

SKEDULERINGSSTATUS: Sal toegeken word sodra geregistreer.

GEREGISTREERDE HANDELSNAAM (en doseringvorm):

Fefol Multi-Preg sagte kapsules

SAMESTELLING:

Die ADI (Aanbevole Daaglikse Inname) vir swangerskap is die vlak van noodsaaklike voedingsstowwe, wat genoegsaam is om aan die behoefte van swanger vroue te voldoen. Gebaseer vir swanger vroue 19-50 jaar.

Samestelling		ADI Swangerskap
Iron (as Ferrous fumarate)	12 mg	44 % van ADI
Fish Oil - Natural (Tuna) Mercury Tested (Providing DHA 200mg, EPA 52.9mg)	741 mg	218 % van ADI
Iodine (as Potassium iodide)	250 mcg	114 % van ADI
Folic Acid	500 mcg	83 % van ADI
d-alpha tocopherol (Natural Vitamin E 10.4iu)	6.98 mg	123 % van ADI
Betacarotene	5 mg	-
Ascorbic Acid (Vitamin C)	60 mg	100 % van ADI
Cholecalciferol (Vitamin D3 500iu)	12.5 mcg	250 % van ADI
Calcium (as Calcium Carbonate)	100 mg	10 % van ADI
Magnesium (as Magnesium Oxide Heavy)	15 mg	4 % van ADI
Zinc (as Zinc Oxide)	10 mg	91 % van ADI
Thiamine Nitrate (Vitamin B1)	1.5 mg	107 % van ADI
Riboflavine (Vitamin B2)	1.5 mg	107 % van ADI
Nicotinamide (Vitamin B3)	7.5 mg	42 % van ADI
Pyridoxine HCL Equiv. to Pyridoxine (Vitamin B6)	1.5 mg 1.23 mg	79 % van ADI -
Cyanocobalamin (Vitamin B12)	12 mcg	462 % van ADI
Biotin (Vitamin B7)	30 mcg	100 % van ADI
Silicon (as Silica-Colloidal Anhydrous)	17 mg	-

FARMAKOLOGIESE KLASIFIKASIE:

MGR – Voedingsaanvullings

FARMAKOLOGIESE WERKING:

Fefol Multi-Preg is spesiaal geformuleer en bevat 17 noodsaaklike vitamiene en minerale om die moeder en haar groeiende baba te help voorsien van voedingsondersteuning **VOOR BEVRUGTING, TYDENS SWANGERSKAP EN MET BORSVOEDING.**

Fefol Multi-Preg bevat 200 mg DHA - Baby Smart kwikgetoetsde Tuna Olie, wat 200 mg DHA lewer vanaf OMEGA 3. DHA is belangrik vir gesonde brein en oog-ontwikkeling van die baba. **250 mcg Jodium** – Help met die ontwikkeling van die baba se brein en sentrale senuweestelsel. **500 mcg Foliensuur, 5 mg Betakarotene en 30 mcg Biotin** - Vir gesonde groei en ontwikkeling van die fetus. Foliensuur help ook om die risiko van neuralebuise geboortedefekte, soos SPINA BIFIDA te verminder indien dit een maand voor bevrugting en tydens swangerskap geneem word. **12 mg Yster** – 44 % van ADI vir swangerskap. Tydens swangerskap en fetale-ontwikkeling verhoog die behoefte vir yster en help dit met die vorming van die rooibloedselle.

Natuurlike Vit E (Belangrike anti-oksident) en Vit D3 – wat die absorpsie van kalsium bevorder, vir normale gesonde groei en gesonde beenvorming. Hierdie medisyne is nog nie deur die Medisynebeheerraad ge-evalueer nie, en is nie bedoel om 'n diagnose te maak, 'n siektetoestand te behandel, te voorkom of om as kuur gebruik te word nie.

PASIËNTINLIGTING VOUBILJET

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Calcium (as Calcium Carbonate)	100 mg	10 % van ADI
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Zinc (as Zinc Oxide)	10 mg	91 % van ADI
Thiamine Nitrate (Vitamin B1)	1.5 mg	107 % van ADI
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INDIKASIES:

Fefol Multi-Preg is spesiaal geformuleer en bevat 17 noodsaaklike vitamiene en minerale om die moeder en haar groeiende baba te help voorsien van voedingsondersteuning **VOOR BEVRUGTING, TYDENS SWANGERSKAP EN MET BORSVOEDING.**

KONTRAINDIKASIES:

Hipersensitiwiteit vir eier, vis of enige van die ander bestanddele.

INDIKASIES:

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KONTRAINDIKASIES:

Hipersensitiwiteit vir eier, vis of enige van die ander bestanddele.

WAARSKUWINGS:

Moet nie die aanbevole dosis oorskry tensy met mediese advies. Indien u 'n baba gehad het met neuralebuise afwyking moet u mediese advies inwin. Vitamiene-aanvullings moet nie 'n gebalanseerde dieet vervang. Raadpleeg u dokter of gesondheidsorg-adviseur vir professionele raad indien u met enige siektetoestand gediagnoseer is, of as u medikasie neem vir enige siektetoestand.

