

**PATIENT INFORMATION LEAFLET****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**  
BIOGEN CURCUMIN ANTI-INFLAMMATORY (vegetarian capsules)**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each vegetarian capsule contains:	
Curcumin C3 Complex®	1250,00 mg
[ <i>Curcuma longa</i> L. (Turmeric), rhizome, as 19,23 mg of a 65:1 extract standardised to a minimum of 75 % curcumin]	
<i>Curcuma longa</i> L. (Turmeric)	500,00 mg
[rhizome powder standardised to a minimum of 2,38 % curcumin]	
BioPerine®	125,00 mg
[ <i>Piper nigrum</i> L. (Black Pepper), fruit, as 2,50 mg of a 50:1 extract, standardised to 95 % piperine]	
Vitamin C (Ascorbic Acid)	15,00 mg

Sugar Free

For a full list of excipients, see section 6.1.

**3. PHARMACEUTICAL FORM**Capsules.  
Size 0, white vegetable capsules.**4. CLINICAL PARTICULARS****4.1 Therapeutic indications**

BIOGEN CURCUMIN ANTI-INFLAMMATORY, with Curcumin C3 Complex® and turmeric powder, promotes joint health and mobility, and may assist with the relief of joint pain. BioPerine® enhances the absorption of curcumin, the principal curcuminoid and active component of turmeric. Added vitamin C contributes to collagen formation for the normal function of cartilage and offers additional antioxidant support.

**4.2 Posology and method of administration**

Posology

**Adults 18 years and older:**

Take 1-2 capsules daily or as recommended by a healthcare provider. The safety and efficacy of BIOGEN CURCUMIN ANTI-INFLAMMATORY in children younger than 18 years has not yet been established.

**Method of administration**

For oral use.

**4.3 Contraindications**

- Hypersensitivity to any of the active ingredients listed in section 2 or to any of the excipients listed in section 6.1.

**4.4 Special warnings and precautions for use**

Special care should be taken with BIOGEN CURCUMIN ANTI-INFLAMMATORY.

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**

- **Alkylating agents:** Turmeric has antioxidant effects, this may reduce the activity of chemotherapy medicine that generate free radicals.
- **Amiodopine:** Taking turmeric with amiodopine may increase levels of amiodopine.
- **Anticoagulant / Antiplatelet medication:** Turmeric and black pepper may have antiplatelet effects and may increase the risk of bleeding if used with anticoagulant or antiplatelet medicine.
- **Antidiabetic medicine:** Concomitant use of turmeric and black pepper extract with antidiabetic medicine might increase the risk of hypoglycaemia.
- **Antiretrovirals:** Black pepper might increase the levels and clinical effects of antiretrovirals.
- **Atorvastatin:** Black pepper might increase blood levels of atorvastatin.
- **Beta-blockers:** Black pepper might increase blood levels of Beta-blockers.
- **Cyclosporine:** Black pepper might increase the effects and side effects of cyclosporine.
- **Cytochrome substrates:** Turmeric might increase or decrease levels of medication metabolised by CYP3A4. Black pepper might increase levels of medication metabolised by CYP1A1, CYP2B1, CYP2D6, and CYP3A4.
- **Hepatotoxic medicine:** Turmeric might increase the risk of liver damage when taken with hepatotoxic medicine.
- **Lithium:** Black pepper might increase blood levels of lithium due to its diuretic effects. The dose of lithium might need to be reduced.
- **Methotrexate:** Turmeric might have additive effects when used with hepatotoxic medication such as methotrexate.
- **Organic anion-transporting polypeptide-substrates:** Turmeric might increase blood levels of OATP4C1 substrates.
- **Sedatives:** Black pepper may enhance sedative effects.
- **Sulfasalazine:** Turmeric might increase the effects and adverse effects of sulfasalazine.
- **Tacrolimus:** Turmeric might increase the effects and adverse effects of tacrolimus.
- **Tamoxifen:** Turmeric might reduce the levels and clinical effects of tamoxifen.
- **Tramadol:** Turmeric might increase or decrease levels of tramadol.
- **Warfarin:** Turmeric might increase the risk of bleeding when used concomitantly with warfarin.

**Interactions with Foods**

- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting BIOGEN CURCUMIN ANTI-INFLAMMATORY.

**4.6 Fertility, pregnancy and lactation**

Safety in fertility, 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 CURCUMIN ANTI-INFLAMMATORY does not adversely affect their performance.

**4.8 Undesirable effects****Summary of adverse reactions**

BIOGEN CURCUMIN ANTI-INFLAMMATORY is generally well tolerated when taken at the recommended dose.

**Gastrointestinal disorders***Less frequent:* Constipation, diarrhea or loose stools, nausea, vomiting, dyspepsia, abdominal pain or fullness, flatulence, distension, gastroesophageal reflux, gastritis, epigastric burning, and yellow or hard stools, burning aftertaste / reduced taste perception.**Skin and subcutaneous tissue disorders***Less frequent:* Itching, rash, pruritus.**Nervous system disorders***Less frequent:* Headache and vertigo.**Oral / eye disorders***Less frequent:* bleeding gums, sore mouth, and visual disturbances.**Immune system disorders***Rare:* Hypersensitivity reactions including angioedema and anaphylaxis.**Renal and urinary disorders***Frequent:* Dose-related urine discoloration.**Hepatobiliary disorders***Rare but serious:* Turmeric / curcumin has been associated with liver injury (including hepatitis, cholestasis, and hepatocellular injury), particularly at high doses or with highly bioavailable formulations (e.g., with piperine).**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 the 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**

Mechanism of action:

**Curcumin:**

Helps to reduce inflammation and support joint comfort. Assists in maintaining healthy joints and mobility. Provides antioxidant protection against oxidative stress that may contribute to inflammation.

**Bioperine:**

Enhance nutrient absorption, including that of curcumin. Supports optimal bioavailability of curcumin and other phytonutrients.

**Vitamin C:**

Contributes to normal collagen formation for the normal function of cartilage, bones, and connective tissue. Provides antioxidant support to help protect cells from oxidative stress.

**5.2 Pharmacokinetic properties****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 faeces following consumption of an extract.**Black pepper:***Absorption / Distribution / Metabolism / Excretion:* There is insufficient reliable information available about the pharmacokinetics of black pepper.**Vitamin C:***Absorption:* Vitamin C is well absorbed orally at lower doses, but absorption decreases as the dose increases.*Distribution:* The distribution of vitamin C is highly compartmentalized. Simple diffusion is unlikely to play a major role in vitamin C transport across membranes, at least in the further distribution from the blood stream.*Metabolism:* Turnover of vitamin C is particularly linked to the catabolism of DHA which occurs through hydrolysis to 2,3-diketogulonic acid and decarboxylation to L-xylose and L-lyxone.*Excretion:* Most vitamin C that is absorbed is excreted in the urine.**6. PHARMACEUTICAL PARTICULARS****6.1 List of excipients****Capsule contents:**

- Magnesium stearate

**Capsule shell:**

- Hypromellose

- Purified water

**6.2 Incompatibilities**

No compatibility studies have been performed, BIOGEN CURCUMIN ANTI-INFLAMMATORY 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 plastic 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

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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.