

PROFESSIONAL INFORMATION

SCHEDULING STATUS:

Not scheduled.

PROPRIETARY NAME AND DOSAGE FORM:

32931 P4

USN APPLE CIDER VINEGAR

(capsules)

COMPOSITION:**Active ingredients:**

Each capsule contains:
 Apple cider vinegar powder
 Chromium picolinate
 Of which chromium
 Gotu Kola (*Centella asiatica*) powder

300 mg
 100 µg
 12 µg
 10 mg

Inactive ingredients: Bovine gelatine capsules, corn starch, magnesium stearate, silicon dioxide.

Sugar Free

CATEGORY AND CLASS:
D 32.3 Slimming preparations**PHARMACOLOGICAL ACTION:**

Apple cider vinegar powder: Apple cider vinegar may significantly increase postprandial insulin sensitivity and reduces postprandial flux in insulin levels. Apple cider vinegar can also affect glucose levels by delaying the gastric emptying rating. Acetic acid in vinegar also seems to suppress disaccharidase activity and increase glucose-6-phosphate levels in skeletal muscle. Therefore, it might also work by preventing the breakdown of carbohydrates into sugars. Apple cider vinegar with "the mother" is simply unrefined, unpasteurized and unfiltered apple cider vinegar. The "mother" contains some enzymes, strands of proteins, minerals and probiotics that may be beneficial to your health.

Chromium: Contributes to the maintenance of normal blood glucose levels. Chromium's mechanism for decreasing insulin resistance is due to an improved first phase of secretion of insulin or facilitated post-receptor insulin sensitivity as a way of potentiating the action of insulin. Therefore, taking chromium before a high carbohydrate meal seems to lessen postprandial hyperglycaemia. Chromium picolinate may also reduce fat cravings and hunger by affecting the brain's hunger receptor. This is due to the fact that chromium might sensitise insulin-sensitive glucoreceptors in the brain, resulting in appetite suppression, stimulation of thermogenesis and down-regulation of insulin secretion.

Gotu Kola (*Centella asiatica*) powder: Gotu Kola may have a positive cognitive effect by binding to cholecystokinin (CCK) and GABA receptors, which might be responsible for reported anxiolytic effects of Gotu Kola.

INDICATIONS:**USN APPLE CIDER VINEGAR** is indicated as an aid to a weight management programme that includes a balanced, energy-restricted diet and regular exercise.**CONTRAINDICATIONS:**

This product is contraindicated for individuals that are hypersensitive (allergic) to any of the listed ingredients.

Not for use in persons under the age of 18 years.

Do not use if you are pregnant or lactating.

WARNINGS AND SPECIAL PRECAUTIONS:

- Use with caution in patients with diabetes. **USN APPLE CIDER VINEGAR** can influence blood sugar levels in diabetic patients; monitor closely. Dose adjustments to antidiabetic medication might be necessary.
- Use with caution in patients with liver disease; **USN APPLE CIDER VINEGAR** might exacerbate liver problems in patients with existing liver diseases such as hepatitis.
- Use with caution in patients with hypokalaemia; apple cider vinegar might cause potassium loss and worsen hypokalaemia.
- Use with caution in patients with behavioural and psychiatric disorders; chromium picolinate in **USN APPLE CIDER VINEGAR** might affect these conditions by altering serotonin, dopamine and norepinephrine metabolism in the central nervous system.
- Use with caution in patients with renal dysfunction, as chromium might exacerbate renal disease.
- Discontinue at least two weeks before elective surgery. Due to Gotu Kola's depressant effects on the central nervous system (**CNS**), **USN APPLE CIDER VINEGAR** might interfere with surgical procedures by causing additive CNS depression when combined with anaesthesia and other medications during and after surgical procedures.

INTERACTIONS:

