

## PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Discipline Specific

33.6 Western Herbal Medicine

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

### META 13 C<sup>®</sup>, 60 Capsules

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU

- **META 13 C<sup>®</sup>** is available without a doctor's prescription.
- Nevertheless, you still need to use **META 13 C<sup>®</sup>** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **META 13 C<sup>®</sup>** with any other person.
- Ask your pharmacist or healthcare professional if you need more information or advice.

#### WHAT IS IN THIS LEAFLET

- What **META 13 C<sup>®</sup>** is and what it is used for.
- What you need to know before you take **META 13 C<sup>®</sup>**.
- How to take **META 13 C<sup>®</sup>**.
- Possible side effects.
- How to store **META 13 C<sup>®</sup>**.
- Contents of the pack and other information.

#### WHAT META 13 C<sup>®</sup> CONTAINS

Each one (1) capsule of **META 13 C<sup>®</sup>** contain the following actives:

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

**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)**

#### WHAT META 13 C<sup>®</sup> IS AND WHAT IT IS USED FOR

**META 13 C<sup>®</sup>** supports healthy metabolic processes and may contribute to overall well-being.

#### BEFORE YOU TAKE META 13 C<sup>®</sup>

If you are taking any chronic medication, do not use this product without consulting your healthcare provider. Do not take **META 13 C<sup>®</sup>** 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 13 C<sup>®</sup>** should be discontinued at least 2 weeks prior to reduce bleeding risks. **LABORATORY TESTS:** **META 13 C<sup>®</sup>** 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 13 C<sup>®</sup>** before having any laboratory tests. 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, consult with your healthcare professional before use. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult with your healthcare professional before taking this supplement.

#### DRIVING AND USING MACHINES

It is not always possible to predict to what extent **META 13 C<sup>®</sup>** 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 **META 13 C<sup>®</sup>** may affect you.

#### TAKING OTHER MEDICINES WITH META 13 C<sup>®</sup>

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.

#### 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.**

#### IF YOU TAKE MORE META 13 C<sup>®</sup> 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 META 13 C<sup>®</sup>

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



#### HOW TO TAKE META 13 C<sup>®</sup>

Do not share medicines prescribed for you with any other person. Always take **META 13 C<sup>®</sup>** 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.

#### POSSIBLE SIDE EFFECTS

**META 13 C<sup>®</sup>** may have side effects.

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): **13C** 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 rosmery 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 practitioner before taking: 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: **13C** 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 13 C<sup>®</sup>** 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 13 C<sup>®</sup>**. 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.

Not all side effects and interactions reported for **META 13 C<sup>®</sup>** 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/B>. By reporting side effects, you can help provide more information on the safety of **META 13 C<sup>®</sup>**.

#### STORAGE AND DISPOSING OF META 13 C<sup>®</sup>

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 **META 13 C<sup>®</sup>** if you notice visible signs of deterioration.

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

#### PRESENTATION OF META 13 C<sup>®</sup>

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

#### IDENTIFICATION OF META 13 C<sup>®</sup>

Clear vegetable capsule, with a light tan fill.

#### REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

#### ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

#### THIS LEAFLET WAS LAST REVISED ON

08 January 2025

#### NAME AND ADDRESS OF REGISTRATION HOLDER

Distributed by:

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# PASIËNT INLIGTINGSBLAD

## SKEDULERINGSSTATUS <sup>50</sup>

Kategorie D: Komplementêre medisyne.  
Dissipline: Dissipline Spesifiek  
33.6 Westerse kruiemidisyne

HANDELSNAAM EN DOSEERVORM,

## META I 3 C<sup>®</sup>, 60 Kapsules

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT

### BELANGRIKE INLIGTING VIR U

- **META I 3 C<sup>®</sup>** is beskikbaar sonder doktersvoorskrif.
- U moet steeds **META I 3 C<sup>®</sup>** versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie **META I 3 C<sup>®</sup>** met enige ander persoon deel nie.
- Vra jou apteker of gesondheidsorgpraktisyn of jy meer inligting of advies benodig.

### WAT IS IN HIERDIE INLIGTINGSBLAD

- Wat **META I 3 C<sup>®</sup>** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **META I 3 C<sup>®</sup>** neem.
- Hoe om **META I 3 C<sup>®</sup>** te neem.
- Moontlike nuwe-effekte.
- Hoe om **META I 3 C<sup>®</sup>** te bère.
- Inhoud van die pak en ander inligting

### WATTER META I 3 C<sup>®</sup> BEVAT

Elke een (1) kapsule **META I 3 C<sup>®</sup>** bevat die volgende aktiewe:

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)**

### WAT IS META I 3 C<sup>®</sup> KAPSULES EN WAARVOOR WORD DIT GEBRUIK

**META I 3 C<sup>®</sup>** ondersteun gesonde metaboliese prosesse en mag bydra tot algehele welstand.

### VOORDAT JY META I 3 C<sup>®</sup> NEEM

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **META I 3 C<sup>®</sup>** neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou **CHIRURGIE: META I 3 C<sup>®</sup>** moet ten minste 2 weke voor die vermindering van bloedsingsrisiko's gestaak word. **LABORATORIUMTOETSE: META I 3 C<sup>®</sup>** kan hormoonverwante toetse verander as gevolg van die impak daarvan op estrogenmetabolisme en ook lewerensiemtoetse beïnvloed. Vertel asseblief jou gesondheidsorgpraktisyn dat jy **META I 3 C<sup>®</sup>** neem voordat enige laboratoriumtoetse ondergaan word.

