

## PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Discipline Specific

33.7 Combination Product

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

### GLUTACLEAR®, 60 & 120 Tablets

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS

IMPORTANT INFORMATION FOR YOU

- **GLUTACLEAR®** is available without a doctor's prescription.
- Nevertheless, you still need to use **GLUTACLEAR®** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **GLUTACLEAR®** with any other person.
- Ask your pharmacist or healthcare professional if you need more information or advice.

#### WHAT IS IN THIS LEAFLET

- What **GLUTACLEAR®** is and what it is used for.
- What you need to know before you take **GLUTACLEAR®**.
- How to take **GLUTACLEAR®**.
- Possible side effects.
- How to store **GLUTACLEAR®**.
- Contents of the pack and other information.

#### WHAT GLUTACLEAR® CONTAINS

Each one (1) tablet of **GLUTACLEAR®** contains the following actives:

Vitamin B3 (as Niacinamide)	375 mg
L-Cysteine (as N-acetyl-L-cysteine)	375 mg
Vitamin C (as ascorbic acid)	250 mg
Selenium (as selenomethionine)	37,5 mcg
Broccoli (Brassica oleracea L. var. Italica)	19,25 mg
[Seed] Extract (providing 2,5 mg glucoraphanin)	

**Inactive Ingredients:** Microcrystalline cellulose, cellulose, stearic acid (vegetable), silica, and coating (hypromellose, medium-chain triglycerides, and hydroxypropylcellulose)

**This product is non-GMO. (Sugar Free)**

#### WHAT GLUTACLEAR® IS AND WHAT IT IS USED FOR

**GLUTACLEAR®** features a blend of key ingredients designed to help support the body's production of glutathione, a primary antioxidant throughout the entire body. Glutathione plays an important role in protecting the body against oxidative stress and supporting liver detoxification processes.

#### BEFORE YOU TAKE GLUTACLEAR®

If you are taking any chronic medication, do not use this product without consulting your healthcare provider. Do not take **GLUTACLEAR®** 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. Stop taking **GLUTACLEAR®** at least two weeks before scheduled surgery.

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

#### PREGNANCY AND BREASTFEEDING

Safety during pregnancy and breastfeeding has not been established. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare practitioner for advice before taking this supplement.

#### DRIVING AND USING MACHINES

It is not always possible to predict to what extent **GLUTACLEAR®** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in activities relating to requiring mental alertness, judgement and/or sound co-ordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment, until they are aware of the measure to which **GLUTACLEAR®** may affect you.

#### TAKING OTHER MEDICINES WITH GLUTACLEAR®

Complementary medicine products contain ingredients which may interact with some medication. If you are taking any chronic medication, do not use this product without consulting your medical practitioner

#### HOW TO TAKE GLUTACLEAR®

Do not share medicines prescribed for you with any other person. Always take **GLUTACLEAR®** exactly as described in this leaflet, or as your doctor, healthcare provider has instructed you. You should check with your doctor, pharmacist or healthcare provider if you are unsure.

#### Directions for use:

**Adults:** Take one (1) tablet daily with food, or as directed by your healthcare practitioner.

**Do not take more than the recommended dose.**

#### IF YOU TAKE MORE GLUTACLEAR® THAN YOU SHOULD

In the event of overdose, consult your doctor, pharmacist. Should none of these be available, contact the nearest hospital or poison control centre.



#### IF YOU FORGET TO TAKE GLUTACLEAR®

Do not take a double dose to make up for a missed dose.

#### POSSIBLE SIDE EFFECTS

**GLUTACLEAR®** may have side effects.

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Allergies, Chest pain (angina), Diabetes, Gallbladder disease, Gout, Kidney disease, Liver disease, Low blood pressure, Stomach or intestinal ulcers, Thyroid disorders, Asthma, Bleeding disorder, Alcohol use disorder, Chronic kidney disease, A metabolic deficiency called "glucose-6-phosphate dehydrogenase" (G6PD) deficiency, Kidney stones, Autoimmune diseases, Hemodialysis, Fertility problems in males, Skin cancer. If you are taking the following medication, please consult with your healthcare practitioner before taking: Diabetes (Antidiabetes drugs), lowering cholesterol (Bile acid sequestrants, statins), high blood pressure (Antihypertensive drugs), Medications that can harm the liver (Hepatotoxic drugs), slow blood clotting (Anticoagulant / Antiplatelet drugs), Thyroid hormone, Nicotine patch (Nicoderm), Aspirin, Nitroglycerin, Activated charcoal, Chloroquine (Aralen), Oestrogens, Medications for cancer (Alkylating agents), Acetaminophen (Tylenol, others), Sedative medications (Barbiturates), Medications that decrease the immune system (Immunosuppressants), Birth control pills (Contraceptive drugs). If any of the following happens, stop using **GLUTACLEAR®** 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.