- **Antidiabetic medicine:** Concomitant use of **USN APPLE CIDER VINEGAR** and antidiabetic medicine might interfere with blood glucose control and increase the risk of hypoglycaemia. Consult your doctor before using. Antidiabetic medicine includes glimepiride, insulin, metformin, and others.
- **Digoxin:** Apple cider vinegar could decrease potassium levels, increasing the risk of toxicity for cardiovascular medicine such as digoxin.
- **Diuretic medicine:** The use of apple cider vinegar along with potassium-depleting diuretics might have an increased risk for hypokalaemia. Some diuretics that can deplete potassium include furosemide, hydrochlorothiazide, chlorothalidone, and others.
- **Levothyroxine:** Chromium might bind to levothyroxine in the intestinal tract and decrease levothyroxine absorption. Take levothyroxine at least 30 minutes before or 3 to 4 hours after taking **USN APPLE CIDER VINEGAR**.
- **Depressants of the central nervous system (CNS):** Concomitant use of Gotu Kola with medicine with sedative properties might cause additive effects and side effects. Some sedative medicine includes clonazepam, lorazepam, zolpidem, and others.
- **Hepatotoxic medicine:** Gotu Kola might exacerbate liver problems in patients with existing liver diseases such as hepatitis. Concomitant use with other potentially hepatotoxic medicine might increase the risk of developing liver damage. Some of these medicines include amiodarone, atorvastatin, carbamazepine, diclofenac, and others.
- **Herbs and supplements with hypoglycaemic potential:** **USN APPLE CIDER VINEGAR** might reduce postprandial blood glucose levels. Concomitant use with other herbs and supplements that decrease blood glucose levels might increase the risk of hypoglycaemia. Some of these products include bitter melon, ginger, panax ginseng, fenugreek, willow bark, and others.
- **Herbs and supplements with sedative properties:** Concomitant use with herbs that have sedative properties might enhance therapeutic and adverse effects when used with **USN APPLE CIDER VINEGAR**. Some of these supplements include 5-HTP, St. John's Wort, valerian, and others.
- **Hepatotoxic herbs and supplements:** Gotu Kola might exacerbate liver problems in patients with existing liver diseases such as hepatitis. Concomitant use with other potentially hepatotoxic products might increase the risk of developing liver damage. Some of these products include androstenedione, DHEA, red yeast, and others.

HUMAN REPRODUCTION:Safety has not been established for use during pregnancy and lactation. Do not use **USN APPLE CIDER VINEGAR** if you are pregnant or lactating.**DOSAGE AND DIRECTIONS FOR USE:***Adults:* Take one capsule twice a day prior to meals.

Do not exceed the recommended daily dosage.

SIDE EFFECTS:The following side effects may be associated with the use of **USN APPLE CIDER VINEGAR**:

- **Immune system disorders:** Frequency unknown - Hypersensitivity and/or allergic reactions.
- **Endocrine disorders:** Frequency unknown - Hypoglycaemia, hypokalaemia, hyperreninaemia.
- **Psychiatric disorders:** Frequency unknown - Irritability, mood changes.
- **Nervous system disorders:** Frequency unknown - Dizziness, sleep disturbances, insomnia, headache, vertigo, paraesthesia, vague cognitive symptoms.
- **Gastrointestinal disorders:** Frequency unknown - Gastrointestinal irritation, flatulence, constipation, nausea, vomiting, diarrhoea, decreased appetite.
- **Hepato-biliary disorders:** Frequency unknown - Hepatotoxicity.
- **Skin and subcutaneous tissue disorders:** Frequency unknown - Skin rash, urticaria.

Should your general health worsen, or if you experience any untoward effects or allergic reactions while taking this medicine, please consult your doctor, pharmacist or other healthcare professional immediately.

KNOWN SYMPTOMS OF OVERDOSEAGE AND PARTICULARS OF ITS TREATMENT:

None known. If suspected overdose occurs, please consult your healthcare practitioner immediately. Treatment should be symptomatic and supportive.

IDENTIFICATION:

White gelatine capsules containing off-white powder with dark speckles.

PRESENTATION:

White HDPE plastic container with a white USN lid, containing 60 capsules.

STORAGE INSTRUCTIONS:

Store in a cool, dry place at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

To be allocated by the Authority.

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

USN Pty (Ltd)
 Building C, Southdowns Office Park, 2nd Floor
 21 Karee Street, Irene Ext 54
 0157
 Tel: 0861 111 876

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:

August 2014.

COMPLEMENTARY MEDICINE:

Discipline: Combination Product – Western Herbal Medicine.

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

SEL010/PI-PIL/B

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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

Not scheduled.

PROPRIETARY NAME AND DOSAGE FORM:



USN APPLE CIDER VINEGAR

(capsules)

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

USN APPLE CIDER VINEGAR is available without a doctor's prescription. Nevertheless, you still need to use USN APPLE CIDER VINEGAR carefully to get the best results from it.

