



CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Unscheduled

PROPRIETARY NAME AND DOSAGE FORM

CHELA-PREG® PRE-NATAL TRIMESTER 2™ (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 2™ (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 2™ (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 2™ (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 2™ (Evening Capsules) CONTAINS

Each capsule contains:	
Omega 3 fatty acids as triglycerides of which	130,0 mg
DHA (Docosahexaenoic acid)	100,0 mg
EPA (Eicosapentaenoic acid)	20,0 mg
Ascorbic acid (Vitamin C)	42,5 mg
Choline bitartrate	24,3 mg
providing Choline	10,0 mg
Iron (from Ferrochel™ ferrous bisglycinate chelate 50,0 mg)	10,0 mg
Nicotinamide (Vitamin B ₃)	9,0 mg
Calcium-D-pantothenate (Vitamin B ₅)	3,0 mg
Thiamine mononitrate	1,5 mg
providing Thiamine (Vitamin B ₁)	1,2 mg
Riboflavin (Vitamin B ₂)	1,0 mg
Pyridoxine hydrochloride	950,0 µg
providing Pyridoxine (Vitamin B ₆)	766,0 µg
Methyltetrahydrofolic acid, glucosamine salt	250,0 µg
providing Folic acid (Vitamin B ₉)	134,9 µg
Vitamin K ₁	27,5 µg
D-Biotin (Vitamin H)	15,0 µg
Cyanocobalamin (Vitamin B ₁₂)	1,3 µg
Vitamin A palmitate (Vitamin A)	1 320 IU
Cholecalciferol (Vitamin D ₃)	300 IU
DL-alpha tocopheryl acetate (Vitamin E)	6 IU

The other ingredients are: Beeswax yellow, dl- α -tocopherol, gelatin, glycerin, hydrogenated coconut oil, iron oxide black, iron oxide red, lecithin, peanut oil, purified water, sunflower oil and titanium dioxide.

WHAT CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) IS USED FOR

Category D Complementary Medicine
Discipline 34.12 Health Supplements. Multiple substance formulation
CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) supports the health of the mother and developing foetus during the second trimester of pregnancy (14-26 weeks). It supports eye, brain and nervous system development. It supports pregnancy health, immunity and improves safer pregnancy outcomes. It helps increase pregnancy energy.

BEFORE YOU TAKE CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules)

Do not take CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) if you are hypersensitive (allergic) to any of the ingredients. Do not take CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) if you are hypersensitive (allergic) to fish and/or peanut oil. Do not take CHELA-PREG® PRE-NATAL TRIMESTER 2™ (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 2™ (Evening Capsules) with food and drink

CHELA-PREG® PRE-NATAL TRIMESTER 2™ (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 2™ (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 2™ (Evening Capsules)

Sugar free.

Taking other medicines with CHELA-PREG® PRE-NATAL TRIMESTER 2™ (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 2™ (Evening Capsules) if you are taking blood thinning medicines.

HOW TO TAKE CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules)

Do not share medicines prescribed for you with any other person. Always take CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) exactly as instructed. You should check with your doctor or pharmacist if you are unsure. The usual dosage is: Take 2 capsules daily in the evening after meals.

If you take more CHELA-PREG® PRE-NATAL TRIMESTER 2™ (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 2™ (Evening Capsules)

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

POSSIBLE SIDE EFFECTS

CHELA-PREG® PRE-NATAL TRIMESTER 2™ (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 2™ (Evening Capsules)

Store all medicines out of reach of children. 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 2™ (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 2™ (Evening Capsules)

A white bottle and cap containing 60 capsules.

IDENTIFICATION OF CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules)

A brown, oblong, soft gelatine capsule.

REGISTRATION NUMBER

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
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+27 11 036 9420

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION

TBA



CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules)

PASIËNTINLIGTINGSBLAADJIE

SKEDULERINGSSTATUS

Ongeskeduleer

HANDELSNAAM EN DOSEERVORM

CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules), sagte gelatien kapsules

Lees die hele inligtingsblaaadjie 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 2™ (Evening Capsules) is beskikbaar sonder 'n doktersvoorskrif om minder ernstige siektes te behandel. Jy moet egter nogsteeds CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) versigtig gebruik om die beste resultate te verkry.