These are all very serious effects. If you have them, you may have had a serious reaction to **GLUTACLEAR®**. 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/vomiting, constipation, loss of appetite, mental/mood changes, unusual tiredness.

Not all side effects and interactions reported for **GLUTACLEAR®** 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. If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or healthcare professional.

#### REPORTING OF SIDE EFFECTS

If you experience side effects, talk to your doctor, pharmacist or other healthcare professional. You can also report side effects to SAHPRA via "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **GLUTACLEAR®**.

#### STORAGE AND DISPOSING OF GLUTACLEAR®

Store all medicines out of the reach of children.

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

Protect from direct sunlight and heat.

Store in the original packaging.

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

Do not use **GLUTACLEAR®** if you notice visible signs of deterioration.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

#### PRESENTATION OF GLUTACLEAR®

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

**120 TABLETS** - A white 250 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

#### IDENTIFICATION OF GLUTACLEAR®

White, coated oval tablet.

#### REGISTRATION NUMBER –

To be allocated by SAHPRA upon registration.

#### ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

#### THIS LEAFLET WAS LAST REVISED ON

19 November 2024

#### NAME AND ADDRESS OF REGISTRATION HOLDER

Distributed by:

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# PASIËNT INLIGTINGSBLAD

SKEDULERINGSSTATUS S0

Kategorie D: Komplementêre medisyne.

Dissipline: Dissipline Spesifiek

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

## GLUTACLEAR®, 60 & 120 Tablette

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT

BELANGRIKE INLIGTING VIR U

- **GLUTACLEAR®** is beskikbaar sonder doktersvoorskrif.
- U moet steeds **GLUTACLEAR®** versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie **GLUTACLEAR®** met enige ander persoon deel nie.
- Vra jou apteker of gesondheidsorgpraktisyn of jy meer inligting of advies benodig.

**WAT IS IN HIERDIE INLIGTINGSBLAD**

- Wat **GLUTACLEAR®** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **GLUTACLEAR®** neem.
- Hoe om **GLUTACLEAR®** te neem.
- Moontlike nuwe-effekte.
- Hoe om **GLUTACLEAR®** te bère.
- Inhoud van die pak en ander inligting

**WAT GLUTACLEAR® BEVAT**

Elke een (1) tablet GLUTACLEAR® bevat die volgende aktiewe:

Vitamiën B3 (as Niacinamide)	375 mg
L-sisteien (as N-asetiel-L-sisteien)	375 mg
Vitamiën C (as askorbienuur)	250 mg
Selenium (as selenometionien)	37,5 mcg
Broccoli (Brassica oleracea L. var. italica)	19,25 mg
[Saad] Uttreksel (verskaf 2,5 mg glucoraphanin)	

**Onaktiewe bestanddele:** Mikrokrystalliene sellulose, sellulose, stearynsuur (groente), silika en laag (hipromellose, mediumketting trigliesiede, en hidroksipropylsellulose)

**Hierdie produk is nie-GGO. (Suikervry)**

**WAT IS GLUTACLEAR® KAPSULES EN WAARVOOR WORD DIT GEBRUIK**

**GLUTACLEAR®** beskik 'n mengsel van sleutelbestanddele wat ontwerp is om die liggaam se produksie van glutathion, 'n primêre antioksidant deur die hele liggaam, te ondersteun. Glutathion speel 'n belangrike rol in die beskerming van die liggaam teen oksidatiewe stres en die ondersteuning van lewerontgiftingsprosesse.

**VOORDAT JY GLUTACLEAR® NEEM**

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **GLUTACLEAR®** 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. Hou op om **GLUTACLEAR®** ten minste twee weke voor die geskeduleerde operasie te neem.

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

**SWANGERSKAP EN BORSVOEDING**

Veiligheid tydens swangerskap en borsvoeding is nie vasgestel, raadpleeg u gesondheidsorgpraktisyn voor gebruik. As u swanger is of borsvoed, dink dat u swanger is of beplan om 'n baba te hê, raadpleeg u gesondheidsorgpraktisyn voordat u hierdie aanvulling neem.

**BESTUUR EN GEBRUIK VAN MASIËNE**

Dit is nie altyd moontlik om te voorspel in watter mate **GLUTACLEAR®** die daaglikse aktiwiteite van 'n pasiënt kan belemmer nie. Pasiënte moet seker maak dat hulle nie betrokke raak by aktiwiteite wat verband hou met die vereiste van verstandelike waaksaamheid, oordeel en/of gesonde koördinasie en visie nie, byvoorbeeld bestuur, ry, vlieg, sell, bedryfsmasjiene/toerusting, totdat hulle bewus is van die mate waartoe **GLUTACLEAR®** jou beïnvloed.

