



CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Unscheduled

PROPRIETARY NAME AND DOSAGE FORM

CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules), soft gelatine capsules

Read all of this leaflet carefully because it contains important information for you

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance. CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) carefully to get the best results from it.

Keep this leaflet. You may need to read it again.

- Do not share CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

WHAT CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) CONTAINS

Each capsule contains:

Omega 3 fatty acids as triglycerides of which	162,5 mg
DHA (Docosahexaenoic acid)	125,0 mg
EPA (Eicosapentaenoic acid)	25,0 mg
Ascorbic acid (Vitamin C)	55,0 mg
Pyridoxine hydrochloride	24,2 mg
providing Pyridoxine (Vitamin B ₆)	1,7 mg
Choline bitartrate	24,3 mg
providing Choline	10,0 mg
Nicotinamide (Vitamin B ₃)	18,0 mg
Iron (from Ferrochel™ ferrous bisglycinate chelate 50,0 mg)	10,0 mg
Calcium-D-pantothenate (Vitamin B ₅)	6,0 mg
Thiamine mononitrate	3,0 mg
providing Thiamine (Vitamin B ₁)	2,4 mg
Riboflavin (Vitamin B ₂)	2,0 mg
Methyltetrahydrofolic acid, glucosamine salt	500,0 µg
providing Folic acid (Vitamin B ₉)	269,9 µg
Vitamin K ₁	55,0 µg
D-Biotin (Vitamin H)	30,0 µg
Cyanocobalamin (Vitamin B ₁₂)	2,6 µg
Vitamin A palmitate (Vitamin A)	2 640 IU
Cholecalciferol (Vitamin D ₃)	600 IU

The other ingredients are:

Beeswax yellow, gelatin, glycerin, hydrogenated coconut oil, iron oxide black, iron oxide red, lecithin, purified water, sunflower oil and titanium dioxide.

WHAT CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) IS USED FOR

Category D Complementary Medicine
Discipline 34.12 Health Supplements. Multiple substance formulation
CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) supports the health of the mother, and the optimal growth and development of the placenta and embryo, including the neural tube (spinal cord), during the first trimester of pregnancy (1-13 weeks). It also helps reduce morning sickness, common during the first trimester.

BEFORE YOU TAKE CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules)

Do not take CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) if you are hypersensitive (allergic) to any of the ingredients. Do not take CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) if you are hypersensitive (allergic) to fish and/or peanut oil. Do not take CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) if you are taking any blood thinning medicines such as warfarin.
Vitamin E should not be used during the first trimester of pregnancy. Therefore, do not use CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) or CHELA-PREG® PRE-NATAL TRIMESTER 3™ (Evening Capsules) during the first trimester of pregnancy since these products contain vitamin E.
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

Taking CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) with food and drink

CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) can be taken after meals.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking this medicine.

CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) is safe for use during pregnancy and lactation.
Vitamin E should not be used during the first trimester of pregnancy.

Therefore, do not use CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) or CHELA-PREG® PRE-NATAL TRIMESTER 3™ (Evening Capsules) during the first trimester of pregnancy since these products contain vitamin E.

Important information about some of the ingredients of CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules)

Sugar free.

Taking other medicines with CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules)

Always tell your healthcare provider if you are taking any other medicine. Anticoagulants (blood thinning) medication: Vitamin K decreases the effect of anticoagulants (such as warfarin). Do not take CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) if you are taking blood thinning medicines.

HOW TO TAKE CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules)

Do not share medicines prescribed for you with any other person. Always take CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) exactly as instructed. You should check with your doctor or pharmacist if you are unsure.

The usual dosage is:

Take 1 capsule daily in the evening after meals.

If you take more CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) than you should

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

If you forget to take a dose of CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules)

Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS

CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) can have side effects.
Side effects may include gastrointestinal complaints.
Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your healthcare provider for advice.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules)

Store all away from the expiry date stated on the label / carton / bottle.

Store at or below 25 °C.

Keep the container in the outer carton.

