

# APPLE CIDER VINEGAR

## PROFESSIONAL INFORMATION

### D 33.7 Combination product. Complementary Medicine

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

**BIOGEN APPLE CIDER VINEGAR (vegetable capsules)**

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegetable capsule contains:

Apple Cider Vinegar [from <i>Malus pumila</i> Mill. fruit, 7% apple acid]	300,00 mg
<i>Zingiber officinal</i> (Ginger) [Root,4:1 extract providing 100,00 mg dried herb equivalent]	25,00 mg
Curcumin C <sub>3</sub> Complex® <i>Curcuma longa</i> L. (Turmeric) [Rhizome, 50:1 extract providing 1 000,00 mg dried herb equivalent]	20,00 mg
BioPerine® <i>Piper nigrum</i> L. (Black Pepper) [Fruit, 50:1 extract standardised to 95 % piperine]	2,50 mg

Sugar Free

For a full list of excipients, see section 6.1.

#### 3. PHARMACEUTICAL FORM

Vegetable Capsules.

#### 4. CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

BIOGEN APPLE CIDER VINEGAR, with Curcumin C<sub>3</sub> Complex®, Ginger and BioPerine®, to boost your metabolism and supports healthy digestion.

##### 4.2 Posology and method of administration

**Adults:** Take 1 (one) vegetable capsule twice per day before a meal, or as recommended by your healthcare provider. The safety and efficacy of BIOGEN APPLE CIDER VINEGAR in children younger than 18 years has not yet been established. Not allowed in children under 18 years.

##### 4.3 Contraindications

- If you have a hypersensitivity to the ingredients or any of the excipients listed in 6.1.

##### 4.4 Special warnings and precautions for use

Special care should be taken with BIOGEN APPLE CIDER VINEGAR.

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine.

Please take note of the following:

- Consult a healthcare provider prior to use if you have gallstones, a bile duct obstruction, stomach ulcers or excess stomach acid.
- Consult a healthcare provider if symptoms persist or worsen.
- Consult a healthcare provider prior to use if you are pregnant or breastfeeding.

Nutritional supplementation should not replace a balanced diet.

Do not exceed the recommended dose without consulting a healthcare provider.

##### 4.5 Interaction with other medicines and other forms of interaction

###### Interactions with Medicines

- Concomitant use of apple cider vinegar, ginger, turmeric and black pepper extract with antidiabetic medicine might increase the risk of hypoglycemia.
- Concomitant use of apple cider vinegar with digoxin might increase the risk of cardiac toxicity.
- Concomitant use of apple cider vinegar with diuretic and insulin medicine might increase the risk of hypokalemia.
- Turmeric has antioxidant effects, this may reduce the activity of chemotherapy medicine that generate free radicals.
- Taking turmeric with amlodipine may increase levels of amlodipine.
- Turmeric, ginger and black pepper may have antiplatelet effects and may increase the risk of bleeding if used with anticoagulant or antiplatelet medicine.
- Turmeric might increase the risk of liver damage when taken with hepatotoxic medicine.

###### Interactions with Diseases/Impairments

- Excessive doses of apple cider vinegar powder may worsen gastric emptying, cause potassium loss and worsen hypokalemia.
- Turmeric can cause gallbladder contractions, patients with gallstones or gallbladder disease are advised to use with caution.
- Turmeric might have mild estrogenic effects, which could theoretically exacerbate hormone-sensitive conditions.
- Ginger and turmeric might increase the risk of bleeding and bruising in individuals with bleeding disorders.
- Excessive doses of ginger might worsen some heart conditions, do not exceed the recommended dosage.
- Ginger has antiplatelet and hypoglycemic effects, which might cause excessive bleeding or interfere with blood glucose control if used perioperatively. Patients are advised to discontinue ginger at least 2 weeks before elective surgical procedures.

###### Interactions with Foods

- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing /suggesting BIOGEN APPLE CIDER VINEGAR.

##### 4.6 Fertility, pregnancy and lactation

Safety in fertility, pregnancy and lactation has not been established (see section 4.3).

##### 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 BIOGEN APPLE CIDER VINEGAR does not adversely affect their performance.

##### 4.8 Undesirable effects

Orally, the ingredients is well-tolerated.

