

# PATIENT INFORMATION LEAFLET

## SCHEDULING STATUS

To be assigned.

## HydraMETICS™ Film-coated Tablets and Soft-Gel Capsules Sucrose, Lactose, Gluten and Tartrazine Free

Complementary Medicine – Health Supplement

### Read this leaflet carefully because it contains important information for you

HydraMETICS™ is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use HydraMETICS™ carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share HydraMETICS™ with any other person.
- Ask your healthcare professional or pharmacist if you need more information or advice.

### What is in this leaflet

1. What HydraMETICS™ is and what it is used for.
2. What you need to know before you take HydraMETICS™.
3. How to take HydraMETICS™.
4. Possible side effects.
5. How to store HydraMETICS™.
6. Contents of the pack and other information.

### 1. What HydraMETICS™ is and what it is used for

HydraMETICS™ is a health supplement intended as nutritional support to aid dry and brittle hair, skin and nails in adults and children from the age of 13 years.

### 2. What you need to know before you take HydraMETICS™

#### Do not take HydraMETICS™ if:

You experience a Hypersensitivity (allergic reaction) to any of the ingredients of HydraMETICS™ (as listed below in section 6).

HydraMETICS™ should not be used if you suffer from:

- conditions associated with hypercalcaemia and hypercalciuria, and in renal impairment (chronic);
- renal osteodystrophy with hyperphosphataemia (risk of metastatic calcification);
- a Fish Allergy.

#### Other medicines and HydraMETICS™

Always tell your healthcare professional if you are taking any other medicines. This includes complementary or traditional medicines.

Take HydraMETICS™ 2 hours before or after taking other medications or natural health products.

High dose Zinc supplementation may cause a copper or iron deficiency.

Vitamin D may increase the risk of hypercalcaemia.

#### Fertility, Pregnancy and Breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist, or other healthcare professional for advice before taking this medicine.

The ingredients in HydraMETICS™ are commonly included in pregnancy products.

#### Driving and using machines

HydraMETICS™ does not have any effect on the ability to drive or the use of machinery.

### 3. How to take HydraMETICS™

Do not share medicines with any other person.

Always take HydraMETICS™ exactly as described in this leaflet or as your doctor, pharmacist or healthcare professional has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one White Film-coated Tablet daily in the Morning with Breakfast and one Omega-3 Soft-Gel Capsule daily in the Evening with Dinner.

Do not take more than the daily dose specified.

HydraMETICS™ should be taken daily for as long as your healthcare professional indicates you to use it.

HydraMETICS™ should not be given to children below the age of 13 years (due to the Zinc content) unless under the direct supervision of a qualified healthcare professional.

#### If you take more HydraMETICS™ than you should

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact your nearest hospital or poison centre.

If an overdose is suspected, HydraMETICS™ should be stopped immediately.

Treatment is generally symptomatic and supportive.

#### If you forget to take HydraMETICS™

Do not take a double dose of HydraMETICS™ to make up for a forgotten individual dose.

### 4. Possible side effects

HydraMETICS™ can have side effects in exceptional instances.

Not all side effects reported for HydraMETICS™ are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking HydraMETICS™ please consult your healthcare professional for advice.

#### Less frequent side effects:

- nausea (feeling sick)
- diarrhoea
- constipation
- indigestion
- bloating
- flatulence

#### Reporting of adverse reactions:

Should you notice any side effects not mentioned in this leaflet, please report it to AnaStellar Brands (Pty) Ltd via [pharmacist@anastellar.co.za](mailto:pharmacist@anastellar.co.za), (011) 792 4601 or <https://anastellar.co.za>.

By reporting side effects, you can help provide more information on the safety of HydraMETICS™.

### 5. How to store HydraMETICS™

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light and moisture.

Store in the original container.

