

PROFESSIONAL INFORMATION

Complementary Medicine: Health Supplement

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

LOCAL HEALTH APPLE CIDER VINEGAR (vegetable capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegetable capsules contains:

Apple Cider Vinegar [as <i>Malus pumila</i> Mill. standardised to 7% apple acid]	500 mg
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Sugar free

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules.

Clear, size 00 vegetable capsules containing a white powder.

LOCAL HEALTH APPLE CIDER VINEGAR contains herbal extracts which may vary in colour and taste from batch to batch.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

LOCAL HEALTH APPLE CIDER VINEGAR is a complementary medicine that:

- Provides a source of antioxidants.
- Supports healthy metabolism.

4.2 Posology and method of administration

Adults 18 years and older:

Take one vegetable capsule twice per day, before a meal, or as directed by your healthcare provider.

Do not exceed the recommended dosage.

Method of administration

For oral use.

4.3 Contraindications

- Hypersensitivity to the active ingredients or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

- Patients should take special care with LOCAL HEALTH APPLE CIDER VINEGAR if they are currently taking any medication or if they are suffering from a medical condition.
- Patients with gastroparesis or hypokalaemia.

4.5 Interaction with other medicines and other forms of interaction

Not all possible interactions are listed in this leaflet. All medicines, including complementary and traditional medicines, should be considered while using LOCAL HEALTH APPLE CIDER VINEGAR.

- **Digoxin:** concomitant use of apple cider vinegar with digoxin might increase the risk of cardiac toxicity.
- **Diuretics:** concomitant use of apple cider vinegar with potassium-depleting diuretics may increase the risk of hypokalaemia.
- **Insulin:** concomitant use of apple cider vinegar with insulin might increase the risk of hypokalaemia.

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

Patients should exercise caution before driving or operating machinery until they are reasonably certain LOCAL HEALTH APPLE CIDER VINEGAR does not adversely affect their performance.

4.8 Undesirable effects

LOCAL HEALTH APPLE CIDER VINEGAR is generally well tolerated.

Renal and urinary disorders

Less frequent: hypokalaemia.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

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

5.1 Pharmacodynamic properties

Category and class: Category D 34.13 Other. Complementary Medicine: Health Supplement.

Apple cider vinegar is fermented juice from crushed apples. Like apple juice, it likely contains some pectin, vitamin B1, B2, and B6, biotin, folic acid, niacin, pantothenic acid, and vitamin C. It also contains small amounts of sodium, phosphorous, potassium, calcium, iron, and magnesium. Apple cider vinegar can also contain significant quantities of acetic acid and citric acid. Apple cider vinegar has antioxidant activity. Some research suggests that apple cider vinegar can increase satiety and/or energy expenditure.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on LOCAL HEALTH APPLE CIDER VINEGAR.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule:

Hydroxypropyl methyl cellulose
Gellan gum
Water

Capsule contents:

Microcrystalline cellulose
Silicon dioxide
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 a dry place away from direct sunlight and moisture.
Store in the original package until required for use.

6.5 Nature and contents of container

250 ml white PET bottle with a white screw-on cap, with an induction seal, containing a sponge and silica gel sachet.
Pack size: 60 vegetable capsules.

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@cjdsa.com
010 589 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: S0

LOCAL HEALTH APPLE CIDER VINEGAR (vegetable capsules)
Apple Cider Vinegar (as *Malus pumila* Mill. standardised to 7% apple acid)
Sugar free

Complementary Medicine: 34.13 Other (Health Supplement)

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

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

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

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

What is in this leaflet

1. What LOCAL HEALTH APPLE CIDER VINEGAR is and what it is used for
2. What you need to know before you use LOCAL HEALTH APPLE CIDER VINEGAR
3. How to use LOCAL HEALTH APPLE CIDER VINEGAR
4. Possible side effects
5. How to store LOCAL HEALTH APPLE CIDER VINEGAR
6. Contents of the pack and other information

1. What LOCAL HEALTH APPLE CIDER VINEGAR is and what it is used for

LOCAL HEALTH APPLE CIDER VINEGAR is a health supplement that:

- Provides a source of antioxidants.
- Supports healthy metabolism.

2. What you need to know before you use LOCAL HEALTH APPLE CIDER VINEGAR

Do not use LOCAL HEALTH APPLE CIDER VINEGAR:

- If you are hypersensitive (allergic) to any of the active ingredients or any of the other ingredients of LOCAL HEALTH APPLE CIDER VINEGAR (listed in section 6).

