

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline Specific

D.33.7 Combination Product

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

HEALTHY WEIGHT WITH GLUCOSE CONTROL, 30 Tablets

COMPOSITION

Each one (1) tablet of **HEALTHY WEIGHT WITH GLUCOSE CONTROL** contains the following actives:

Pasteurised Akkermansia muciniphila MucT	30 billion cells
Green tea (Camellia sinensis) [leaf] Extract	265 mg
of which EGCG	115 mg
Vitamin B2	0,21 mg
Chromium	60 ug
Vitamin D3	5 ug

Inactive Ingredients: Microcrystalline cellulose, calcium phosphate, mono and diglycerides of fatty acids, magnesium salts of fatty acids, hydroxypropyl cellulose, corn starch, silicon dioxide, polyethylene glycol.

This product is gluten, lactose, allergen, GMO and colourant free.

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

HEALTHY WEIGHT WITH GLUCOSE CONTROL supports metabolic and digestive well-being by assisting with normal gut microflora balance, glucose metabolism, and healthy energy utilisation.



These are all very serious effects. If you have them, you may have had a serious reaction to **HEALTHY WEIGHT WITH GLUCOSE CONTROL**. You may need urgent medical attention or hospitalisation.

Side effects that usually do not require medical attention (report to your healthcare professional if they continue):

- nausea, stomach pain, loss of appetite, headache

These are all very serious effects. If you have them, you may have had a serious reaction to **HEALTHY WEIGHT WITH GLUCOSE CONTROL**. You may need urgent medical attention or hospitalisation.

Seek advice from a healthcare professional if you have any medical condition. Discontinue use immediately should any adverse reaction occur.

Read this leaflet carefully because it contains important information for you. This product is available without a doctor's prescription.

- Keep this leaflet. You may need to read it again.
- Do not share medication with any other person.
- Ask your pharmacist if you need more information or advice.
- You must consult a doctor should your condition worsen or does not improve.

DO NOT USE THIS PRODUCT:

- If you are hypersensitive (allergic) to any of the ingredients listed.
- Do not accept this package if seals are broken.

INTERACTIONS

Always tell your healthcare professional if you are taking any other medicine. It is possible that exposure of certain supplement ingredients may interfere with certain medications. (See **Warnings & Special precautions**)

DOSAGE AND DIRECTIONS FOR USE

Adults: Take one (1) tablet once per day, with food or as directed by your healthcare practitioner.

Do not take more than the recommended dose.

SIDE EFFECTS

Should your general health worsen, or if you experience any untoward effects while being exposed to this product, please consult your doctor, pharmacist or other healthcare professional for advice.

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT

TREATMENT

See side-effects.

Treatment:

Discontinue use and consult your doctor, pharmacist or other healthcare professional for advice.

STORAGE INSTRUCTION

Store in a cool, dark place, below 25 °C.

Protect from direct sunlight and heat.

Store in the original bottle.

Keep the bottle tightly closed.

Replace the protective cap after each use.

Do not use after the expiry date stated on the bottle.

Do not use **HEALTHY WEIGHT WITH GLUCOSE CONTROL** if you notice visible signs of deterioration.

IDENTIFICATION

Tablet.

PRESENTATION

30 TABLETS - A white 175 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

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

NAME AND BUSINESS ADDRESS OF APPLICANT

Distributed by:
Amipro Advanced Development Products (Pty) Ltd
Galaxy Park,
Unit 5B
17 Galaxy Avenue, Limbro Park
Sandton, 2090, Tel: 011-802-8101

DATE OF PUBLICATION

To be allocated by the regulatory authority.

Ingredients	Uses for ingredient
Pasteurised Akkermansia muciniphila MucT	Supports normal gut microflora balance and contributes to digestive well-being.
Green tea (Camellia sinensis) [leaf] Extract	Provides antioxidant support and assists with healthy metabolic and energy processes.
Vitamin B2	Contributes to normal energy production and helps reduce tiredness and fatigue.
Chromium	Contributes to normal glucose metabolism and the maintenance of healthy blood sugar levels.
Vitamin D3	Supports normal immune function and contributes to the maintenance of healthy bones and muscle function.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take **HEALTHY WEIGHT WITH GLUCOSE CONTROL** if you are hypersensitive (allergic) to any of the ingredients. If you have allergies, be sure to check with your healthcare professional before taking this supplement. Not suitable for persons under the age of 18 years. If the patient has been advised by their healthcare provider to avoid supplements containing green tea extract, chromium, or vitamin D3.

Green tea extract contains naturally occurring caffeine and catechins (including EGCG), which may cause jitteriness, irritability, digestive discomfort or headache in sensitive individuals; discontinue use and consult a healthcare provider if adverse effects occur.