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

### 6. Contents of the pack and other information

#### What HydraMETICS™ contains

##### Component 1:

Each White Tablet contains

<b>Vitamin A</b> derived from Vitamin A Acetate 2 mg	1 000	IU
<b>Vitamin C</b> derived from Ascorbic Acid 200 mg	200	mg
<b>Vitamin D3</b> derived from Cholecalciferol 10 mg	1 000	IU
<b>Vitamin E</b> derived from dl- $\alpha$ -Tocopherol Acetate 30 mg	20	IU
<b>Biotin</b>	500	$\mu$ g
<b>Calcium</b> derived from Calcium Carbonate 200 mg	80	mg
<b>Copper</b> derived from Copper Sulphate 4 mg	1	mg
<b>Folate</b> derived from (6S)-5-Methyltetrahydrofolate 226 $\mu$ g	200	$\mu$ g
<b>Magnesium</b> derived from Magnesium Oxide 133 mg	80	mg
<b>Zinc</b> derived from Zinc Oxide 25 mg	20	mg

All minerals are expressed in their elemental and non-elemental forms.

The other ingredients are:

Tablet Core – Calcium Phosphate Dibasic, Magnesium Stearate, Maize Starch, Microcrystalline Cellulose, Povidone, Silicon Dioxide, Sodium Starch Glycolate and Solvent 45.

Tablet Coating – Castor Oil, Flexicoat, and Shellac.

##### Component 2:

Each Soft-Gel Omega-3 Capsule contains

<b>Docosahexaenoic Acid (DHA)</b>	400	mg
<b>Eicosapentaenoic Acid (EPA)</b> derived from Fish Oil Triglyceride 800 mg	80	mg

The other ingredients are d- $\alpha$ -Tocopherol Acetate, Gelatin (Fish origin) and Glycerol.

#### What HydraMETICS™ looks like and contents of the pack

HydraMETICS™ contains White Film-coated Tablets and Clear Shell Oval shaped Soft-Gel Capsules filled with a Yellow-coloured oily liquid.

Each pack contains 3 x PVC/PVDC/Aluminium blister strips with 10 x Film-coated Tablets contained in each strip as well as 3 x PVC/PVDC/Aluminium blister strips with 10 x Soft-Gel Capsules contained in each strip. The 6 x blister strips are enclosed within a cardboard carton.

#### Holder of Certificate of Registration

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#### Registration Number

To be assigned

#### This leaflet was last revised in May 2023

The Professional Information leaflet is available on <https://anastellar.co.za>

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

# PASIËNT-INLIGTINGSPAMFLET

## SKEDULERINGSSTATUS

Moet toegeken word.

## HydraMETICS™ Filmbedekte Tablette Sukrose-, Laktose-, Gluten- en Tartrasienvry

Aanvullende Middels – Gesondheidsaanvulling

### Lees hierdie pamflet sorgvuldig want dit bevat belangrike inligting vir jou

HydraMETICS™ is sonder 'n doktersvoorskrif aan jou beskikbaar om jou gesondheid in stand te hou. Nogtans moet jy bedagsaam wees wanneer jy HydraMETICS™ gebruik om die beste resultate daarvan te kry.

- Hou hierdie pamflet, want dit mag dalk nodig wees om dit weer te lees.
- Moenie HydraMETICS™ met iemand anders deel nie.
- Vra jou gesondheidspraktisyn of apteker as jy meer inligting of advies benodig.

### Wat is in hierdie pamflet

1. Wat HydraMETICS™ is en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy HydraMETICS™ neem.
3. Hoe om HydraMETICS™ te neem.
4. Moontlike nuwe-effekte.
5. Hoe om HydraMETICS™ te bewaar.
6. Die inhoud van die kartondosie en ander inligting.

### 1. Wat HydraMETICS™ is en waarvoor dit gebruik word

HydraMETICS™ is 'n gesondheidsaanvulling en dit ondersteun en voed droë en bros vel, hare en naels by volwassenes en kinders van 13 jaar en ouer.