Moet nie gebruik word deur persone wat allergies is vir Jodium.

INTERAKSIES: Geen bekend.

SWANGERSKAP EN BORSVOEDING:

Fefol Multi-Preg is spesiaal geformuleer om 17 noodsaaklike vitamiene en minerale te bevat om die moeder en haar groeiende baba te help voorsien van voedingsondersteuning **VOOR BEVRUGTING, TYDENS SWANGERSKAP EN MET BORSVOEDING.**

DOSERING EN GEBRUIKSAANWYSINGS:

As voedingsaanvulling vir volwassenes neem een (1) sagte kapsule daaglik na ontbyt of soos voorgeskryf deur u dokter of gesondheidsorg-adviseur. Moet nie die daaglikse dosering verhoog sonder dat u dokter of gesondheidsorg-adviseur geraadpleeg is. **Fefol Multi-Preg** moet ten minste een maand voor bevrugting, tydens swangerskap en met borsvoeding geneem word.

NEWE-EFFEKTE EN SPESIALE VOORSORGMATREËLS:

Pasiënte wat sensitief is vir enige van die bestanddele mag velreaksies soos jeuk en vel uitslag ervaar. Moet nie gebruik word deur persone wat allergies is vir Jodium.

SPESIALE VOORSORGMATREËLS:

Dit word aanbeveel dat u altyd die doseringsaanwysings volg en om gebruik te staak indien u enige negatiewe simptome ontwikkel.

Uitwerking op die vermoë om te bestuur en masjinerie te gebruik:

Fefol Multi-Preg behoort nie die vermoë om te bestuur of die gebruik van masjinerie te beïnvloed nie. Dit is egter altyd raadsaam om bedagsaam te wees vir bogenoemde totdat u seker is daar is nie nuwe-effekte nie.

BEKEDE SIMPTOME VAN OORDOSERING:

Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:

22 minim sagte, langwerpige kapsule met 'n ondeursigtige rooi kleur.

AANBIEDING:

Fefol Multi-Preg sagte kapsules is beskikbaar stolpakkies verpak in 'n buite kartonverpakking.

BERGINGSINSTRUKSIES:

Moet nie gebruik indien die stolpakkie gebreek is. Sodra oopgemaak hou dig toe en berg teen of benede 25 °C in 'n droë omgewing. Beskerm teen lig en hou buite die bereik van kinders.

REGISTRASIENOMMER: Sal toegeken word.

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE

REGISTRASIESERTIFIKAAT:

KCP Products cc, Posbus 1072, Knysna 6570 Suid Afrika

Verspreider Suid Afrika vir PharmaCare Laboratories Australia.

Klante Diens +27 (0) 44 382 0382

www.ahealthysa.com // www.fefol.com.au

DATUM VAN PUBLISERING VAN HIERDIE VOUBILJET:

15 Mei 2014

Pro-Print



WAARSKUWINGS:

Moet nie die aanbevole dosis oorskry tensy met mediese advies. Indien u 'n baba gehad het met neuralebuise afwyking moet u mediese advies inwin. Vitamiene-aanvullings moet nie 'n gebalanseerde dieet vervang. Raadpleeg u dokter of gesondheidsorg-adviseur vir professionele raad indien u met enige siektetoestand gediagnoseer is, of as u medikasie neem vir enige siektetoestand.

Moet nie gebruik word deur persone wat allergies is vir Jodium.

INTERAKSIES: Geen bekend.

SWANGERSKAP EN BORSVOEDING:

Fefol Multi-Preg is spesiaal geformuleer om 17 noodsaaklike vitamiene en minerale te bevat om die moeder en haar groeiende baba te help voorsien van voedingsondersteuning **VOOR BEVRUGTING, TYDENS SWANGERSKAP EN MET BORSVOEDING.**

DOSERING EN GEBRUIKSAANWYSINGS:

As voedingsaanvulling vir volwassenes neem een (1) sagte kapsule daaglik na ontbyt of soos voorgeskryf deur u dokter of gesondheidsorg-adviseur. Moet nie die daaglikse dosering verhoog sonder dat u dokter of gesondheidsorg-adviseur geraadpleeg is. **Fefol Multi-Preg** moet ten minste een maand voor bevrugting, tydens swangerskap en met borsvoeding geneem word.

NEWE-EFFEKTE EN SPESIALE VOORSORGMATREËLS:

Pasiënte wat sensitief is vir enige van die bestanddele mag velreaksies soos jeuk en vel uitslag ervaar. Moet nie gebruik word deur persone wat allergies is vir Jodium.

Uitwerking op die vermoë om te bestuur en masjinerie te gebruik:

Fefol Multi-Preg behoort nie die vermoë om te bestuur of die gebruik van masjinerie te beïnvloed nie. Dit is egter altyd raadsaam om bedagsaam te wees vir bogenoemde totdat u seker is daar is nie nuwe-effekte nie.

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22 minim sagte, langwerpige kapsule met 'n ondeursigtige rooi kleur.

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Fefol Multi-Preg sagte kapsules is beskikbaar in stolpakkies verpak in 'n buite kartonverpakking.