WARNING AND SPECIAL PRECAUTIONS

Use with caution if you have a diagnosed medical condition: Diabetes or impaired glucose tolerance, as chromium and green tea extract may influence glucose regulation. Liver conditions or a history of liver sensitivity, due to green tea extract. Kidney disorders, abnormal calcium levels, hyperparathyroidism, or any condition affecting calcium metabolism (vitamin D3 consideration). Any chronic gastrointestinal, metabolic, endocrine or cardiovascular condition—consult your healthcare provider before use.

Interactions With Medicines: Green tea extract and chromium may influence the effects of medicines used to regulate blood glucose levels (e.g., insulin or oral antidiabetic medicines). May interact with blood-thinning medicines such as warfarin and related anticoagulants. Green tea extract may interact with stimulant-containing products, certain cardiovascular medicines, and medicines that affect liver function. Vitamin D3 may interact with medicines that alter calcium levels, such as corticosteroids, thiazide diuretics and some antiepileptic medicines. If any of the following happens, stop using **HEALTHY WEIGHT WITH GLUCOSE CONTROL** and tell your doctor or go to the casualty department at your nearest hospital:

- Allergic reactions—rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing;

PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: **B2**

Kategorie D: Komplementêre medisyne.
Dissipline-spesifiek
D.33.7 Kombinasieprodukt

HANDELSNAAM EN DOSEERVORM,

HEALTHY WEIGHT WITH GLUCOSE CONTROL, 30 tablette

SAMESTELING

Elke (1) tablet HEALTHY WEIGHT WITH GLUCOSE CONTROL bevat die

volgende aktiewe stowwe:

Gepasteuriseerde Akkermansia muciniphila	30 miljard selle
MucT	
Groen tee (Camellia sinensis) [blaar] Ekstrak	265 mg
waarvan EGCG	115 mg
Vitamiën B2	0,21 mg
Chroom	60 ug
Vitamiën D3	5 ug

Onaktiewe bestanddele: Mikrokristallyne sellulose, kalsiumfosfaat, mono en diglisieriede van vetsure, magnesiumsoute van vetsure, hidroksipropielcellulose, mielietysel, silikondioksied, polietileenlikool.

Hierdie produk is vry van gluten, laktose, allergeen, GGO en kleurmiddels.

FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

HEALTHY WEIGHT WITH GLUCOSE CONTROL bevat sink as 'n aminosuurcheelaat met glisien wat ontwerp is om hoogs opneembaar en goed verdra te wees. Sink is veral belangrik vir immuun- en weefselgesondheid en help om normale vel, hare, naels en bene te handhaaf.

Bestanddele	Gebruik vir bestanddele
Gepasteuriseerde Akkermansia muciniphila MucT	Ondersteun normale dermmikroflora-balans en dra by tot spysverteringswelstand.
Groen tee (Camellia sinensis) [blaar] Ekstrak	Bied antioksidantondersteuning en help met gesonde metabolisme en energieprosesse.
Vitamiën B2	Dra by tot normale energieproduksie en help om moegheid en moegheid te verminder.
Chroom	Dra by tot normale glukosemetabolisme en die handhawing van gesonde bloedsuikervlakke.
Vitamiën D3	Ondersteun normale immuunfunksie en dra by tot die instandhouding van gesonde bene en spierfunksie.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **HEALTHY WEIGHT WITH GLUCOSE CONTROL** neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisyn gaan voordat jy hierdie aanvulling neem. Nie geskik vir persone onder die ouderdom van 18 jaar nie. As die pasiënt deur hul gesondheidsorgverskaffer aangeraam is om aanvullings wat groen tee-ekstrak, chroom of vitamien D3 bevat, te vermy. Groen teeblaar-ekstrak bevat natuurlike kafeïen en katekiens (insluitend EGCG), wat rusteloosheid, geïrriteerdheid, spysverteringsongemak of hoofpyn in sensitiwiese individue kan veroorsaak; staak gebruik en raadpleeg 'n gesondheidsorgpraktisyn indien nadelige effekte voorkom.

