

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Discipline Specific

33.6 Western Herbal Medicine

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM -

META I 3 C[®], 60 Capsules

COMPOSITION

Each one (1) capsule of META I 3 C[®] contain the following actives:

Indole-3-Carbinol	150 mg
Rosemary (Rosmarinus officinalis) [Leaf	50 mg
Extract standardized to 7,6 % min sum of	
carnosol + carnosic acid]	

Inactive Ingredients: Capsule (hydroxypropylmethylcellulose), maltodextrin, magnesium stearate (vegetable), and silica

This product is suitable for Vegetarians, dairy and gluten free and is non-GMO. (Sugar Free)

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

META I 3 C[®] supports healthy metabolic processes and may contribute to overall well-being.

Ingredients	Uses for ingredient
Indole-3-Carbinol	Supports oestrogen metabolism and hormone balance, potentially aiding in hormone-related health conditions.
Rosemary (Rosmarinus officinalis) [Provides antioxidant support, promotes cognitive health, and supports healthy digestion and circulation.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take **META I 3 C[®]** 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. **SURGERY:** **META I 3 C[®]** should be discontinued at least 2 weeks prior to reduce bleeding risks. **LABORATORY TESTS:** **META I 3 C[®]** may alter hormone-related tests due to its impact on estrogen metabolism and also impact liver enzyme tests. Please tell your healthcare practitioner that you are taking **META I 3 C[®]** before having any laboratory tests.

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**)

DOSE AND DIRECTIONS FOR USE

Adults: Take one (1) capsule twice daily with food or as directed by your healthcare practitioner. **Do not take more than the recommended dose.**

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT

See side-effects.

Treatment:

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

WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Hormone-sensitive conditions (e.g., breast cancer, uterine cancer, endometriosis): I3C may have oestrogen-modulating effects that could exacerbate these conditions. Liver dysfunction: High doses may alter liver enzyme levels and should be avoided without medical supervision. Epilepsy: May exacerbate seizures due to the potential neurotoxic effects of certain rosemary constituents at high doses. Liver health: High doses of either ingredient may alter liver enzyme activity; caution is advised in individuals with liver conditions. If you are taking the following medication, please consult with your healthcare professional before taking: Antidiabetic drugs (e.g., insulin, metformin): Can enhance glucose-Anticoagulants/Antiplatelets: May enhance bleeding risk due to its potential interaction with blood clotting. Hormonal therapies (e.g., oral contraceptives, hormone replacement therapy): May reduce their effectiveness due to oestrogen-modulating effects. CYP450 enzyme substrates: I3C can induce or inhibit certain CYP450 enzymes, potentially altering drug metabolism (e.g., statins, warfarin). Antiepileptic drugs: May reduce efficacy or increase seizure risk. Diuretics: Potential additive diuretic effects, leading to electrolyte imbalance. ACE inhibitors: Rosemary may lower blood pressure and enhance the effects of antihypertensive medications. If any of the following happens, stop using META I 3 C[®] 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).



These are all very serious effects. If you have them, you may have had a serious reaction to **META I 3 C[®]**. 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):

- Gastrointestinal issues.
- These are all very serious effects. If you have them, you may have had a serious reaction to **META I 3 C[®]**. 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.

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 **META I 3 C[®]** if you notice visible signs of deterioration.

IDENTIFICATION

Clear vegetable capsule, with a light tan fill.

PRESENTATION

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

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.

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
Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension,
Sandton, 2146, Tel: 011-802-8101

DATE OF PUBLICATION

To be allocated by the regulatory authority.

Document reference: MIC360C.PIV1 01-25

PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: **S0**

Kategorie D: Komplementêre medisyne.

Dissipline: Dissipline Spesifiek

33.6 Westerse kruiemedyne

HANDELSNAAM EN DOSEERVORM,

META I 3 C®, 60 Kapsules

SAMESTELING

Elke een (1) kasule van META I 3 C® bevat die volgende aktiewe stowwe:

Indool-3-karbinol	150 mg
Roosmaryn (Rosmarinus officinalis)	50 mg

[Blaarekstrak gestandaardiseer tot 7,6 % minimum som van karnosol + karnosiensuur]

Onaktiewe bestanddele: Kapsule (hydroxypropylmethylcellulose), maltodextrine, magnesiumstearaat (groente) en silika
Hierdie produk is geskik vir vegetariërs, suiwel- en glutenvry en is nie-GGO. (Suikervry)

FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

META I 3 C® ondersteun gesonde metaboliese prosesse en mag bydra tot algehele welstand.

