



PROFESSIONAL INFORMATION

Scheduling Status: **SO**

1. Proprietary Name

Berberine Complex

2. Qualitative and Quantitative Composition

Each capsule contains the composition as per table 2.1 below.

2.1 Composition

Each capsule contains:

<i>Berberis aristata</i> (Berberine)	
(herb extract standardised to 97% Berberine HCL)	500 mg
<i>Cinnamomum verum</i> (Organic cinnamon) bark powder	120 mg
Other Ingredients: Milled Rice	

2.2 Sugar Free. Free from gelatine, dairy, soy, synthetic fillers, gluten, preservatives and artificial colourants. GMO-free and suitable for vegans.

2.3 For full list of excipients see section 7.1.

3. Pharmaceutical Form

60 white size 00 capsules containing tan coloured powder.

4. Clinical Information

4.1 Indications for Use

May assist in balancing blood sugar levels, aiding in weight management. May support hormonal balance and cardiovascular health.

4.2 Method of Administration and Posology

4.2.1 Administration

Orally.

4.2.2 Posology

Adults and children over 18 only.

Take 1 capsule twice daily after a meal.

Take capsules with a sufficient quantity of water.

Do not chew the capsules swallow whole.

Take capsules at approximately the same time every day.

Take only the recommended dosage

4.3 Contraindications

Not recommended for individuals who are hypersensitive (allergic) to berberine or cinnamon bark.

4.4 Special Warnings and Precautions

Not recommended for individuals who are pregnant or breastfeeding. Not recommended for individuals who are under the age of 18. Do not exceed the recommended daily dose.

4.5 Interactions

Anticoagulant drugs: berberine might increase the risk of bleeding due to the anticoagulant effect.

Antidiabetic drugs: berberine and cinnamon might both increase the risk of hypoglycaemia.

Cytochrome P450 2C9 & 2D6: berberine might increase levels of drugs metabolized by CYP2C9 and CYP2D6.

Research is however conflicting, for cinnamon.

Hepatotoxic Drugs: There is some concern that ingesting large amounts of cassia cinnamon for an extended duration might cause hepatotoxicity in some people. Cassia cinnamon contains coumarin. In humans very high doses of coumarin from 50-7000 mg/day can result in hepatotoxicity that resolves when coumarin use is discontinued. Lower



amounts might also cause liver problems in sensitive people, such as those with liver disease or those taking potentially hepatotoxic agents.

4.6 Pregnancy and Lactation

Not recommended for individuals who are pregnant or breastfeeding.

4.7 Effects on ability to drive and use machinery.

No known effect.

4.8 Side Effects

No known side effects.

5 Pharmacological Classification

Category D: 33.7. Combination product.

6 Pharmacokinetic Properties

Cinnamon:

There is insufficient reliable information available about the pharmacokinetics of cassia cinnamon.

Berberine:

Absorption: berberine has poor oral bioavailability. It appears to be a substrate of nuclear transporters such as P-glycoprotein and organic cation transporter, which might explain its low oral bioavailability. Dihydroberberine, a reduced derivative of berberine, has shown improved bioavailability when compared with berberine. Animal research shows that the time to maximum blood concentration of berberine after oral administration is 2.4 hours.

Metabolism: berberine appears to undergo phase I hepatic metabolism. Three metabolites have been found in human urine after ingestion of berberine chloride. These are jatrorrhizine-3-sulfate, demethyleneberberine-2-sulfate, and thalifendine-10-sulfate.

Elimination: berberine is excreted in the urine and faeces.

7 Pharmaceutical Information

7.1 List of Excipients

Vegetarian capsules, milled rice flour.

7.2 Incompatibilities

None.

7.3 Shelf Life

24 months from date of manufacture.

7.4 Storage

Store in a cool dry place, between 15°C -25°C. Store in original container.

7.5 Presentation

60 white capsules packed in a 300 ml cylindrical white container with a lid and packaged in a single carton.

7.6 Disposal and handling of product

All unused medication should be disposed of in accordance with local regulatory authority.

8. Holder of certificate of registration

FoodGrown™©

371 Angus Crescent

Northlands Business Park

North Riding

Gauteng

South Africa

9. Registration Number

Still to be allocated

10. Date of first authorisation

Still to be allocated

11. Date of review

New



12. Reference: <https://naturalmedicines.therapeuticresearch.com/>

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