WAARSKUWING EN SPESIALE VOORSORGMATREËLS

Gebruik dit met omsigtigheid as jy 'n gediagnoseerde mediese toestand het: Diabetes of verminderde glukosetoleransie, aangesien chroom en groen tee-ekstrak glukoseregulering kan beïnvloed

Lewertoestande of 'n geskiedenis van lewersensitiewe, as gevolg van groen tee-ekstrak. Niersiektes, abnormale kalsiumvlakke, hiperparatirose, of enige toestand wat kalsiummetabolisme beïnvloed (vitamien D3 oorweging). Enige chroniese gastro-intestinale, metabolisme, endokriene of kardiowaskulêre toestand—raadpleeg jou gesondheidsorgverskaffer voor gebruik. Interaksies met medisyne: Groen tee-ekstrak en chroom kan die effek van medisyne wat gebruik word om bloedglukosevlakke te reguleer (bv. insulien of orale anti-diabetiese middels) beïnvloed. Kan interaksie hê met bloedverdunde medisyne soos warfarien en verwante antikoagulant. Groen tee-ekstrak kan interaksie hê met produkte wat stimulanse bevat, sekere kardiowaskulêre medisyne, en medisyne wat lewerfunksie beïnvloed. Vitamiën D3 kan interaksie hê met medisyne wat kalsiumvlakke verander, soos kortikosteroïede, tiazied-diuretika en sommige anti-epileptiese middels. As enige van die volgende gebeur, hou op om **HEALTHY WEIGHT WITH GLUCOSE CONTROL** te gebruik en vertel jou dokter of gaan na die ongevallen-afdeling by jou naaste hospitaal:

- Allergiese reaksies-uitslag, jeuk / swelling (veral van die gesig / tong / keel), erge duiseligheid, probleme met asemhaling;

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op **HEALTHY WEIGHT WITH GLUCOSE CONTROL** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê. Nuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan jou gesondheidsorgpraktisyn as hulle voortduur):

- naarheid, maagpyn, verlies aan eetlus, hoofpyn.

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **HEALTHY WEIGHT WITH GLUCOSE CONTROL** gehad. Miskien het u dringende mediese hulp of hospitalisasie nodig. Raadpleeg 'n gesondheidsorgpraktisyn as u enige mediese toestand het. Staak gebruik onmiddellik indien enige nadelige reaksie plaasvind. Lees hierdie inligtingsblad aandagtig deur, want dit bevat belangrike inligting vir u. Hierdie produk is beskikbaar sonder doktersvoorskrif.

- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.

- Moenie medisyne met enige ander persoon deel nie.

- Vra jou apteker of jy meer inligting of advies benodig.

- Jy moet 'n dokter raadpleeg indien jou toestand vererger of nie verbeter nie.

MOENIE HIERDIE PRODUK GEBRUIK NIE:

- As jy hipersensitief (allergies) is vir enige van die bestanddele wat gety is word.

- Jy moet nie hierdie produk aanvaar as seëls gebreek word nie.

INTERAKSIES

Vertel altyd jou gesondheidsorgpraktisyn as jy enige ander medisyne gebruik. Dit is moontlik dat blootstelling van sekere aanvullingsbestanddele met sekere medisyne 'n interaksie mag hê. (Sien **Waarskuwings en Spesiale Voorsorgmaatreëls**)

DOSES EN AANWYSINGS VIR GEBRUIK

Volwassenes: Neem een (1) tablet een keer daaglik, saam met kos of soos voorgeskryf deur jou gesondheidsorgpraktisyn.

Moenie meer as die aanbevole dosis neem nie.

NEWE-EFFEKTE

Indien jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar tydens die gebruik van hierdie medisyne, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn vir raad. As jy enige nuwe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

BEKENDTE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Sien nuwe-effekte.

Behandeling:

Staak gebruik en raadpleeg jou dokter, apteker of ander gesondheidsorgpraktisyn vir advies.

BERGING INSTRUKSIE

Bêre in 'n koel, donker plek, onder 25 °C.

Beskermer teen direkte sonlig en hitte.

Bêre n die oorspronklike bottel.

Hou die bottel styf toe.

Vervang die beskermende dop na elke gebruik.

Moet nie gebruik word na die vervaldatum wat op die bottel aangedui word nie.

Moenie **HEALTHY WEIGHT WITH GLUCOSE CONTROL** gebruik as u sigbare tekens van agteruitgang opmerk nie.

IDENTIFIKASIE

Tablet.

AANBIEDING

30 TABLETTE - 'n Wit 175 ml HDPE-bottel met 'n wit dop, induksiesed, peuterkrimpesêl, spons en silikagelakkie.

REGISTRASIE NOMMER

Om by registrasie deur SAHPRA toegeken te word.

Hierdie medisyne is nie deur SAHPRA geëvalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

NAAM EN BESIGHEIDSDADRES VAN APPLIKANT

Versprei deur: Amipro Advanced Development Products (Pty) Ltd
Galaxy Park,
Unit 5B
17 Galaxy Avenue, Limbro Park
Sandton, 2090, Tel: 011- 802-8101

DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.