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

1. WHAT USN APPLE CIDER VINEGAR CONTAINS:

Active ingredients:

Each capsule contains:	300 mg
Apple cider vinegar powder	100 µg
Chromium picolinate	12 µg
Of which chromium	
Gotu Kola (<i>Centella asiatica</i>) powder	10 mg

Inactive ingredients: Bovine gelatine capsules, corn starch, magnesium stearate, silicon dioxide.

Sugar Free

2. WHAT USN APPLE CIDER VINEGAR IS USED FOR:

USN APPLE CIDER VINEGAR is indicated as an aid to a weight management programme that includes a balanced, energy-restricted diet and regular exercise.

3. BEFORE YOU TAKE USN APPLE CIDER VINEGAR:

Do not take USN APPLE CIDER VINEGAR:

- If you are hypersensitive (allergic) to any of the active or inactive ingredients (see **WHAT USN APPLE CIDER VINEGAR CONTAINS**).
- If you are pregnant or breastfeeding your baby (see **Pregnancy and Breastfeeding**).
- If you are under 18 years of age.

Take special care with USN APPLE CIDER VINEGAR:

- If you have diabetes, USN APPLE CIDER VINEGAR can influence blood sugar levels. Dose adjustments to antidiabetic medicine might be necessary. Monitor closely.
- If you have a liver disease, USN APPLE CIDER VINEGAR might worsen liver damage in patients with existing liver disease. Use with caution.
- If you have hypokalaemia (low blood potassium levels), Apple cider vinegar might cause potassium loss and worsen this condition.
- If you have any behavioural or psychiatric disorder, Chromium picolinate might affect serotonin, dopamine and norepinephrine levels.
- If you have any renal dysfunction, as chromium might worsen kidney damage.
- If you are having elective surgery within two weeks. The depressant effects of Gotu Kola on the central nervous system (CNS) might interfere with surgical procedures when combined with anaesthesia and other medications during and after surgical procedures.

Taking USN APPLE CIDER VINEGAR with food and drink:

- USN APPLE CIDER VINEGAR should be taken prior to meals.

Pregnancy and Breastfeeding:

- Safety has not been established for use during pregnancy and breastfeeding. Avoid use.

Driving and using machinery:

It is unlikely that USN APPLE CIDER VINEGAR will affect your ability to drive a vehicle or operate machinery requiring your attention.

Taking other medicines with USN APPLE CIDER VINEGAR:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines).

If you are on any of the following medicine or treatment, you should discuss the use of USN APPLE CIDER VINEGAR with your doctor or pharmacist first:

- Antidiabetic medicine (such as glimepiride, insulin, metformin, etc.). Use of these medicines with USN APPLE CIDER VINEGAR might interfere with blood glucose control and increase the risk of low blood sugar.
- Digoxin, as apple cider vinegar could decrease potassium levels and increase the risk of toxicity for cardiovascular medicine such as digoxin.
- Potassium-depleting diuretics (such as furosemide, hydrochlorothiazide, chloralidone, etc.) used together with USN APPLE CIDER VINEGAR can increase the risk for developing low potassium levels (hypokalaemia).
- Levothyroxine, as chromium might bind to levothyroxine in the intestinal tract and decrease levothyroxine absorption. Take levothyroxine at least 30 minutes before or 3 to 4 hours after taking USN APPLE CIDER VINEGAR.
- Depressants of the central nervous system (CNS) (such as clonazepam, lorazepam, zolpidem, etc.), as the use of Gotu Kola with these medicines can have additive sedative effects.
- Hepatotoxic medicine (such as amiodarone, atorvastatin, carbamazepine, diclofenac, etc.) used with Gotu Kola in USN APPLE CIDER VINEGAR may worsen liver damage in patients with existing liver disease.
- Herbs and supplements with hypoglycaemic potential (such as bitter melon, ginger, panax ginseng, fenugreek, willow bark, etc.), as USN APPLE CIDER VINEGAR may reduce blood glucose levels and the use of USN APPLE CIDER VINEGAR with these supplements can increase the risk of developing hypoglycaemia (low blood sugar).
- Herbs and supplements with sedative properties (such as 5-HTP, St. John's Wort, valerian, etc.) might have additive sedative effects when used with USN APPLE CIDER VINEGAR.
- Hepatotoxic herbs and supplements (such as androstenedione, DHEA, red yeast, etc.), as Gotu Kola in USN APPLE CIDER VINEGAR might worsen liver damage in patients with existing liver disease when used together with these supplements.

4. HOW TO TAKE USN APPLE CIDER VINEGAR:

Do not share medicines prescribed for you with any other person. Always take USN APPLE CIDER VINEGAR exactly as directed. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

- Adults: Take one capsule twice a day prior to meals.
Do not exceed the recommended daily dosage.

