

SCHEDULING STATUS Not scheduled
PROPRIETARY NAME (and dosage form)

BIOGEN

BIOGEN GARCINIA CAMBOGIA

(capsule)

COMPOSITION

Each capsule contains:
GarCitrin® (standardized *Garcinia cambogia* extract
- 50% HCA, 5% Garcinol)

500mg

Other Ingredients: Magnesium Stearate

Sugar-Free

PHARMACOLOGICAL CLASSIFICATION

Category D, 32.3 Slimming Preparations

PHARMACOLOGICAL ACTION

GarCitrin® (Garcinol 5%) is a standardized extract obtained from *Garcinia cambogia* and contains a minimum of 50% (-) Hydroxycitric acid (HCA) and 5% Garcinol. Garcinol enhances the biological action of HCA. HCA has been shown to inhibit citrate cleavage enzyme, suppress de novo fatty acid synthesis and food intake, and decrease body weight gain. It competitively inhibits the extra mitochondrial enzyme adenosine triphosphate-citrate (pro-3S)-lyase which catalyzes the conversion of citrate and coenzyme A to oxaloacetate and acetyl coenzyme A (acetyl-CoA), the primary building blocks of fatty acid and cholesterol synthesis. As a citrate cleavage enzyme it may play a role in de novo lipogenesis inhibition. HCA's efficacy in inhibiting ATP citrate-lyase depends entirely on the presence of HCA inside the target cell, and reduced HCA absorption would decrease its weight-lowering effects.

INDICATION

Indicated as an aid to a weight management programme, including an energy-restricted diet and regular exercise.

CONTRA-INDICATIONS

Avoid with a known allergy or hypersensitivity to *Garcinia cambogia*, any of its constituents including caffeine or tannins, or members of the *Theaceae* family.

Do not use if you are pregnant or lactating.

HCA is likely unsafe to use in patients with Alzheimer's disease and other dementia syndromes due to the theoretical possibility of forming acetylcholine in the brain.

WARNINGS AND SPECIAL PRECAUTIONS

Not recommended for use in children under the age of 18 years.

Diabetics/hypoglycaemic individuals should take note that this product may reduce blood sugar levels - diabetics may need to reduce medication dosages. Please discuss with your healthcare professional before taking this medicine.

Use cautiously in patients with a history of rhabdomyolysis or in patients taking HMG-CoA reductase inhibitors ("statins") as it may increase the risk for rhabdomyolysis.

Potential evidence that shows that when HCA is used in patients with blood disorders or those who are using anti-coagulants or anti-platelets, HCA may inhibit platelet aggregation and increase the risk of bleeding.

Taking more than the recommended dose will not improve the results and may cause adverse reactions. Please discuss with your healthcare professional before taking this medicine.

PREGNANCY AND LACTATION

Do not take this medicine during pregnancy or lactation.

INTERACTIONS

Always tell your healthcare professional if you are taking any other medicine.

DOSAGE AND DIRECTIONS FOR USE

Take 1 capsule 2-3 times daily, 30-60 minutes before meals.

Do not exceed the daily recommended dose. In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Do not share medicines prescribed for you with any other person.

SIDE-EFFECTS

The following side-effects may be associated with the use of BIOGEN *Garcinia Cambogia* and are listed under their corresponding body-organ class:

Gastro-intestinal disorders: Abdominal discomfort, diarrhoea, constipation, nausea, vomiting, heartburn.

Immune system: Hypersensitivity and/or allergic reactions.

Endocrine system: Patients taking oral hypoglycaemic agents are cautioned against the use of *Garcinia cambogia* due to the theoretical possibility of increasing the action of other hypoglycaemic agents.

Cardiovascular system: Potential risk of rhabdomyolysis in patients with a history thereof or in patients taking HMG-CoA reductase inhibitors ("statins") as it may increase the risk for rhabdomyolysis.

Neurologic: Headache, dizziness, agitation, insomnia, depression.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

None known. Treatment is symptomatic and supportive.

IDENTIFICATION

White capsule, containing a white powder.

PRESENTATION

Plastic container with 60 capsules.

STORAGE INSTRUCTIONS

Store in a cool, dry place, at or below 25°C.
STORE OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

To be allocated by the Medicines Control Council.

NAME AND BUSINESS ADDRESS OF THE APPLICANT

Biogen PTY (Ltd)
23 Stag Rd, Glen Austin, Midrand, 1685.
Tel: 0860 246 436

DATE OF PUBLICATION OF THIS PACKAGE INSERT/PATIENT LEAFLET

July 2014

DISCIPLINE

Herbal medicine

This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease.

SKEDULERINGSSTATUS Nie geskeduleerd
EIENDOMSNAAM (en doseervorm)

BIOGEN

BIOGEN GARCINIA CAMBOGIA

(kapsule)

SAMESTELLING

Elke kapsule bevat:
GarCitrin® (gestandaardiseerde *Garcinia cambogia* ekstrakt - 50% HCA, 5% Garsinol) 500mg

Ander bestanddele: Magnesium stearaat

Suiker-vry

FARMAKOLOGIESE KLASSEFIKASIE

Kategorie D, 32.3 Verslankingsmiddels.