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

### BESTUUR EN GEBRUIK VAN MASIËNE

Dit is nie altyd moontlik om te voorspel in watter mate **META I 3 C<sup>®</sup>** die daaglikse aktiwiteit 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, seil, bedryfsmasjien/toerusting, totdat hulle bewus is van die mate waartoe **META I 3 C<sup>®</sup>** jou beïnvloed.

### NEEM VAN ANDER MEDISYNE SAAM MET META I 3 C<sup>®</sup>

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.

### SWANGERSKAP EN BORSVOEDING

Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie, 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.

### HOE OM META I 3 C<sup>®</sup> TE NEEM

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **META I 3 C<sup>®</sup>** 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 een (1) kapsule twee keer per dag saam met kos, of soos voorgeskryf deur jou gesondheidsorgpraktisyn.

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

**AS JY MEER META I 3 C<sup>®</sup> 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 VERGET OM META I 3 C<sup>®</sup> TE NEEM**

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

### MOONTLIKE NUWE-EFFEKTE

**META I 3 C<sup>®</sup>** kan nuwe-effekte hê.

Indien jy enige van die volgende diagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Hormoonsensitiwe toestande (bv. borskanker, baarmoederkanker, endometriose); I3C kan estrogenmodulerende effekte hê wat hierdie toestande kan vererger, Lewerdisfunksie: Hoë dosisse kan lewerensiemvlakke verander en moet vermy word sonder mediese toetsing, Epilepsie: Kan aanvalle vererger as gevolg van die potensieële neurotoksiese effekte van sekere roosmarynbestanddele by hoë dosisse. Lewerensie: Hoë dosisse van enige bestanddeel kan lewerensiemaktiwiteit verander; Wees versigtig by individue met lewertoestande. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidsorgpraktisyn voordat jy neem: Antidiabetiese middels (bv. insulien, metformien); Antikoagulanse / Antiplaatjies: Kan bloedsingsrisiko verhoog as gevolg van sy potensieële interaksie met bloedstolling. Hormonale terapieë (bv. orale voorbehoedmiddels, hormoonvervangings terapie): Kan hul doeltreffendheid verminder as gevolg van estrogenmodulerende effekte. CYP450-ensiemsubstrate: I3C kan sekere CYP450-ensieme indueer of inhibeer, wat moontlik geneesmiddelmetabolisme kan verander (bv. Antiepileptiese middels: Kan doeltreffendheid verminder of die risiko van aanvalle verhoog. Diuretika: Potensieële additiewe diuretiese effekte, wat lei tot elektrolietwanbalans. ACE-rhieverders: Roosmaryn kan bloeddruk verlaag en die effekte van antihertepiensiwere medikasie verbeter. As enige van die volgende gebeur, hou op om **META I 3 C<sup>®</sup>** te gebruik en vertel jou dokter of gaan na die ongevallende afdeling by jou naaste hospitaal:

- Allergiese reaksies- uitslag, jeuk / swelling (veral van die gesig / tong / keel).

Dit is alles baie ernstige effekte. As jy dit het, het jy dalk 'n ernstige reaksie op **META I 3 C<sup>®</sup>** 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):

- Gastrointestinale probleme, metaalsmaak in die mond.

Nie alle nuwe-effekte en interaksies wat vir **META I 3 C<sup>®</sup>** 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 aanlyn 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 **META I 3 C<sup>®</sup>**.

### HOE OM META I 3 C<sup>®</sup> TE BÈRE

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 **META I 3 C<sup>®</sup>** gebruik as u sigbare tekens van agteruitgang opmerk nie.

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

### AANBIEDING VAN META I 3 C<sup>®</sup>

'n Wit 175 ml HDPE-bottel met 'n wit dop, indieseëel, peuterkrimpseel, spons en silikagelsakke.

### IDENTIFIKASIE VAN META I 3 C<sup>®</sup>

Duidelike groentekapsule, met 'n ligte bruin vulsel.

### REGISTRASIONOMMER

Om deur SAHPRA toegeken te word by registrasie.

### TOEGANG TOT DIE OOREENSTEMMENDE PROFESSIONELE INLIGTING

Skandeer QR-kode.

### HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP

08 Januarie 2025

### NAAM EN ADRES VAN REGISTRASIEHOUER

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