

**PROFESSIONAL INFORMATION**
**COMPLEMENTARY MEDICINE: MULTIPLE SUBSTANCE FORMULATION**

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

**SCHEDULING STATUS:** 
**1. NAME OF THE MEDICINE**

BIOGEN QUERCETIN COMPLEX (Vegetarian Capsules)

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**
**Quercetin**

(as 284,20 mg of a *Sophora japonica* L. flower extract standardised to 95 % quercetin)

270,00 mg

Ascorbic acid (Vitamin C)

250,00 mg

*Ananas comosus* L. (Pineapple)

[Fruit, extract standardised to 80 GDU\*\*/g bromelain]

35,00 mg

**Sugar free.**

For a full list of excipients, see section 6.1.

\*\*GDU – Gelatine Digestion Unit

**3. PHARMACEUTICAL FORM**

Capsules.

Size 00, white vegetarian capsules.

Capsules may appear off-white to yellow in colour due to the natural pigmentation of quercetin.

**4. CLINICAL PARTICULARS**
**4.1 Therapeutic indications**

BIOGEN QUERCETIN COMPLEX contains a combination of Quercetin, Vitamin C, and Bromelain that provides antioxidant support and contributes to the maintenance of a healthy immune system.

**4.2 Posology and method of administration**
**Posology**
**Adults 18 years and older:**

Take one (1) capsule twice daily with a meal, or as recommended by your healthcare provider.

Do not exceed 4 capsules per day.

Consult a healthcare provider for use beyond 12 weeks.

**Method of administration**

For oral use.

**4.3 Contraindications**

- If you have a hypersensitivity (allergy) to any of the active ingredients listed in section 2 or excipients listed in section 6.1.
- Not recommended for individuals with hyperoxaluria or a history of oxalate kidney stones.

**4.4 Special warnings and precautions for use**

- Use with caution in patients with diabetes mellitus, glucose-6-phosphate dehydrogenase deficiency, haemochromatosis, sickle cell anaemia, sideroblastic anaemia, and thalassaemia.
- Patients on iron overload treatment, with associated cardiac dysfunction, should not use BIOGEN QUERCETIN COMPLEX due to its ascorbic acid content.
- Discontinue use should any adverse reaction occur. Patients sensitive to latex, pineapple, or other members of the Bromeliaceae family, might also have allergic reactions to BIOGEN QUERCETIN COMPLEX.
- Use with caution in patients with bleeding or haemostatic disorders as bromelain content may inhibit platelet aggregation.
- Consult a healthcare provider prior to use if you are pregnant or breastfeeding.

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

- **Fexofenadine:** BIOGEN QUERCETIN COMPLEX inhibits P-glycoprotein and elevates plasma concentrations of fexofenadine in short-term use.
- **Anticoagulants / antiplatelet medicine (warfarin):** Warfarin therapy may be affected. Quercetin increases warfarin displacement from serum albumin, and ascorbic acid reduces warfarin activity. Bromelain inhibits platelet aggregation and may increase bleeding tendencies when used with anticoagulants, aspirin and antiplatelet drugs.
- **Estrogens:** Concomitant use with oral contraceptives can increase oestrogen plasma levels due to high ascorbic acid content. Associated breakthrough bleeding can also occur if BIOGEN QUERCETIN COMPLEX is withdrawn.
- **Antibiotics (amoxicillin and tetracyclines):** BIOGEN QUERCETIN COMPLEX increases plasma and urinary levels of amoxicillin and tetracycline antibiotics.
- **Barbiturates and primidone:** Barbiturate- and primidone-containing medicines may increase urinary excretion of ascorbic acid contained in BIOGEN QUERCETIN COMPLEX.

**4.6 Fertility, pregnancy and lactation**

Safety in 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 BIOGEN QUERCETIN COMPLEX does not adversely affect their performance.

**4.8 Undesirable effects**

BIOGEN QUERCETIN COMPLEX is generally well tolerated when taken at the recommended dose.

**Gastrointestinal disorders**

Frequency unknown: Nausea, vomiting, heartburn, abdominal cramps and diarrhoea.

**Nervous system disorders**

Frequency unknown: Headache and tingling of the extremities.

**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**

**Class and category:** Category D 34.12 Multiple substance formulation

BIOGEN QUERCETIN COMPLEX contains a combination of Quercetin, Vitamin C, and Bromelain that provides antioxidant support and contributes to the maintenance of a healthy immune system.

**5.2 Pharmacokinetic properties**
**Quercetin**

**Absorption:** Quercetin has limited oral bioavailability due to extensive metabolism in the intestine. Quercetin glycosides are hydrolysed in the intestine to produce the aglycone, which is subsequently conjugated to glucuronides or sulfates to enable absorption.

**Metabolism:** Following absorption, quercetin undergoes further metabolism in the liver, where it is methylated to form isorhamnetin and tamarixetin. Quercetin circulates in plasma predominantly as glucuronide, sulfate, and O-methylated conjugates.

**Distribution:** In plasma, quercetin is extensively bound to plasma proteins.

**Excretion:** Quercetin is excreted in the urine primarily as glucuronide and sulfate conjugates, as well as methylated metabolites.

**Ascorbic acid**

**Absorption:** Ascorbic acid is readily absorbed from the gastrointestinal tract.

**Distribution:** Ascorbic acid is widely distributed throughout body tissues. Concentrations are higher in leucocytes and platelets than in erythrocytes and plasma. Ascorbic acid crosses the placenta and is distributed into breast milk.

**Metabolism:** Ascorbic acid is reversibly oxidised to dehydroascorbic acid and further metabolised to inactive ascorbate-2-sulfate and oxalic acid.

**Excretion:** Metabolites are excreted in the urine. Excess ascorbic acid (exceeding 100 mg daily) is rapidly eliminated unchanged in the urine.

**Bromelain**

**Absorption:** Bromelain may increase the permeability of the intestinal mucosal epithelium and facilitate its own absorption via self-enhanced paracellular transport.

**6. PHARMACEUTICAL PARTICULARS**
**6.1 List of excipients**
**Vegetable capsule shell:**

- Carrageenan
- Hydroxypropyl
- Methylcellulose
- Potassium acetate
- Purified water

**Capsule fill:**

- Cornstarch
- Maltodextrin
- Magnesium stearate

**6.2 Incompatibilities**

Not applicable

**6.3 Shelf life**

24 months from date of manufacturing.

**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 plastic container with a Biogen cap.

Pack size: 60 Vegetarian Capsules.

**6.6 Special precautions for disposal**

No special requirements.

**7. HOLDER OF CERTIFICATE OF REGISTRATION**

Biogen  
23 Stag Road  
Glen Austin  
South Africa  
Tel: 0860 347 243  
Email: info@biogen.co.za  
Website: www.biogen.co.za

**8. REGISTRATION NUMBER**

Will be allocated by SAHPRA upon registration.

**9. DATE OF FIRST AUTHORISATION**

Will be allocated by SAHPRA upon registration.