- Hou hierdie voubljief, dit mag dalk nodig wees om dit weer te lees.
- Moenie CHELA-PREG® PRE-NATAL TRIMESTER 2™ (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 2™ (Evening Capsules) BEVAT

Eike kapsule bevat:	
Omega 3 vetseure as triglisieriede waarvan	130,0 mg
DHS (Dokosaheksanoësuur)	100,0 mg
EPS (Eikosapentanoësuur)	20,0 mg
Askorbienisuur (Vitamin C)	42,5 mg
Cholienbitraat	24,3 mg
verskaf Chollien	10,0 mg
Yster (van Ferrochel™ ysterhoudende-bisgisiinatchelate 50,0 mg)	10,0 mg
Nikotienamied (Vitamin B ₃)	9,0 mg
Kalsium-D-pantotenaat (Vitamin B ₅)	3,0 mg
Tiamienmononitrat	1,5 mg
D-Biotien (Vitamin H)	1,2 mg
Riboflavin (Vitamin B ₂)	1,0 mg
Piridoksiensuur (Vitamin B ₆)	950,0 µg
verskaf Piridoksiën (Vitamin B ₆)	766,0 µg
Metielltetrahidrofoliëensuur, glukosamiën sout	250,0 µg
verskaf Foliëensuur (Vitamin B ₉)	134,9 µg
Vitamin K ₁	27,5 µg
D-Biotien (Vitamin H)	15,0 µg
Sianokobalامين (Vitamin B ₁₂)	1,3 µg
Vitamin A palmitaat (Vitamin A)	1 320 IU
Cholekalsiferol (Vitamin D ₃)	300 IU
DL-alfa-tokolerolasetaat (Vitamin E)	6 IU

Die ander bestanddele is: Geel bye-was, dl- α -tokiferol, gelatien, gliserien, gehidrogeneerde klapperolie, ysteroksied swart, ysteroksied rooi, lesitiën, grondboontjie-olie, gesuiwerde water, sonneblomolie en titaniumdoksied.

WAARVOOR CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) GEBRUIK WORD

Kategorie D Komplementêre Medisyne
Discipline 34.12 Gesondheidsaanwilling. Veevuldige middel formulasie
CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) ondersteun die gesondheid van die ma en die ontwikkelende fetus gedurende die tweede trimester van swangerskap (14-26 weke). Dit ondersteun ontwikkeling van die oë, brein en senuweestelsel. Dit ondersteun gesondheid in swangerskap, immuniteit en verbeter swangerskap uitkomst. Dit help om energie in swangerskap te verhoog.

VOORDAT CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) GEBRUIK WORD

Moenie CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) gebruik indien jy hipersensitief (allergies) is vir enige van die bestanddele nie. Moenie CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) gebruik indien jy hipersensitief (allergies) is vir vis en/of grondboontjie-olie nie. Moenie CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) gebruik as 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 2™ (Evening Capsules) met voedsel en vloeistof

CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) kan geneem word na ete.

Swangerskap en Borsvoeding

As jy swanger is of jou baba borsvoed, raadpleeg jou gesondheidsorgverskaffer voordat jy hierdie medisyne gebruik. CHELA-PREG® PRE-NATAL TRIMESTER 2™ (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 2™ (Evening Capsules)

As jy ander medisyne saam met CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) neem

Stel altyd jou gesondheidsorgverskaffer in kennis indien jy enige ander medisyne gebruik. Antikoagulanste (bloedverdunnings) medikasie: Vitamin K verminder die effek van antikoagulanste (soos warfarin). Moenie CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) gebruik indien jy bloedverdunnings medikasie neem nie.

HOE OM CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) TE GEBRUIK

Moenie jou medisyne met enige iemand anders deel nie. Moenie CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) gebruik indien jy bloedverdunnings medikasie neem nie.

Die normale dosering is:

Neem 2 kapsules daaglik in die aand na ete.

Indien jy meer CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) gebruik as wat jy behoort

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

Indien jy vergeet het om CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) te neem

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

MOONTLIKE NEWE-EFFEKTE

CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) kan moontlik newe-effekte veroorsaak. Newe-effekte mag insluit gastroïntestinale klages.

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

BERGING EN WEGDOEN VAN CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules)

Bewaar alle medikasie buite bereik van kinders. Bewaar teen of benede 25 °C. Bewaar die houër in die kartonverpakking. Bewaar in die oorspronklike houër. Maak die houër 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 2™ (Evening Capsules) gebruik indien jy enige sigbare tekens van produkafbraak opmerk nie. Besorg enige ongebruikte medisyne terug aan jou apteker. Moenie van ongebruikte medisyne ontstae raak in dreine of rioolstelsels nie (bv. toilette).