If you take more USN APPLE CIDER VINEGAR than you should:

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

If you forget to take USN APPLE CIDER VINEGAR:

Take the missed dose as soon as you remember. If it is almost time for your next dose, do not take the missed dose but simply take your next dose at the normal time.

Do not take a double dose to make up the one you missed.

5. POSSIBLE SIDE EFFECTS:

- USN APPLE CIDER VINEGAR can have side effects.
- Not all side effects reported for USN APPLE CIDER VINEGAR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your health care provider for advice.
- If any of the following happens, stop taking USN APPLE CIDER VINEGAR and tell your doctor immediately or go to the casualty department at your nearest hospital:
 - Swelling of your hands, feet, ankles, face, lips, 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 USN APPLE CIDER VINEGAR. You may need urgent medical attention or hospitalisation.

• Tell your doctor as soon as possible if you notice any of the following:

- Low blood sugar.
- Dizziness.
- Increased irritability/mood changes.
- Insomnia (difficulty falling/staying asleep).
- Sleep disturbances.
- Headache.
- Vertigo (spinning sensation).
- Cognitive symptoms (slow thought processes).
- Burning/prickling sensation of the skin.
- Gastrointestinal irritation.
- Flatulence (gas), constipation.
- Nausea, vomiting.
- Diarrhoea.
- Decreased appetite.
- Raised, itchy rash (urticaria).

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

6. STORING AND DISPOSING OF USN APPLE CIDER VINEGAR:

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from light and moisture.
- Do not store in the bathroom.
- Store in original container.
- Keep the container tightly closed.
- Do not use after the expiry date stated on the container.
- Do not use USN APPLE CIDER VINEGAR if you notice visible signs of deterioration.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF USN APPLE CIDER VINEGAR:

White HDPE plastic container with a white USN lid, containing 60 capsules.

8. IDENTIFICATION OF USN APPLE CIDER VINEGAR:

White gelatine capsules containing off-white powder with dark speckles.

9. REGISTRATION NUMBER:

To be allocated by the Authority.

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

USN Pty (Ltd)
Building C, Southdowns Office Park, 2nd Floor
21 Kare Street, Irene Ext 54
0157
Tel: 0861 111 876

11. DATE OF PUBLICATION:

August 2014.

12. COMPLEMENTARY MEDICINE:

Discipline: Combination Product – Western Herbal Medicine.

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

PASIËNTINLIGTINGSBLAADJIE

SKEDULERINGSTATUS:

Nie geskeduleer nie.

HANDELSNAAM, STERKTE EN FARMASEUTIESE VORM:



USN APPLE CIDER VINEGAR

(capsules)

Lees die hele pamflet noukeurig deur, aangesien dit belangrike inligting vir u bevat.

USN APPLE CIDER VINEGAR is beskikbaar sonder 'n dokter se voorskrif. Nieemin moet u steeds USN APPLE CIDER VINEGAR versigtig gebruik om die beste resultate te verkry.

- Bewaar hierdie pamflet. U mag dit dalk weer moet lees.
- Moenie USN APPLE CIDER VINEGAR met enige ander persoon deel nie.
- Vra u apteker indien u verdere inligting of advies benodig.

1. WAT USN APPLE CIDER VINEGAR BEVAT:

Aktiewe bestanddele:

Elke kapsule bevat:	300 mg
Appelsyn poeier	100 µg
Chroompicolinaat	12 µg
Waarvan chroom	
Gotu Kola (<i>Centella asiatica</i>) poeier	10 mg

Onaktiewe bestanddele: Beesgelatienkapsules, magnesiumstearaat, mieliestysel, silikondioksied.

Suiker-vry

2. WAARVOOR USN APPLE CIDER VINEGAR GEBRUIK WORD:

USN APPLE CIDER VINEGAR word aangedui as 'n hulpmiddel in 'n gewigsbeheerprogram wat 'n gebalanseerde, energiebeperkte diëet en gereelde oefening insluit.

3. VOOR U USN APPLE CIDER VINEGAR NEEM:

Moenie USN APPLE CIDER VINEGAR neem:

- Indien u hypersensitiviteit (allergies) is vir enige van die aktiewe of onaktiewe bestanddele (sien **WAT USN APPLE CIDER VINEGAR BEVAT**).
- Indien u swanger is of u baba borsvoer (sien **Swangerskap en Borsvoeding**).
- Indien u jonger is as 18 jaar is.