Store in the original package / container.

Keep the container tightly closed.

Protect from moisture.

Do not store in a bathroom.

Do not use after the expiry date stated on the label / carton / bottle.

Do not use CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) if you notice visible signs of deterioration.

Return all unused medicine to your pharmacist.

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

PRESENTATION OF CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules)

A white bottle and cap containing 30 capsules.

IDENTIFICATION OF CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) GEBRUIK WORD

A brown oblong, soft gelatine capsule.

REGISTRATION NUMBER

RSA: TBA

DATE OF REGISTRATION

TBA

PROFESSIONAL INFORMATION

For further information refer to the Professional Information of the product.

NAME AND ADDRESS OF REGISTRATION HOLDER

Ascendis Consumer Brands (Pty) Ltd
1 Carey Street
Wynberg, Gauteng 2090
South Africa
+27 11 036 9420

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION

TBA



CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules)

PASIËNTINLIGTINGSBLAADJIE

SKEDULERINGSSTATUS

Ongeskeduleer

HANDELSNAAM EN DOSEERVORM

CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules), sagte gelatien kapsules

Lees die hele inligtingsblaadjie noukeurig deur, dit bevat belangrike inligting vir jou.

'n Dieët met verskeidenheid is die doeltreffendste en veiligste manier om goeie voeding, gesondheid, liggaamsamstelling sowel as geestelike en fisiese prestasies te bewerkstellig.

CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) is beskikbaar sonder 'n doktersvoorskrif om minder ernstige siektes te behandel. Jy moet egter nougeestde CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) versigtig gebruik om die beste resultate te verkry.

- Hou hierdie voubljet, dit mag dalk nodig wees om dit weer te lees.
- Moenie CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) met enige ander persoon deel nie.
- Raadpleeg jou gesondheidsorgverskaffer of apteker indien jy meer inligting of advies benodig.

WAT CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) BEVAT

Eike kapsule bevat:	
Omega 3 vetseure as trigliseriede waarvan	162,5 mg
DHS (Dokosaheksanoësuur)	125,0 mg
EPS (Eikosapentanoësuur)	25,0 mg
Askorbien suur (Vitamin C)	55,0 mg
Piridoksiendihidrochloried	24,2 mg
verskaf Piridoksien (Vitamin B ₆)	1,7 mg
Cholienbitartraat	24,3 mg
verskaf Cholien	10,0 mg
Nikotienamied (Vitamin B ₃)	18,0 mg
Yster (van Ferrochel™ ysterhoudende-bisgylsinaat)chelataat 50,0 mg)	10,0 mg
Kalsium-D-pantotienaat (Vitamin B ₅)	6,0 mg
Tiamienmononitrat	3,0 mg
verskaf Tiamien (Vitamin B ₁)	2,4 mg
Riboflavin (Vitamin B ₂)	2,0 mg
Metielteetrahidrofoliensuur, glukosamien sout	500,0 µg
verskaf Foliensuur (Vitamin B ₉)	269,9 µg
Vitamin K ₁	55,0 µg
D-Biotin (Vitamin H)	30,0 µg
Sianokobalامين (Vitamin B ₁₂)	2,6 µg
Vitamin A palmitaat (Vitamin A)	2 640 IU
Cholekalsiferol (Vitamin D ₃)	600 IU

Die ander bestanddele is:

Gee! bye-was, gelatien, gliserien, gehidrogeneerde klapperolie, ysteroksied swart, ysteroksied rooi, lesitien, gesuwerde water, sonnbiomolie en titaniumdoksied.

WAARVOOR CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) GEBRUIK WORD

Kategorie D Komplementêre Medisyne

Dissipline 34.12 Gesondheidsaanvulling. Veevuldige middel formulase
CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) ondersteun die gesondheid van die moeder, en die optimale groei en ontwikkeling van die plasenta en embrio, insluitend die neurale buis (spinale koord), gedurende die eerste trimester van swangerskap (1-13 weke). Dit help ook om oggendnaarheid, wat algemeen is gedurende die eerste trimester, te verminder.