##### Summary of adverse reactions

Gastrointestinal disorders:

*Frequent:* Burning aftertaste, dyspepsia, and reduced taste perception, constipation, flatulence and yellow, hard stools, nausea and vomiting, diarrhea or loose stool, dyspepsia, gastritis, distension and gastroesophageal reflux disease, abdominal fullness and pain, epigastric burning, and tongue staining.

Nervous system disorders:

*Frequent:* Sedation, drowsiness, or dizziness

##### 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. Health care 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

##### 5.1 Pharmacodynamic properties

Mechanism of action:

*Curcumin*, the major active constituents are the curcuminoids. Curcumin may have a beneficial effect in obesity through down regulation of Janus kinase, which is thought to have a role in the pathogenesis of obesity, and inhibition of an enzyme that activates cortisol in adipocytes, playing a role in central obesity.

*Apple cider vinegar powder*, taking apple cider vinegar daily for 12 weeks was associated with an increase in high-density lipoprotein (HDL) cholesterol and a decrease in triglyceride levels, but with no change in low-density lipoprotein (LDL) cholesterol levels or the LDL/HDL ratio

*Ginger*, the rhizome the active constituent of ginger include gingerol, gingerdione, shogaol, and sesquiterpene and monoterpene volatile oils. These constituents seem to have a variety of pharmacological properties including antipyretic, analgesic, antitussive, anti-inflammatory, sedative, antibiotic, weak antifungal, and other properties.

*Black pepper extract*, black pepper is said to influence metabolic function and have lipolytic activity.

##### 5.2 Pharmacokinetic properties

Apple cider vinegar powder:

*Absorption /Distribution/ Metabolism/ Excretion:* There is insufficient reliable information available about the pharmacokinetics of apple cider vinegar.

Curcumin:

*Absorption:* Curcumin absorption appears to increase when taken with food or piperine.

*Metabolism:* Curcumin undergoes significant metabolism in the liver and intestines, contributing to low oral bioavailability.

*Excretion:* Curcumin is present in the feces following consumption of an extract.

Ginger:

*Absorption:* Maximum concentrations occur at 40-80 minutes, with undetectable levels at most time points later than 24 hours.

*Distribution:* Their metabolites lacked evidence of accumulation in plasma or colon tissues following multiple daily doses.

*Excretion:* Metabolism: Conjugates of the gingerols and 6-shogaol are usually glucuronide or sulfate conjugates, and not mixed conjugates.

*Metabolism:* At one hour after administration peak plasma concentrations is achieved.

*Elimination:* The half-life of 6-gingerol, 8-gingerol, 10-gingerol, and 6-shogaol has been estimated to be 0.5-3 hours.

Black pepper:

*Absorption /Distribution/ Metabolism/ Excretion:* There is insufficient reliable information available about the pharmacokinetics of black pepper.

Distribution/ Metabolism/ Excretion:

No clinical data are available on the effects of BIOGEN APPLE CIDER VINEGAR.

#### 6. PHARMACEUTICAL PARTICULARS

##### 6.1 List of excipients

- Microcrystalline Cellulose, Magnesium stearate.

##### 6.2 Incompatibilities

No compatibility studies has been performed, BIOGEN APPLE CIDER VINEGAR must not be mixed with other medications.

##### 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

250 ml white PET container with a Biogen cap.

Pack size: 60 capsules.

##### 6.6 Special precautions for disposal

No special requirements.

#### 7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen  
23 Stag Rd,  
Glen Austin, South Africa.  
info@biogen.co.za  
www.biogen.co.za  
086 034 7243.

#### 8. REGISTRATION NUMBER


Will be allocated by SAHPRA upon registration.

#### 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.

#### 10. DATE OF REVISION OF THE TEXT

March 2023.

<b>JOB:</b> BPS_Apple Cider Vinegar	<b>SIZE:</b> 270mm x 220mm
<b>STOCK:</b> Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input type="checkbox"/> Other: <input checked="" type="checkbox"/>	
<b>COLOURS:</b>  K	<b>FINISHING:</b> <input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Doming <input type="checkbox"/> Embossing
<b>PLEASE CHECK CAREFULLY</b> Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.	