Bestanddele	Gebruike vir bestanddeel
Indool-3-karbinol	Ondersteun estrogenmetabolisme en hormoonbalans, wat maontlik help met hormoonverwante gesondheidstoestande.
Roosmaryn (Rosmarinus officinalis) [Bied antioksidantondersteuning, bevorder kognitiewe gesondheid en ondersteun gesonde spysvertering en sirkulasie.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **META I 3 C®** 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. **CHIRURGIE: META I 3 C®** moet ten minste 2 weke voor die tyd gestaak word om bloedingsrisiko's te verminder. **LABORATORIUMTOETSE: META I 3 C®** kan hormoonverwante toetse verander as gevolg van die impak daarvan op estrogenmetabolisme en ook lewensiemtoetse beïnvloed. Vertel asseblief jou gesondheidsorgpraktisyn dat jy **META I 3 C®** neem voordat enige laboratoriumtoetse ondergaan word.

INTERAKSIES

Vertel altyd jou gesondheidsorgpraktisyn as jy enige ander medisyne gebruik. Dit is maontlik 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) kapsule twee keer per dag saam met kos of soos voorgeskryf deur jou gesondheidsorgpraktisyn.
Moenie meer as die aanbevole dosis neem nie.

DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.

WAARSKUWING EN SPESIALE VOORSORGMATREËLS

Indien jy enige van die volgende gedignoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Hormoonensitiewe toestande (bv. borskanker, baarmoederkanker, endometriose); IBC kan estrogenmodulerende effekte hê wat hierdie toestande kan vererger, Lewerdisfunksie: Hoë dosisse kan lewerensiemlavke verander en moet vermy word sonder mediese toesig, Epilepsie: Kan aanvalle vererger as gevolg van die potensiele neurotoksiese effekte van sekere roosmarynbestanddele by hoë dosisse. Lewergesondheid: Hoë dosisse van enige bestanddele kan lewerensiemaktiwiteit verander; Wees versigtig in individue met lewertoestande. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidsorgpraktisyn voordat jy neem: Antidiabetiese middels (bv. insulien, metformien); Kan glukose-Antikoagulanter / Antiplaatjies verbeter. Kan bloedingsrisiko verhoog as gevolg van die potensiele interaksie met bloedstolling. Hormonale terapieë (bv. orale voorbehoedemiddels, hormoonvervangings terapie): Kan hul doeltreffendheid verminder as gevolg van estrogenmodulerende effekte. CYP450-ensiemsubstrate: I3C kan sekere CYP450-ensieme induuseer of inhibeer, wat maontlik geneesmiddelmetabolisme kan verander (bv. Antiepileptiese middels: Kan doeltreffendheid verminder of die risiko van aanvalle verhoog. Diuretika: Potensiele additiewe diuretiese effekte, wat lei tot elektrolietwanbalans. ACE-ribeiders: Roosmaryn kan bloeddruk verlaag en die effekte van antihypertensiewe medikasie verbeter. As enige van die volgende gebeur, hou op om **META I 3 C®** te gebruik en vertel jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Allergiese reaksie- uitslag, jeuk / swelling (veral van die gesig / tong / keel);

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op **META I 3 C®** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê. Nuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteur aan jou gesondheidsorgpraktisyn as hulle voortduur):

- Gastrointestinale probleme.

Dit is alles baie ernstige gevolge. As u dit het, het u maontlik 'n ernstige reaksie op **META I 3 C®** 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 gelys word.
 - Jy moet nie hierdie produk aanvaar as seëls gebreek word 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.

BEKENDE 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.

Beskerem 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 **META I 3 C®** gebruik as u sigbare tekens van agteruitgang opmerk nie.

IDENTIFIKASIE

Duidelike groentekapsule, met 'n ligte bruin vulsel.

AANBIEDING

'n Wit 175 ml HDPE-bottel met 'n wit dop, induksieseël, peuterkrimpseël, spous en silikagelsakkie.

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 BESIGHEIDSADRES VAN APPLIKANT

Versprei deur:

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