Warnings and precautions

Take special care:

- If you have a medical condition or if you are currently taking any other medicine.
- If you have gastroparesis (a condition also known as delayed gastric emptying) or hypokalaemia (low levels of potassium in your blood).

Children and adolescents

Not suitable for individuals 18 years and younger.

Other medicines and LOCAL HEALTH APPLE CIDER VINEGAR

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

Tell your doctor or pharmacist before taking LOCAL HEALTH APPLE CIDER VINEGAR if you are currently using:

- **Digoxin:** concomitant use of apple cider vinegar with digoxin might increase the risk of cardiac toxicity.
- **Diuretics:** concomitant use of apple cider vinegar with potassium-depleting diuretics may increase the risk of hypokalaemia (low levels of potassium in your blood).
- **Insulin:** concomitant use of apple cider vinegar with insulin might increase the risk of hypokalaemia (low levels of potassium in your blood).

LOCAL HEALTH APPLE CIDER VINEGAR with food and drink

LOCAL HEALTH APPLE CIDER VINEGAR has no known interaction with food and drink.

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 APPLE CIDER VINEGAR.

Driving and using machinery

LOCAL HEALTH APPLE CIDER VINEGAR has no known effect on the ability to drive or use machines. However, patients should be careful until they are reasonably certain that LOCAL HEALTH APPLE CIDER VINEGAR does not adversely affect their performance.

3. How to use LOCAL HEALTH APPLE CIDER VINEGAR

Do not share medicines with any other person.

Always use LOCAL HEALTH APPLE CIDER VINEGAR exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults 18 years and older

Take one vegetable capsule twice per day, before a meal, or as directed by your healthcare provider.

Do not exceed the recommended dosage.

If you take more LOCAL HEALTH APPLE CIDER VINEGAR than you should

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the remaining capsules with you so the doctor will know what you have taken.

If you forget to take LOCAL HEALTH APPLE CIDER VINEGAR

Do not take a double dose to make up for individual forgotten doses.

4. Possible side effects

LOCAL HEALTH APPLE CIDER VINEGAR can have side effects.

Not all side effects reported for LOCAL HEALTH APPLE CIDER VINEGAR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LOCAL HEALTH APPLE CIDER VINEGAR, please consult your healthcare provider for advice.

If any of the following happens, stop using LOCAL HEALTH APPLE CIDER VINEGAR and tell your doctor 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 all very serious side effects. If you have them, you may have had a serious allergic reaction to LOCAL HEALTH APPLE CIDER VINEGAR. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- Hypokalaemia (low levels of potassium in your blood).

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, inform your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of LOCAL HEALTH APPLE CIDER VINEGAR.

5. How to store LOCAL HEALTH APPLE CIDER VINEGAR.

- Store at or below 25 °C in a dry place away from moisture and direct sunlight.
- Store all medicines out of reach of children.
- Store in the original packaging until required for use.
- Do not use after the expiry date stated on the packaging.
- 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 LOCAL HEALTH APPLE CIDER VINEGAR contains

Each vegetable capsule contains:

Apple Cider Vinegar 500 mg

[as *Malus pumila* Mill. standardised to 7% apple acid]

The other ingredients are the vegetable capsule (hydroxypropyl methyl cellulose, gellan gum, water), microcrystalline cellulose, silicon dioxide, magnesium stearate.

Sugar free

What LOCAL HEALTH APPLE CIDER VINEGAR looks like and contents of the pack

Clear, size 00 vegetable capsules containing a white powder, packed in a 250 ml white PET bottle with a white screw-on cap, with an induction seal, containing a sponge and silica gel sachet.

LOCAL HEALTH APPLE CIDER VINEGAR contains herbal extracts which may vary in colour and taste from batch to batch. Pack size: 60 vegetable capsules.

Holder of Certificate of Registration

Manufactured for: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, South Africa, 1685

Careline: 010 589 2729; careline@cjdsa.com; www.localhealth.co.za

This pamphlet was last revised in

October 2024.

Registration number

Will be allocated by SAHPRA upon registration.