### 2. Wat jy moet weet voordat jy HydraMETICS™ neem

#### Moenie HydraMETICS™ gebruik indien:

Jy 'n Hipersensitiwiteit (allergiese reaksie) vir enige van die bestanddele van HydraMETICS™ toon nie (word in afdeling 6 aangegee).

HydraMETICS™ behoort nie gebruik te word as jy ly aan:

- toestande geassosieer met hiperkalsemie en hiperkalsiurie en aan nierontoereikendheid (kronies);
- nier-osteodistrofie met hiperfosfatemie (risiko van metastatiese kalsifisering);
- 'n Allergie vir Vis het nie.

#### Ander medisyne en HydraMETICS™

Vertel altyd vir jou gesondheidsdeskundige as jy enige ander medisyne neem. Dit sluit gesondheidsaanvullings of tradisionele medisyne in.

Neem HydraMETICS™ 2 uur voor of na jy enige ander medikasies of natuurlike gesondheidsprodukte geneem het.

'n Hoë-dosis Sinkaanvulling mag moontlik 'n koper- of ystergebrek veroorsaak.

Vitamiën D mag die risiko van hiperkalsemie verhoog.

#### Vrugbaarheid, Swangerskap en Borsvoeding

Indien jy swanger is of borsvoed, dink dat jy swanger mag wees of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsdeskundige voordat jy hierdie medisyne neem.

Die bestanddele in HydraMETICS™ word algemeen in swangerskapprodukte gebruik.

#### Motorbestuur en die gebruik van masjinerie

HydraMETICS™ het nie 'n effek op die vermoë om te bestuur of wanneer 'n persoon masjinerie hanteer nie.

### 3. Hoe om HydraMETICS™ te neem

Moenie enige medisyne met iemand anders deel nie.

Neem HydraMETICS™ altyd presies soos in hierdie pamflet beskryf of soos jou dokter, apteker of ander gesondheidsdeskundige vir jou aanbeveel het. Vra jou dokter of apteker as jy nie seker is nie.

Die gewone dosis is een Wit Filmbedekte Tablet in die Oggend saam met Ontbyt en een Omega-3 Sagtejel-Kapsule daaglik in die Aand saam met Aandete.

Moenie meer as die daaglikse dosis wat aanbeveel word, neem nie.

HydraMETICS™ behoort daaglik geneem te word vir so lank as wat jou gesondheidsdeskundige dit vir jou aanbeveel het.

HydraMETICS™ behoort nie aan kinders onder die ouderdom van 13 jaar gegee te word nie (vanweë die Sink-inhoud) tensy onder die direkte toetsing van 'n gekwalifiseerde gesondheidsdeskundige.

#### As jy meer HydraMETICS™ neem as wat jy moes

In die geval van 'n oordosering, raadpleeg jou dokter of apteker. As nie een van die twee beskikbaar is nie, kontak jou naaste hospitaal of gifbeheersentrum.

As 'n oordosis vermoed word, behoort HydraMETICS™ dadelik gestaak te word.

Behandeling is oor die algemeen simptomaties en ondersteunend.

#### As jy vergeet om HydraMETICS™ te neem

Moenie 'n dubbele dosis van HydraMETICS™ neem om te vergoed vir 'n individuele dosis wat jy vergeet het nie.

### 4. Moontlike nuwe-effekte

HydraMETICS™ kan in buitengewone gevalle nuwe-effekte hê.

Nie alle nuwe-effekte wat vir HydraMETICS™ vermeld is, is in hierdie pamflet ingesluit nie. As jou algemene gesondheid versleg of as jy enige ongewenste nuwe-effekte ondervind terwyl jy HydraMETICS™ neem, vra asseblief jou gesondheidsdeskundige vir advies.