Neem spesiale sorg met USN APPLE CIDER VINEGAR:

- Indien u 'n diëet is, kan USN APPLE CIDER VINEGAR bloedsuikervlakke beïnvloed. Dosisaanpassings ten opsigte van antidiabetiese medisyne mag nodig wees. Monitor noukeurig.
- Indien u aan 'n lewersiekte ly, USN APPLE CIDER VINEGAR mag lewerskade vererger in pasiënte met bestaande lewersiekte. Gebruik met omsigtigheid.
- Indien u aan hipokalemie ly (lae kaliumvlakke in die bloed). Appelsyn mag kaliumverlies veroorsaak en hierdie toestand vererger.
- Indien u aan enige gedrags- of psigiatrysche afwyking ly. Chroompicolinaat kan serotonien-, dopamien- en norepinefrinelvlakke beïnvloed.
- Indien u enige nierdisfunksie het, aangesien chroom nierskade mag vererger.
- Indien u binne twee weke elektive chirurgie ondergaan. Die onderdrukende effekte van Gotu Kola op die sentrale senuweestelsel (SSS) mag inmeng met chirurgiese prosedures wanneer gekombineer word met harkose en ander medikasies gedurende en na chirurgiese prosedures.

Neem van USN APPLE CIDER VINEGAR met voedsel en drank:

- USN APPLE CIDER VINEGAR moet verkiessel vir maaltye geneem word.

Swangerskap en Borsvoeding:

- Die veiligheid van die gebruik van hierdie produk tydens swangerskap en borsvoeding is nie vasgestel nie. Verminder gebruik.

Bestuur en gebruik van masjienerie:
Dit is onwaarskynlik dat USN APPLE CIDER VINEGAR u vermoë sal beïnvloed om 'n voertuig te bestuur of masjienerie te gebruik wat u aandag verga.

Die neem van ander medikasie saam met USN APPLE CIDER VINEGAR:

Stel altyd u gesondheidsorgdeskundige daarvan in kennis indien u enige ander medikasie gebruik.

(Dit sluit aanvullende of tradisionele medikasies in).

Indien u enige van die volgende medisyne gebruik of behandeling ondergaan, bespreek eers die gebruik van USN APPLE CIDER VINEGAR met u dokter of apteker:

- Antidiabetiese medisyne (soos glimepiride, insulien, metformien, ens.). Gebruik van hierdie medisyne saam met USN APPLE CIDER VINEGAR mag inmeng met bloedglukosebeheer en die risiko van lae bloedsuiker verhoog.
- Digoksin, aangesien appelsyn kaliumvlakke kan verlaag en die risiko van toksisiteit vir kardiovaskulêre medisyne soos digoksin verhoog.
- Kaliumuitputtende diureties (soos furosemide, hidrochlorothiazide, chloortalidon, ens.) gebruik saam met USN APPLE CIDER VINEGAR, kan die risiko vir lae kaliumvlakke (hipokalemie) verhoog.
- Leviotriksien, aangesien chroom aan levotriksien mag bind in die spysverteringskanaal en levotriksienabsorpsie mag verminder. Neem levotriksien ten minste 30 minute voor of 3 tot 4 ure na USN APPLE CIDER VINEGAR neem.
- Onderdrukkers van die sentrale senuweestelsel (SSS) (soos klonasepam, lorasepam, zolpidem, ens.), aangesien die gebruik van Gotu Kola saam met hierdie medisyne 'n additiewe sedatieve uitwerking kan hé.
- Hepatotoksiese medisyne (soos amiodarone, atorvastatin, karbamepien, diklofenak, ens.) gebruik saam met Gotu Kola in USN APPLE CIDER VINEGAR mag lewerskade vererger in pasiënte met bestaande lewersiekte.
- Kruie en aanvullings met hipoglykemiese potensiaal (soos bitterkomkommer, gemmer, panax ginseng, fenegriek, wilgerbas, ens.), aangesien USN APPLE CIDER VINEGAR bloedglukosevlakke mag verlaag en die gebruik van USN APPLE CIDER VINEGAR saam met hierdie aanvullings die risiko van hipoglykemie (lae bloedsuiker) mag verhoog.
- Kruie en aanvullings met kalmerende eienskappe (soos 5-HTP, Sint Janskruid, valeriaan, ens.) mag 'n additiewe sedatieve uitwerking hé w