

D 33.7 Combination Product; Complementary Medicine

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

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE  
JOINT CARE ACUTE (Vegetarian Capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegetarian capsule contains	
Vitamin C (as Calcium ascorbate)	250,00 mg
<i>Camellia sinensis</i> (L.) Kuntze (Green tea Extract) [Leaf; extract standardised to 40 % polyphenols]	100,00 mg
Boswellin® (Boswellia serrata extract) [Gum resin; 5:1 - 10:1 extract standardised to a minimum of 20% boswellic acids]	100,00 mg
Collagen (Chicken cartilage) providing 6 mg Undenatured Type II Collagen	40,00 mg
Manganese(II) Sulfate Monohydrate	2,00 mg
BioPerine® [ <i>Piper nigrum</i> (Black Pepper), Fruit, 50:1 extract standardised to 95% piperine providing 250 mg DHE]	5,00 mg
Sugar Free	

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM  
Tablet

4. CLINICAL PARTICULARS

**4.1 Therapeutic indications**  
**BIOGEN JOINT CARE ACUTE** may relieve joint pain of the knee while supporting overall joint health and mobility. May assist in reducing joint discomfort and enhancing range of motion, promoting a healthy, active lifestyle.

4.2 Posology and method of administration

*Adults 18 years and older:* Take 1 capsule daily, or as recommended by your healthcare provider.

Do not exceed the recommended dose.

Paediatric population

The safety and efficacy of BIOGEN JOINT CARE ACUTE has not been established in children under the age of 18 years.

Method of administration

For oral use only.

Use for at least 2 months to see beneficial effects.

4.3 Contraindications

- Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 6.1.
- Do not use this product if you are pregnant or breastfeeding.

4.4 Special warnings and precautions for use

Special care should be taken with BIOGEN JOINT CARE ACUTE.  
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 are taking any other medications or natural health products.
- Consult a healthcare provider prior to use if you are pregnant or breastfeeding.
- Consult a healthcare provider prior to use if symptoms worsen or persist.
- Consult a healthcare provider prior to use if you have a biliary disorder, digestive disorders, liver disorder or iron deficiency.
- Consult a registered healthcare professional if you are taking any other medicine (such as lithium) including chronic, complementary, or traditional medicines; or if you have high blood pressure, glaucoma, and/or detrusor instability (overactive bladder syndrome).
- Not recommended before bedtime as it may cause sleep disturbances.
- Discontinue use and consult a healthcare provider if you develop symptoms of liver trouble such as yellowing of the skin / eyes (jaundice), stomach pain, dark urine, sweating, nausea, unusual tiredness and/or loss of appetite.
- Consult a health care provider for use beyond 12 weeks.
- Total caffeine intake of more than 200 mg per day is not recommended during pregnancy or breastfeeding. A cup of instant coffee contains approximately 80 mg of caffeine.
- Use of caffeine may result in sleep deprivation. Limit the use of caffeine-containing products (including tea and coffee) when taking this product.

Paediatric population

- Not suitable for children under the age or 18 years.

4.5 Interaction with other medicines and other forms of interaction

Interactions with Medicine

- Anticoagulants and Antiplatelets: Green tea extract and piperine may have a mild blood-thinning effect. Combining it with blood thinners, such as warfarin, aspirin, or clopidogrel, may increase the risk of bleeding.
- Antidiabetic medication: black pepper might increase the risk of hypoglycemia when taken with antidiabetic medication.
- Antihypertensive medication: Piperine may lower blood pressure, so if combined with antihypertensive medications, it could potentially lead to low blood pressure.
- Stimulants: Caffeine content can heighten effects of stimulants, raising heart rate and blood pressure.
- Beta-blockers: Green tea extract may reduce the effectiveness of beta-blockers like nadolol for blood pressure.
- Liver-metabolised Medications: Can affect liver enzymes, potentially altering the effects of medicine like antidepressants and statins.
- Iron supplements: Green tea appears to have a small, or no, effect on the absorption of iron. and manganese may inhibit iron absorption, take separately from iron supplements.
- Chemotherapy: Antioxidants in green tea extract could interfere with certain chemotherapy medications.
- Lithium: Green tea extract may reduce levels, impacting bipolar disorder management. Black pepper extract might increase blood levels of lithium due to its diuretic effects.
- Atorvastatin (Lipitor): black pepper extract might increase blood levels of atorvastatin.
- Oral contraceptives: May slow caffeine breakdown, intensifying side effects.
- Calcium: Taking manganese with calcium might reduce the absorption of manganese, potentially decreasing its effects.
- Zinc: Taking manganese with zinc might increase the absorption of manganese, potentially increasing its effects and adverse effects.
- IP-6 (Phytic acid): Taking manganese with IP-6 might reduce the absorption of manganese, potentially decreasing its effects.

Interactions with Diseases / Impairments

- Green tea appears to have a small, or no, effect on the absorption of iron.
- Taking green tea extract might aggravate bleeding disorders. Caffeine is reported to have antiplatelet activity.
- Green tea extract contains caffeine, which might induce cardiac arrhythmias in sensitive individuals.
- Green tea extract contains caffeine, which might interfere with glucose control in patients with diabetes.
- Use with caution in patients with diarrhea. Green tea extract contains caffeine, which can exacerbate diarrhea, especially when taken in large amounts.
- Use with caution in patients with chronic liver disease. Manganese might accumulate and cause toxic effects in patients.

4.6 Fertility, pregnancy and lactation

The safety and efficacy of BIOGEN JOINT CARE ACUTE in pregnancy and lactation has not been established.