#### Minder dikwelse nuwe-effekte:

- naarheid (voel mislik)
- diarree
- hardlywigheid
- slegte spysvertering
- opgeblaaide maag
- winderigheid

#### Aanmelding van nuwe-effekte:

As jy enige nuwe-effekte opmerk wat nie in hierdie pamflet genoem word nie, meld dit asseblief by AnaStellar Brands (Edms) Bpk aan by [pharmacist@anastellar.co.za](mailto:pharmacist@anastellar.co.za), (011) 792 4601 of <https://anastellar.co.za>.

Deur nuwe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van HydraMETICS™ te verskaf.

### 5. Hoe om HydraMETICS™ te bewaar

Hou alle medisyne buite kinders se bereik.

Bewaar teen 25 °C of benede.

Beskermt teen lig en vogtigheid.

Bewaar in die oorspronklike houer.

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

### 6. Die inhoud van die kartondosie en ander inligting

#### Wat HydraMETICS™ bevat

##### Komponent 1:

Elke Wit Tablet bevat

<b>Vitamiën A</b> afgelei van Vitamiën A Asetaat 2 mg	1 000	IE
<b>Vitamiën C</b> afgelei van Askorbiensuur 200 mg	200	mg
<b>Vitamiën D3</b> afgelei van Cholekalsiferol 10 mg	1 000	IE
<b>Vitamiën E</b> afgelei van dl- $\alpha$ -Tokoferolasetaat 30 mg	20	IE
<b>Biotien</b>	500	$\mu$ g
<b>Kalsium</b> afgelei van Kalsiumkarbonaat 200 mg	80	mg
<b>Koper</b> afgelei van Kopersulfaat 4 mg	1	mg
<b>Folaat</b> afgelei van (6S)-5-Metieltetrahydrofolaat 226 $\mu$ g	200	$\mu$ g
<b>Magnesium</b> afgelei van Magnesiumoksied 133 mg	80	mg
<b>Sink</b> afgelei van Sinkoksied 25 mg	20	mg

Alle minerale word in hul element- en nie-elementvorm weergegee.

Die ander bestanddele is:

Tabletkern – Kalsiumfosfaat-dibasies, Magnesiumstearaat, Mieliestysel, Mikrokristallyne Sellulose, Povidoon, Silikondioksied, Natriumstyselglukolaat en Oplosmiddel 45.

Tabletbedekking – Kasterolie, Flexicoat en Skellak.

##### Komponent 2:

Elke Sagtejel Omega-3 Kapsule bevat

<b>Dokosaheksaënoësuur (DHA)</b>	400	mg
<b>Eikosapentaënoësuur (EPA)</b> afgelei van Visolietrigliseried 800 mg	80	mg

Die ander bestanddele is d- $\alpha$ -Tokoferolasetaat, Gelatien (Vis oorsprong) en Gliserol.

### Hoe HydraMETICS™ lyk en die inhoud van die kartondosie

HydraMETICS™ bevat Wit Ovaal Filmbedekte Tablette en Deursigtige-dop Ovaal Sagtejel-Kapsules gevul met 'n Geel-gekleurde oliegevoelige vloeistof.

Elke kartondosie bevat 3 x PVC/PVDC/Aluminium stulpstrok wat elk 10 x Filmbedekte Tablette per stulpstrok bevat sowel as 3 x PVC/PVDC/Aluminium stulpstrok wat elk 10 x Sagtejel-Kapsules per stulpstrok bevat. Daar is 6 x stulpstrok binne-in 'n kartondosie.

#### Houer van die Registrasiesertifikaat

AnaStellar Brands (Edms) Bpk  
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#### Registrasienommer

Moet toegeken word

#### Hierdie pamflet is laas in Mei 2023 hersien

Die Professionele Inligtingspamflet is beskikbaar by webtuiste <https://anastellar.co.za>

Hierdie ongeregistreerde middel is nie deur die SAHPRA vir sy gehalte, veiligheid of beoogde gebruik geëvalueer nie.