FARMAKOLOGIESE AKSIE

GarCitrin® HCA het getoon dat dit sitraat spetings-ensiem inhibeer, de novo vetsuursintese en voedselinnam onderdruk, en gewigstoename verminder. Dit inhibeer die ekstra mitochondriale ensiem adenosientrifosfaat-sitraat (pro-3S)-lase mededingend, wat die omskakeling van sitraat en koënsiem A na oksaalasetaat en asetiel koënsiem A (asetiel-KoA), die primêre boustene van vetsure en cholesterol sintese, kataliseer. As 'n sitraat spetings-ensiem kan dit 'n rol speel in die inhering van de novo lipogense. HCA se doeltreffendheid om ATP sitraat-lase te inhibeer is heeltemal afhanklik van die teenwoordigheid van HCA binne die teikensel, en verminderde HCA opname sal die gewigsverlagende effekte verminder.

INDIKASIES

Aangedui as hulpmiddel tot gewigsbeheerprogram, wat energie-beperkte dieet en gereelde oefening insluit.

KONTRA-INDIKASIES

Verny met 'n bekende allergie of hipersensitiwiteit vir *Garcinia cambogia*, enige van sy bestanddele, insluitende kafeïen of tannien, of lede van die Theaceae familie.

Moenie tydens swangerskap of borsvoeding gebruik nie.

HCA is waarskynlik onveilig vir gebruik in pasiënte met Alzheimer se siekte en ander demensia sindrome te wyle aan die teoretiese moontlikheid van die vorming van asetielcholin in die brein.

WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS

Nie aanbeveel vir gebruik in kinders jonger as 18 jaar nie.

Diabete/hipoglukemiese individue moet daarop let dat hierdie produk bloedsuikervlakke kan verlaag – diabete sal moontlik medisyne dosisse moet verminder. Bespreek die gebruik van hierdie medikasie met u geneesheer vir gebruik.

Gebruik versigtig in pasiënte met 'n geskiedenis van rabdomiolise of in pasiënte wat HMG CO-A reduktase-inhibeerders ('statiene') neem – dit kan die risiko vir rabdomiolise verhoog.

Potensiële bewyse dat wanneer HCA geneem word deur pasiënte met bloedstollings distinkiesies of die behandel word met anti-koagulant/anti-stol middies die gebruik van HCA plaatjie aggrebasie mag inhibeer en die risiko vir bloeding verhoog.

Die neem van meer as die aanbevole dosis sal nie die resultate verbeter nie en kan nadelige reaksies veroorsaak.

Bespreek asseblief met jou gesondheidspraktisyn voordat jy hierdie medisyne gebruik.

SWANGERSKAP EN LAKTASIE

Moenie hierdie medisyne tydens swangerskap of borsvoeding gebruik nie.

INTERAKSIES

Lig altyd jou gesondheidspraktisyn in as jy enige ander medisyne neem.

DOSIS EN GEBRUIKSAANWYSINGS

Neem 1 kapsule 2-3 keer per dag, 30-60 minute voor etes.

Moenie die aanbevole dosis oorskry nie. In die geval van oordosering, skakel dringend u dokter of apteker. Indien hul nie beskikbaar is nie, kontak u naaste hospitaal of gifbeheersentrum.

Moenie medisyne wat vir jou voorgeskryf is met ander mense deel nie.

NEWE-EFFEKTE

Die volgende nuwe-effekte kan geassosieer word met die gebruik van BIOGEN *Garcinia Cambogia* en word onder hulle ooreenstemmende liggaamsorgane klas gelys:

Gastro-intestinale versteurings: Abdominale ongemak, diarree, hardtygheid, naarheid, vomering.

Immuunsisteem versteuring: Hipersensitiwiteit en/of allergiese reaksies.

Endokriene sisteem: Pasiënte wat orale hipoglukemiese middels gebruik, word waarsku teen die gebruik van *Garcinia cambogia* as gevolg van die teoretiese moontlikheid van die verhoging van die aksie van hipoglukemiese medisyne.

Neurolgiese: Hoofpyn, duiseligheid, rusteloosheid, slapeloosheid, depressie.

Nie alle nuwe-effekte wat vir hierdie medisyne aangemeld is, word in hierdie voerbiljet genoem nie. Indien jou algemene gesondheid agteruitgaan of jy enige ongunstige effekte ervaar terwyl jy hierdie medisyne neem, raadpleeg asseblief jou dokter, apteker of ander gesondheidspraktisyn.

BEKEUDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING

Geen. Behandeling is simptomaties en ondersteunend van aard.

IDENTIFIKASIE

'n Wit kapsule wat wit poeier bevat.

AANBIEDING

'n Plastiek houer met 60 kapsules.

BERIGINGSAAANWYSINGS

Bêre op 'n koel, droë plek teen of benede 25°C.
STOOR BUITE DIE BEREIK VAN KINDERS.

REGISTRASIE NOMMER

Sal deur die Medisynbeheerraad toegeken word.

NAAM EN BESIGHEIDSADRES VAN DIE APPLIKANT

Biogen (Edms) Bpk
Stagstraat 23, Glen Austin, Midrand, 1685.
Tel: 0860 246 436

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET

Julie 2014

DISCIPLINE

Kruie medisyne.

Hierdie medikasie is nie deur die Medisynbeheerraad geëvalueer nie. Hierdie medikasie is nie bedoel om enige siekte te diagnoseer, behandel, genees of te voorkom nie.