PASIËNTINLIGTINGSBLAD
SKEDULERINGSSTATUS: S0

LOCAL HEALTH APPLE CIDER VINEGAR (groentekapsules)
Appelasyn (as *Malus pumila* Mill. gestandaardiseer tot 7% appelsuur)
Suikervry

Komplementêre Medisyne: 34.13 Ander (Gesondheidsaanvulling)

Hierdie ongeregistreerde medisyne is nie deur SAHPRA vir gehalte, veiligheid of beoogde gebruik geëvalueer nie.

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

LOCAL HEALTH APPLE CIDER VINEGAR is beskikbaar sonder 'n dokter se voorskrif, om jou gesondheid te handhaaf. Nietemin moet LOCAL HEALTH APPLE CIDER VINEGAR versigtig gebruik word ten einde die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit kan nodig wees dat jy dit weer lees.
- Moenie LOCAL HEALTH APPLE CIDER VINEGAR met enige ander persoon deel nie.
- Vra jou gesondheidsorgverskaffer of apteker indien jy meer inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat is LOCAL HEALTH APPLE CIDER VINEGAR en waarvoor word dit gebruik
2. Wat jy moet weet voordat jy LOCAL HEALTH APPLE CIDER VINEGAR gebruik
3. Hoe om LOCAL HEALTH APPLE CIDER VINEGAR te gebruik
4. Moontlike newe-effekte
5. Hoe om LOCAL HEALTH APPLE CIDER VINEGAR te bêre
6. Inhoud van die pak en ander inligting

1. Wat is LOCAL HEALTH APPLE CIDER VINEGAR en waarvoor word dit gebruik

LOCAL HEALTH APPLE CIDER VINEGAR is 'n gesondheidsaanvulling wat:

- 'n Bron van antioksidante verskaf.
- Gesonde metabolisme ondersteun.

2. Wat jy moet weet voordat jy LOCAL HEALTH APPLE CIDER VINEGAR gebruik

Moenie LOCAL HEALTH APPLE CIDER VINEGAR neem nie:

- Indien jy hipersensitief (allergies) is vir enige van die aktiewe bestanddele of vir enige van die ander bestanddele van LOCAL HEALTH APPLE CIDER VINEGAR (gelys in afdeling 6).

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg:

- Indien jy 'n mediese toestand het of as jy tans enige ander medisyne gebruik.
- Indien jy gastropareses ('n toestand wat ook bekend staan as vertraagde maaglediging) of hipokalemie (lae vlakke van kalium in jou bloed) het.

Kinders en adolessente

Nie geskik vir individue 18 jaar en jonger nie.

Ander medisyne en LOCAL HEALTH APPLE CIDER VINEGAR

Lig altyd jou gesondheidsorgverskaffer in indien jy 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 gesondheidsorgverskaffer voor gebruik indien jy enige ander medikasie neem.

Lig jou dokter of apteker in voordat jy LOCAL HEALTH APPLE CIDER VINEGAR neem indien jy tans enige van die volgende neem:

- **Digoksien:** gelyktydige gebruik van appelasyn met digoksien kan die risiko van kardiaale toksisiteit verhoog.
- **Diuretika:** gelyktydige gebruik van appelasyn met kalium-afbrekende diuretika kan die risiko van hipokalemie (lae vlakke van kalium in jou bloed) verhoog.
- **Insulien:** gelyktydige gebruik van appelasyn met insulien kan die risiko van hipokalemie (lae vlakke van kalium in jou bloed) verhoog.

LOCAL HEALTH APPLE CIDER VINEGAR met kos en drinkgoed

Gebruik LOCAL HEALTH APPLE CIDER VINEGAR het geen bekende interaksie met kos of drinkgoed nie.

Swangerskap, borsvoeding en vrugbaarheid

Indien jy swanger is of borsvoed, vermoed dat jy swanger is of beplan om 'n baba te hê, raadpleeg jou dokter, apteker of ander gesondheidsorgpraktisyn vir advies voordat jy LOCAL HEALTH APPLE CIDER VINEGAR gebruik.

Bestuur en die gebruik van masjinerie

LOCAL HEALTH APPLE CIDER VINEGAR het geen bekende uitwerking op die vermoë om te bestuur of masjiene te gebruik nie. Pasiënte moet egter versigtig wees totdat hulle redelik seker is dat LOCAL HEALTH APPLE CIDER VINEGAR nie hul werkverrigting nadelig beïnvloed nie.