**NEEM VAN ANDER MEDISYNE SAAM MET GLUTACLEAR®**

Komplementêre medisyne produkte bevat bestanddele wat met sommige medisyne 'n interaksie kan hê. As jy enige chroniese medisyne gebruik, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie.

**HOE OM GLUTACLEAR® TE NEEM**

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **GLUTACLEAR®** presies soos beskryf in hierdie inligtingsblad, of soos u dokter, gesondheidsorgpraktisyn voorgeskryf het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktisyn as jy onseker is.

**Aanwysings vir gebruik:**

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

**Moenie meer as die aanbevole dosis neem nie.**

**AS JY MEER GLUTACLEAR® NEEM AS WAT JY MOET**

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een hiervan beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

**AS JY VERGEET OM GLUTACLEAR® TE NEEM**

Moenie 'n dubbele dosis neem om op te maak vir 'n dosis wat oorgeslaan is nie.

**MOONTLIKE NUWE-EFFEKTE**

**GLUTACLEAR®** kan nuwe-effekte hê.

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Allergieë, borspyn (angina), diabetes, galblaasiekte, jig, niersiekte, lewersiekte, lae bloeddruk, maag- of dermsere, skildklierafwykings, asma, bloedingsversteuring, alkoholgebruiksversteuring, chroniese niersiekte, 'n metaboliese tektor genaamd "glukose-6-fosfaat dehidrogenase" (GGPD) tektor, nierstene, Outo-immuun siektes, hemodialise, rugbaarheidsprobleme by mans, velkanker. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: Diabetes (Antidiabetes middels), verlag van cholesterol (Galsuursekwestrants, statiene), hoë bloeddruk (Antihypertensiewe middels), medisyne wat die lewer kan benadeel (Hepatotoksiese middels), stadige bloedstolling (Antikoagulerende / Antiplaatjie-middels), Skildklierhormoon, Nikoïenpleister (Nicoderm), Aspirien, Nitroglyserien, Geaktiveerde houtskool, Chlorokien (Aralen), Estrogeen, medisyne vir kanker (Alkileringsmiddels), Acetaminophen (Tylenol, ander), Kalmeermiddels (Barbiturate), medisyne wat die immuunstelsel verminder (immuunonderdrukkers), Geboortebeperkingspille (Voorbehoedmiddels). As enige van die volgende gebeur, hou op om **GLUTACLEAR®** te gebruik en vertel jou dokter of gaan na die ongevallende afdeling by jou naaste hospitaal:

- Allergiese reaksie-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 **GLUTACLEAR®** gehad. Jy mag dalk dringende mediese hulp of hospitalisasie nodig hê.

Nuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteur aan u gesondheidsorgpraktisyn as dit voortduur):

- naarheid / braking, hardlywigheid, verlies aan eetlust, geestelike / gemoedsveranderinge, ongewone moegheid.

Nie alle nuwe-effekte en interaksies wat vir **GLUTACLEAR®** gerapporteer word, is by hierdie inligtingsblad ingesluit nie. 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.

**AANMELDING VAN NUWE-EFFEKTE**

As jy nuwe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisyn. U kan ook nuwe-effekte aan SAHPRA rapporteer via "6.04 Adverse Drug Reaction Reporting Form", wat aantly gevind word onder SAHPRA se publikasies:

<https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van **GLUTACLEAR®**.

**HOE OM GLUTACLEAR® TE BÈRÊ**

Bère alle medisyne buite bereik van kinders.

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

Beskermt teen direkte sonlig en hitte.

Bère in die oorspronklike verpakking.

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

Moenie **GLUTACLEAR®** gebruik as u sigbare tekens van agteruitgang opmerk nie.

Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

**AANBIEDING VAN GLUTACLEAR®**

**60 TABLETTE** - 'n Wit 175 ml HDPE-bottel met 'n wit dop, induksieseël, peuterkrimpsieël, spons en silikagelsakke.

**120 TABLETTE** - 'n Wit 250 ml HDPE-bottel met 'n wit dop, induksieseël, peuterkrimpsieël, spons en silikagelsakke.

**IDENTIFIKASIE VAN GLUTACLEAR®**

Wit, bedekte ovaal tablet.

**REGISTRASIONOMMER**

Om deur SAHPRA toegeken te word by registrasie.

**TOEGANG TOT DIE OOREENSTEMMENDE PROFESSIONELE INLIGTING** Skander QR-kode.

**HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP**

19 November 2024

**NAAM EN ADRES VAN REGISTRASIEHOUER**

Versprei deur:

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