VOORDAT CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) GEBRUIK WORD

Moenie CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) gebruik indien jy hipersensitief (allergies) is vir enige van die bestanddele nie.
Moenie CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) gebruik indien jy hipersensitief (allergies) is vir vis en/of grondboontjie-olie nie.

Moenie CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) gebruik es jy enige bloedverdunnings medikasie soos warfarin neem nie. Vitamin E moet nie gedurende die eerste trimester van swangerskap gebruik word nie. Daarom moet CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) of CHELA-PREG® PRE-NATAL TRIMESTER 3™ (Evening Capsules) nie gedurende die eerste trimester van swangerskap gebruik word nie aangesien hierdie produkte vitamien E bevat. Hierdie ongeregistreerde medisyne is nie deur SAHPRA geëvalueer vir sy gehalte, veiligheid of beoogde gebruik nie.

Neem van CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) met voedsel en vloeistof

CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) kan geneem word na etes.

Swangerskap en Borsvoeding

As jy swanger is of jou baba borsvoed, raadpleeg jou gesondheidsorgverskaffer voordat jy hierdie medisyne gebruik.

CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) is veilig vir gebruik gedurende swangerskap en laktasie.

Vitamien E moet nie gedurende die eerste trimester van swangerskap gebruik word nie. Daarom moet CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) of CHELA-PREG® PRE-NATAL TRIMESTER 3™ (Evening Capsules) nie gedurende die eerste trimester van swangerskap gebruik word nie aangesien hierdie produkte vitamien E bevat.

Belangrike inligting in verband met sommige van die bestanddele in CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules)

Suikervry.

As jy ander medisyne saam met CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) neem

Stel altyd jou gesondheidsorgverskaffer in kennis indien jy enige ander medisyne gebruik.

Antikoagulate (bloedverdunnings) medikasie: Vitamin K verminder die effek van antikoagulate (soos warfarin). Moenie CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) gebruik indien jy bloedverdunnings medikasie neem nie.

HOE OM CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) TE GEBRUIK

Moenie jou medisyne met enige iemand anders deel nie.

Neem CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) altyd presies soos aanbeveel. Bepvestig met jou dokter of apteker indien jy onseker is.

Die normale dosering is:

Neem 1 kapsule daaglik in die aand na etes.

Indien jy meer CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) gebruik as wat jy behoort

Indien oordosering vermoed word, raadpleeg onmiddellik jou dokter of apteker. Indien genees beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet het om CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) te neem

Moenie 'n dubbele dosis neem om vir oorgeslane dosisse te vergoed nie.

MOONTLIKE NIEWE-EFFEKTE

CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) kan moontlik newe-effekte veroorsaak.

Newe-effekte mag insluit gastroïntestinale klagtes.

Nie alle newe-effekte wat vir hierdie medisyne aangemeld is, word in hierdie voubljet genoem nie. Indien jou algemene gesondheid verswak of indien jy enige nadelige effekte ondervind terwyl jy hierdie medikasie gebruik, moet jy asselblief jou gesondheidsorgverskaffer raadpleeg.
Indien jy enige newe-effekte waarneem wat nie in hierdie voubljet genoem word nie, moet jy jou dokter of apteker daarvan vertel.

BERGING EN WEGDOEN VAN CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules)

Bewaar alle medikasie buite bereik van kinders.

Bewaar teen of benede 25 °C.

Bewaar die houer in die kartonverpakking.

Bewaar in die oorspronklike houer.

Maak die houer dig toe.

Beskerm teen vog.

Moenie die produk in die badkamer bewaar nie.

Moenie na die vervaldatum wat op die etiket / karton / bottel aangedui is, gebruik nie.

Moenie CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) gebruik indien jy enige sigbare tekens van produktafbraak opmerk nie.

Besorg enige ongebruikte medisyne terug aan jou apteker.

Moenie van ongebruikte medisyne ontlae raak in dreine of rioolstelsels nie (bv. toilette).