AANBIEDING VAN CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules)

'n Wit bottel en deksel wat 60 kapsules bevat.

IDENTIFIKASIE VAN CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules)

'n Bruin, langwerpige, sagte gelatien kapsule.

REGISTRASIEOMMER

TBA

DATUM VAN REGISTRASIE

TBA

PROFESIONELE INLIGTING

Verwys na die voubljief met professionele inligting vir meer inligting.

NAAM EN BESIGHEIDSAADRES VAN DIE HOUER VAN DIE REGISTRASIEERTIFIKAAT

Ascendis Consumer Brands (Pty) Ltd
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DATUM VAN PUBLIKASIE VAN DIE PROFESIONELE INLIGTING

TBA

905M344/00



CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules)

PROFESSIONAL INFORMATION

SCHEDULING STATUS

Unscheduled

PROPRIETARY NAME AND DOSAGE FORM

CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules), soft gelatine capsules

COMPOSITION

Each capsule contains:	
Omega 3 fatty acids as triglycerides of which	130,0 mg
DHA (Docosahexaenoic acid)	100,0 mg
EPA (Eicosapentaenoic acid)	20,0 mg
Ascorbic acid (Vitamin C)	42,5 mg
Choline bitartrate	24,3 mg
providing Choline	10,0 mg
Iron (from Ferrochel™ ferrous bisglycinate chelate 50,0 mg)	10,0 mg
Nicotinamide (Vitamin B ₃)	9,0 mg
Calcium-D-pantothenate (Vitamin B ₅)	3,0 mg
Thiamine mononitrate	1,5 mg
providing Thiamine (Vitamin B ₁)	1,2 mg
Riboflavin (Vitamin B ₂)	1,0 mg
Pyridoxine hydrochloride	950,0 µg
providing Pyridoxine (Vitamin B ₆)	766,0 µg
Methyltetrahydrofolic acid, glucosamine salt	250,0 µg
providing Folic acid (Vitamin B ₉)	134,9 µg
Vitamin K ₁	27,5 µg
D-Biotin (Vitamin H)	15,0 µg
Cyanocobalamin (Vitamin B ₁₂)	1,3 µg
Vitamin A palmitate (Vitamin A)	1 320 IU
Cholecalciferol (Vitamin D ₃)	300 IU
DL-alpha tocopheryl acetate (Vitamin E)	6 IU

Inactive ingredients:

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

PHARMACOLOGICAL CLASSIFICATION

Category D Complementary Medicine

Discipline 34.12 Health Supplements. Multiple substance formulation

PHARMACOLOGICAL ACTION

CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) is a combination of multivitamin, iron, folate and DHA-rich omega-3 supplement formulated for pregnant women. It includes iron-chelate (ferrous bisglycinate chelate) and a stabilised Quatrefolic® 5-methyltetrahydrofolate folate form of folic acid.

INDICATIONS

CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) supports foetal and maternal health during the second trimester of pregnancy (14-26 weeks).

It supplies micronutrients including DHA-omega 3 for central nervous system and eye development. Vitamins A, C, D and E, and choline support pregnancy health, immunity and improve safer pregnancy outcomes. Iron supports increased maternal red blood cells and foetal metabolic demands.

B-Vitamins contribute to normal energy-yielding metabolism.

CONTRAINDICATIONS

Do not use CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) if you are hypersensitive (allergic) to any of the ingredients. Do not use CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) if you are hypersensitive (allergic) to fish and/or peanut oil. Individuals taking anticoagulants must not take CHELA-PREG® PRE-NATAL TRIMESTER 2™ (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.

Vitamin E should not be used during the first trimester of pregnancy, hence do not use CHELA-PREG® PRE-NATAL TRIMESTER 2™ (Evening Capsules) and CHELA-PREG® PRE-NATAL TRIMESTER 3™ (Evening Capsules) in the first trimester as they contain vitamin E.

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

Take 2 capsules daily in the evening after meals.

SIDE EFFECTS

Side effects may include gastrointestinal complaints .

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Treatment should be symptomatic and supportive. In the case of accidental overdose of the product, contact the nearest hospital or poison control centre.

IDENTIFICATION

A brown, oblong, soft gelatine capsule.

PRESENTATION

A white bottle and cap containing 60 capsules.

STORAGE INSTRUCTIONS

Store at or below 25 °C. KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

RSA- TBA

DATE OF REGISTRATION

TBA

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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