

PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE: MULTIPLE SUBSTANCE FORMULATION (HEALTH SUPPLEMENT)

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 QUERCETIN COMPLEX (capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Quercetin [Sophora japonica L. flower extract standardised to 95% quercetin dihydrate]	270 mg
Ascorbic acid (Vitamin C)	250 mg
Bromelain [Ananas comosus (L.) Merr fruit extract standardised to 80 GDU*/g]	35 mg

Sugar free  
For a full list of excipients, see section 6.1.  
\*GDU – Gelatine digestion unit

3. PHARMACEUTICAL FORM  
Size 00 white vegicapsules

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BIOGEN QUERCETIN COMPLEX support good health and normal functioning of the immune system.

4.2 Posology and method of administration

Adults and children older than 18 years:  
One (1) capsule twice daily with a meal.  
  
Do not exceed 4 capsules per day.  
For use beyond 12 weeks, consult a registered health care practitioner.

4.3 Contraindications

Hyperoxaluria  
  
BIOGEN QUERCETIN COMPLEX must not be used in patients that are allergic or sensitive to the active substances or to any of the excipients listed in section 6.1.

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.

4.5 Interaction with other medicines and other forms of interaction

BIOGEN QUERCETIN COMPLEX inhibits P-glycoprotein and elevates plasma concentrations of fexofenadine in short-term use.  
  
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.  
  
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.  
  
BIOGEN QUERCETIN COMPLEX increases plasma and urinary levels of amoxicillin and tetracycline antibiotics.  
  
Barbiturate and primidone containing medicines increases urinary excretion of ascorbic acid contained in BIOGEN QUERCETIN COMPLEX.

4.6 Fertility, pregnancy and lactation

Safety in fertility, pregnancy and lactation has not been established. Do not use BIOGEN QUERCETIN COMPLEX during pregnancy or lactation

4.7 Effects on ability to drive and use machines

Studies on the ability to drive or use machinery have not been performed. Patients should exercise caution before driving, or use of machinery, until they are reasonably certain BIOGEN QUERCETIN COMPLEX does not adversely affect their performance.

4.8 Undesirable effects

Below side effects are based on available literature information. Frequencies are defined as frequent (≥ 1/100), less frequent (≥ 1/10 000, < 1/100) and frequency unknown (cannot be estimated from available data).  
  
**Nervous system disorders:**  
Headache and tingling of the extremities (*less frequent*).  
  
**Gastrointestinal disorders:**  
Nausea, vomiting, heartburn, abdominal cramps and diarrhoea (*frequent*).  
  
**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 professionals should 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

Category D 34.12 Multiple substance formulation

Quercetin is a flavonol with anti-inflammatory and antioxidant properties. It inhibits the nitric oxide pathway and prevents oxidation of low-density lipoproteins.  
  
Ascorbic acid contributes to the maintenance of good health and supports the normal functioning of the immune system.  
  
Bromelain acts on inflammatory mediators, such as bradykinin, and inhibits thromboxane synthetase that converts prostaglandin H2 into pro-inflammatory prostaglandins and thromboxanes.

5.2 Pharmacokinetic properties

*Quercetin*  
Quercetin is extensively metabolized in the intestine, limiting its oral bioavailability. Quercetin glycosides are hydrolysed in the intestine to produce aglycone that is subsequently conjugated to glucuronides or sulfates for absorption. Following conjugation, quercetin is methylated in the liver to isorhamnetin and tamarixetin. Quercetin is present in the plasma as glucuronides, sulfates, and O-methylated derivatives. In plasma, quercetin is extensively protein-bound. Quercetin is excreted in the urine as glucuronide and sulfate derivates, as well as methylated metabolites.  
  
*Ascorbic acid*  
Ascorbic acid is readily absorbed from the gastrointestinal tract and is widely distributed in the body tissues. Concentrations are higher in leucocytes and platelets than in erythrocytes and plasma. It is reversibly oxidised to dehydroascorbic acid; and metabolised to an inactive ascorbate-2-sulfate and oxalic acid which are excreted in the urine. Excess ascorbic acid (exceeding 100 mg daily) is rapidly eliminated unchanged in the urine. Ascorbic acid crosses the placenta and is distributed into breast milk.  
  
*Bromelain*  
Bromelain may increase the permeability of the intestinal mucosal epithelium and facilitate its own absorption by means of self-enhanced paracellular diffusion. Bromelain is distributed in plasma and blood, and research indicates an elimination half-life of 6-9 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

*Capsule shell:*  
Vegicapsule  
  
*Capsule fill:*  
Cornstarch  
Maltodextrin  
Sugar free

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Protect from moisture and store at or below 25 °C.  
Keep capsules in original container until required for use.  
KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

White vegicapsules containing a yellow powder, packed into white PET bottles with a white PET screw cap. Capsules may appear off-white to light yellow in colour due to the natural pigmentation of quercetin.  
  
Pack-size: 60 capsules.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen  
23 Stag Road, Glen Austin, South Africa  
info@biogen.co.za  
www.biogen.co.za  
Tel: 0860 347243

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

JOB: BPS_Quercetin Complex_60's		SIZE: 210mm x 327mm	
STOCK: Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>			
COLOURS:		FINISHING:	
<input checked="" type="checkbox"/> K	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot
<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot
<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	