3. Hoe om LOCAL HEALTH APPLE CIDER VINEGAR te gebruik

Moenie medisyne met enige ander persoon deel nie.

Gebruik LOCAL HEALTH APPLE CIDER VINEGAR altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat jou dokter of apteker vir jou aangewys het. Vra gerus jou dokter of apteker indien jy onseker is.

Volwassenes 18 jaar en ouer

Neem een kapsule twee keer per dag, voor etes, of soos aanbeveel deur jou gesondheidsorgverskaffer.

Moenie die aanbevole daaglikse dosis oorskry nie.

Wat om te doen indien jy meer LOCAL HEALTH APPLE CIDER VINEGAR geneem het as wat jy moet

In die geval van 'n oordosis, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gisentrum. Neem hierdie inligtingsblad en die res van die kapsules saam sodat die dokter weet wat jy geneem het.

Indien jy vergeet het om LOCAL HEALTH APPLE CIDER VINEGAR te neem

Moenie 'n dubbele dosis neem om op te maak vir die individuele dosisse wat oorgestaan is nie.

4. Moontlike newe-effekte

LOCAL HEALTH APPLE CIDER VINEGAR kan newe-effekte hê.

Nie alle newe-effekte wat vir LOCAL HEALTH APPLE CIDER VINEGAR gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte onderwring terwyl LOCAL HEALTH APPLE CIDER VINEGAR geneem word, raadpleeg asseblief jou gesondheidsverskaffer.

Indien jy enige van die volgende ervaar, hou op om LOCAL HEALTH APPLE CIDER VINEGAR te neem en sê dadelik vir jou dokter of gaan na die ongevalle-afdeling by jouse naase hospitaal:

- swelling van jou hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak met sluk en asemhaling;
- uitslag of gejeuk;
- floute.

Hierdie is baie ernstige newe-effekte. Indien jy dit het, mag jy 'n ernstige allergiese reaksie op LOCAL HEALTH APPLE CIDER VINEGAR gehad het. Jy mag dringende mediese bystand of hospitalisasie benodig.

Sê vir jou dokter indien jy enige van die volgende opmerk:

- Hipokalemie (lae vlakke van kalium in jou bloed).

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genome word nie, lig asseblief jou dokter of apteker in.

Rapportering van newe-effekte

Indien jy newe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety APP (Medsafety X SAHPRA) en eReporting platform (whoumc.org) wat op die SAHPRA-webwerf gevind word. Deur newe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van LOCAL HEALTH APPLE CIDER VINEGAR te verskaf.

5. Hoe om LOCAL HEALTH APPLE CIDER VINEGAR te bêre

- Bêre by of onder 25 °C in 'n droë plek weg van vog en direkte sonlig.
- Bêre alle medisyne buite bereik van kinders.
- Bêre in die oorspronklike verpakking tot benodig word vir gebruik.
- Moenie gebruik na die vervaldatum op die verpakking nie.
- Neem alle ongebruikte medisyne na u apteker terug.
- Moenie ongebruikte medisyne in afvoerpype of rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat LOCAL HEALTH APPLE CIDER VINEGAR bevat

Elke groentekapsule bevat: 500 mg

Appelasyn 500 mg

[as *Malus pumila* Mill. gestandaardiseer tot 7% appelsuur]

Die ander bestanddele is die groentekapsule (hidroksipropielmetielsellulose, gellangom, water), mikrokristallyne sellulose, silikondioksied, magnesiumstearaat.

Suikervry

Hoe LOCAL HEALTH APPLE CIDER VINEGAR lyk en inhoud van die verpakking

Deursigtige, grootte 00 groentekapsules wat 'n wit poeier bevat, verpak in 'n 250 ml wit PET-bottel met 'n wit skroefdoop, met 'n induksie seël, wat 'n spons en silikagel sakkie bevat.

LOCAL HEALTH APPLE CIDER VINEGAR bevat kruie-ekstrakte wat in kleur en smaak van lot tot lot kan verskil.

Verpakkingsgrootte: 60 groentekapsules.

Houer van Registrasiesertifikaat

Vervaardig vir: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, Suid Afrika, 1685

Sorglyn: 010 589 2729; careline@cjdsa.com; www.localhealth.co.za

Hierdie pamflet is laas hersien in

Oktober 2024.

Registrasienuommer

Sal met registrasie deur SAHPRA toegeken word.