van LOCAL HEALTH L. REUTERI en raadpleeg u dokter of apteker onmiddellik, of gaan na die ongevalle afdeling van u naaste hospitaal: swelling van u hande, voete, enkels, gesig, lippe en mond of keel, wat dit moeilik kan maak om te sluk of asem te haal, veluitslag, gejuuk, of floutes. Hierdie is baie ernstige nuwe-effekte. Indien u dit het, mag u 'n ernstige allergiese reaksie teen LOCAL HEALTH L. REUTERI gehad het. U mag dringende mediese bystand of hospitalisasie nodig hê.

Minder dikwels: epigastriese ongemak, buikpyn, dispepsie, rommelende maag, opgeblansheid, diarree, winde opbreek.

Lig asseblief u dokter of apteker in indien u enige nuwe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.

Rapportering van nuwe-effekte

Praat met u dokter of apteker as u nuwe-effekte ervaar. U kan ook nuwe-effekte by SAHPRA aanmeld via die "6.04 Adverse Drug Reactions Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies: <http://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van LOCAL HEALTH L. REUTERI.

5. Hoe om LOCAL HEALTH L. REUTERI te bêre

- Beskerm teen vog en bêre by of onder 25 °C.
- HOU BUITE BEREIK VAN KINDERS.
- Bêre die stulpstrokke in die buitenste kartonhouer.
- Moenie gebruik na die vervaldatum op die etiket nie.
- Neem alle ongebruikte LOCAL HEALTH L. REUTERI na u apteker terug.
- Moenie ongebruikte LOCAL HEALTH L. REUTERI in afvoertype of rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat LOCAL HEALTH L. REUTERI bevat

Elke koubare tablet bevat:

Lactobacillus reuteri 200 Miljoen KVE (Kolonievormende Eenhede)
Ander bestanddele: sorbitol, xylitol, natriumsiklamaat en acesulfame-K mengsel, watervrye sitroensuur, geurmiddel, isomalt, magnesiumstearaat.

Bevat suiker: sorbitol (75 mg) en xylitol (35 mg) per koubare tablet.
Bevat versoeter: natriumsiklamaat en acesulfame-K mengsel (0,7 mg) per koubare tablet.

Aanbieding en identifikasie van LOCAL HEALTH L. REUTERI

Klein, ronde, wit gespikkelde koubare tablette met 'n aarbeigursel, in PVC / foelie stulpstrokke van 10, verpak in 'n buitenste karton.

Verpakkingsgrootte: 10 tablette.

Houer van Registrasiesertifikaat

Vervaardig vir: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, Suid Afrika, 1685
Sorglyn: 011 589 2729; careline@cjdsa.com; www.localhealth.co.za

Hierdie pamflet is laas hersien in

Sal met registrasie deur SAHPRA toegeken word.

Registrasienommer

Sal met registrasie deur SAHPRA toegeken word.