AANBIEDING VAN CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules)

'n Wit bottel en deksel wat 30 kapsules bevat.

IDENTIFIKASIE VAN CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules)

'n Bruin, langwerpige, sagte gelatien kapsule.

REGISTRASIENOMMER

RSA: TBA

DATUM VAN REGISTRASIE

TBA

PROFESIONELE INLIGTING

Verwys na die voubljet met professionele inligting vir meer inligting.

NAAM EN BESIGHEIDSAADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

Ascendis Consumer Brands (Pty) Ltd
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South Africa
+27 11 036 9420

DATUM VAN PUBLIKASIE VAN DIE PROFESIONELE INLIGTING

TBA

905M343/00



CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules)

PROFESSIONAL INFORMATION

SCHEDULING STATUS

Unscheduled

PROPRIETARY NAME AND DOSAGE FORM

CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules), soft gelatine capsules

COMPOSITION

Each capsule contains:	
Omega 3 fatty acids as triglycerides of which	162,5 mg
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EPA (Eicosapentaenoic acid)	25,0 mg
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providing Pyridoxine (Vitamin B ₆)	1,7 mg
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providing Choline	10,0 mg
Nicotinamide (Vitamin B ₃)	18,0 mg
Iron (from Ferrochel™ ferrous bisglycinate chelate 50,0 mg)	10,0 mg
Calcium-D-pantothenate (Vitamin B ₅)	6,0 mg
Thiamine mononitrate	3,0 mg
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Cyanocobalamin (Vitamin B ₁₂)	2,6 µg
Vitamin A palmitate (Vitamin A)	2 640 IU
Cholecalciferol (Vitamin D ₃)	600 IU

Inactive ingredients:

Beeswax yellow, gelatin, glycerin, hydrogenated coconut oil, iron oxide black, iron oxide red, lecithin, purified water, sunflower oil and titanium dioxide.

Sugar free.

PHARMACOLOGICAL CLASSIFICATION

Category D Complementary Medicine

Discipline 34.12 Health Supplements. Multiple substance formulation

PHARMACOLOGICAL ACTION

CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) is a combination of multivitamin, iron (ferrous bisglycinate chelate), folic acid and DHA-rich omega-3 supplement formulated for pregnant women. It includes a stabilised Quatrefolic® 5-methyltetrahydrofolate (MTHF) folate form of folic acid.
Quatrefolic® 5-MTHF bypasses the need for enzymatic activation and is effective in cases of absorption-enzyme such as dihydrofolate reductase (DHFR) and MTHF reductase genetic polymorphisms. Quatrefolic® 5-MTHF is a stable form of folic acid with a better absorption than folic acid, for neural tube development.

INDICATIONS

CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) is indicated to support foetal and maternal health during the first trimester of pregnancy (1-13 weeks). It supplies micronutrients including DHA-omega 3 to boost maternal red blood cells and maternal tissue growth.

Vitamin B₉ helps to reduce morning sickness which is common during the first trimester of pregnancy.

It contains iron which assists with red blood cell formation and folic acid which helps to reduce the risk of neural tube defects.

CONTRAINDICATIONS

Do not use CHELA-PREG® PRE-NATAL TRIMESTER 1™ if you are hypersensitive (allergic) to any of the ingredients.

Do not use CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules) if you are hypersensitive (allergic) to fish and/or peanut oil. Individuals taking anticoagulants must not take CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules).

WARNINGS and SPECIAL PRECAUTIONS

If you are on any medication or suffering from any medical condition, it is advisable to seek medical advice before starting any new medicine, supplement or remedy.

Do not exceed recommended dosage(s) unless on the advice of a healthcare practitioner.

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

INTERACTIONS

All forms of vitamin K may interact with blood thinning medications such as warfarin. (See Contraindications).

HUMAN REPRODUCTION

This product is safe for use during pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE

CHELA-PREG® PRE-NATAL TRIMESTER 1™ (Evening Capsules):

Take 1 capsule daily in the evening after meals.

SIDE EFFECTS