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 JOINT CARE ACUTE does not adversely affect their performance.

4.8 Undesirable effects

Summary of adverse reactions

**Gastrointestinal:** *Frequency unknown* : gastrointestinal discomfort / disturbances, diarrhea, heartburn and nausea.  
**Neurologic/ CNS:** *Common:* Headache and fatigue.

*Rare:* dizziness and vertigo

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. 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 overdose, undesirable effects as listed in 4.8 can be precipitated and / or be of increased severity.

5. PHARMACOLOGICAL PROPERTIES

BIOGEN JOINT CARE, may relieve joint pain while supporting overall joint health and mobility. May assist in reducing joint discomfort and enhancing range of motion, promoting a healthy, active lifestyle.

5.1 Pharmacodynamic properties

**Class and category: D 33.7 Combination product.**

*Ascorbic acid:* Contributes to normal collagen formation for the normal function of bones and cartilage.

*Green tea extract:* Green tea extract, In human research, green tea and its catechins have been shown to protect against the oxidative damage caused by exercise. The antioxidant effects of green tea and its constituents may relate to their ability to scavenge free radicals, chelate redox active transition-metal ions, inhibit redox active transcription factors, inhibit pro-oxidant enzymes, and induce antioxidant.

*Boswellia serrata:* Boswellia serrata, Boswellia oleo-gum-resin has been stated to have antiarthritic, antiseptic, astringent, diaphoretic, diuretic, expectorant, and stimulant properties. It has been used traditionally for inflammatory disorders such as asthma and arthritis.

*Undenatured Type II Collagen:* Collagen type II (native) should not be confused with another type of undenatured collagen, Collagen Type I (native). Collagen type II is a structural protein found in cartilage.

*Manganese:* Contributes to the development and maintenance of normal bones. Contributes to the normal formation of connective tissue.

*Bioperine:* For enhanced nutrient absorption

5.2 Pharmacokinetic properties

General introduction:

Vitamin C

*Absorption:* Vitamin C is well absorbed orally at lower doses, but absorption decreases as the dose increases. Approximately 87% of a 30 mg oral dose is absorbed, 80% of a 100 mg dose is absorbed, 63 % of a 500 mg dose is absorbed, and less than 50% of a 1250 mg does is absorbed.

*Distribution:* Vitamin C is transported from the intestines into the blood by the sodium-dependent vitamin C transporter (SVCT1), which is saturable.

*Metabolism:* Vitamin C itself is oxidized to the comparatively stable radical intermediate, ascorbyl free radical, two molecules of which may be disproportionate at a physiological pH to one molecule of ASC and one of DHA.

*Elimination:* Most vitamin C that is absorbed is excreted in the urine

Green tea:

Absorption: green tea or green tea extract has been shown to rapidly increase general levels of plasma polyphenols, as well as levels of epigallocatechin gallate (EGCG) and other individual catechins. Absorption of green tea catechins is increased when tea polyphenols were given as a green tea supplement in capsule form. Taking green tea catechins in the fasting state increases plasma levels of EGCG. However, fasting does not appear to have a significant effect on the plasma levels of total (free and conjugated) epigallocatechin, and results in lower plasma levels of total epicatechin.

*Distribution:* green tea ingestion resulted in the identification of 4'-O-methyl EGCG, EGCG, and epicatechin-3-gallate in prostatectomy tissue, at levels of 38.9 ± 19.5, 42.1 ± 32.4, and 17.8 ± 10.1 pmol/gram tissue, respectively. Catechins accumulated in the protein-rich fraction of plasma (60 %), in high-density lipoproteins (HDL) (23 %), and in low-density lipoproteins (LDL).

*Metabolism:* green tea ingestion resulted in the identification of methylated epigallocatechin and epicatechin in the urine; it was estimated that 50 % to 60 % of these catechins were methylated.

*Excretion:* green tea ingestion resulted in increased polyphenols in the urine.

Boswellia serrata:

*Absorption:* Following the ingestion of a Boswellia serrata gum resin extract (H15) 4200 mg, boswellic acids reach a peak after 1-2 hours, and plateau at 2 hours.

*Distributions:* A specific Boswellia serrata extract, 333 mg was shown to have an apparent volume of distribution of about 143 liters

*Metabolism:* According to laboratory research, oxidation to hydroxylated metabolites is the principal metabolic route for some boswellic acids, such as KBA.

*Excretion:* A specific Boswellia serrata extract (Wokvel) 333 mg has an elimination half-life of approximately 6 hours and a plasma clearance of about 296 mL/min.

Undenatured Type II Collagen:

*Absorption / Distribution / Metabolism / Excretion:* There is insufficient reliable information available regarding the pharmacokinetics of collagen type II.

Manganese:

*Absorption:* Typically, less than 5% of dietary manganese is absorbed.

*Distribution:* Absorbed manganese stays in the blood for a relatively short time, but accumulates in tissues, including bone, where it can remain for many years.

*Excretion:* Manganese is cleared hepatically. Chronic liver disease and biliary disorders can cause manganese accumulation and toxicity.

Bioperine:

*Absorption / Distribution / Metabolism / Excretion:* There is insufficient reliable information available regarding the pharmacokinetics of Bioperine.

5.2 Preclinical safety data

No pre-clinical safety data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate, corn starch

6.2 Incompatibilities

In the absence of compatibility studies, this medicine must not be mixed with other medicines.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Protect from light and store in airtight container at or below 25 °C.  
KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents

175 / 250 ml white PET container with a Biogen cap.

Pack size: 30/ 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](mailto:info@biogen.co.za)  
[www.biogen.co.za](http://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.