BERGINGSINSTRUKSIES:

Moet nie gebruik indien die stolpakkie gebreek is. Sodra oopgemaak hou dig toe en berg teen of benede 25 °C in 'n droë omgewing. Beskerm teen lig en hou buite die bereik van kinders.

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DATUM VAN PUBLISERING VAN HIERDIE VOUBILJET:

15 Mei 2014

Pro-Print

SCHEDULING STATUS: To be allocated once registered.

PROPRIETARY NAME (and dosage form):

Fefol Multi-Preg soft capsules

COMPOSITION:

The RDI (Recommended Daily Intake) for pregnancy is the level of intake of essential nutrients considered adequate to meet the needs of a pregnant woman.
* Based on pregnant women 19-50 years.

Composition		RDI During Pregnancy
Iron (as Ferrous fumarate)	12 mg	44 % of RDI
Fish Oil - Natural (Tuna) Mercury Tested (Providing DHA 200mg, EPA 52.9mg)	741 mg	218 % of RDI
Iodine (as Potassium iodide)	250 mcg	114 % of RDI
Folic Acid	500 mcg	83 % of RDI
d-alpha tocopherol (Natural Vitamin E 10.4iu)	6.98 mg	123 % of RDI
Betacarotene	5 mg	-
Ascorbic Acid (Vitamin C)	60 mg	100 % of RDI
Cholecalciferol (Vitamin D3 500iu)	12.5 mcg	250 % of RDI
Calcium (as Calcium Carbonate)	100 mg	10 % of RDI
Magnesium (as Magnesium Oxide Heavy)	15 mg	4 % of RDI
Zinc (as Zinc Oxide)	10 mg	91 % of RDI
Thiamine Nitrate (Vitamin B1)	1.5 mg	107 % of RDI
Riboflavin (Vitamin B2)	1.5 mg	107 % of RDI
Nicotinamide (VitaminB3)	7.5 mg	42 % of RDI
Pyridoxine HCL Equiv. to Pyridoxine (Vitamin B6)	1.5 mg 1.23 mg	79 % of RDI -
Cyanocobalamin (Vitamin B12)	12 mcg	462 % of RDI
Biotin (Vitamin B7)	30 mcg	100 % of RDI
Silicon (as Silica-Colloidal Anhydrous)	17 mg	-

PHARMACOLOGICAL CLASSIFICATION:

MGR – Nutritional Substances

PHARMACOLOGICAL ACTION:

Fefol Multi-Preg is a comprehensive multivitamin and mineral formula that provides a source of essential vitamins and minerals specially formulated for use during preconception, pregnancy and whilst breastfeeding. **Fefol Multi-Preg** contains docosahexaenoic acid (DHA) derived from Mercury Tested Tuna Oil, which is important for healthy brain and eye development in babies and infants. **25 mcg Iodine** – Assists with the development of the baby's brain and central nervous system. **500 mcg Folic Acid, 5mg Betacarotene and 30 mcg of Biotin** – Are important for the healthy development of the foetus. Folic Acid also help reduce the risk of Neural tube birth defects such as Spina bifida, if taken one month prior to conception and during pregnancy. **12 mg Iron** – (44 % of RDI for pregnancy). Iron requirements increase during pregnancy and during foetal growth assist in the formation of red blood cells. **Natural Vit E** (Important Antioxidant) and Vitamin D3 which supports calcium absorption, normal healthy growth and healthy bone formation. This medicine has not been evaluated by the Medicines Control Council and is not intended to diagnose, treat, cure or prevent any disease.

INDICATIONS:

Fefol Multi-Preg has been specially formulated to contain 17 essential vitamins and minerals to help provide the mother and her growing baby with

nutritional support **PRIOR TO CONCEPTION, DURING PREGNANCY and whilst BREASTFEEDING.**

CONTRAINDICATIONS:

Hypersensitivity to egg, fish or any of the other ingredients.

WARNINGS:

Unless otherwise prescribed, do not exceed the stated dose. If you have had a baby with neural tube defect/spina bifida, seek specific medical advice. Vitamin and nutritional supplements should not replace a balanced diet. Consult your doctor or registered healthcare professional for advice if you have any medical conditions or if you are taking medications for any illness. Not to be used by persons allergic to Iodine.

INTERACTIONS:

None known.

PREGNANCY AND LACTATION:

Fefol Multi-Preg has been specially formulated to contain 17 essential vitamins and minerals to help provide the mother and her growing baby with nutritional support **PRIOR TO CONCEPTION, DURING PREGNANCY and whilst BREASTFEEDING.**

DOSAGE AND DIRECTIONS FOR USE:

As a nutritional supplement for adults take one (1) capsule daily with breakfast or as directed by a healthcare professional. Do not increase the daily dosage unless advised by your doctor or healthcare professional. **Fefol Multi-Preg** should be taken at least one month before falling pregnant, during pregnancy and whilst breastfeeding.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Patients that could be allergic or sensitive to any of the ingredients could experience itching and skin reactions.

SPECIAL PRECAUTIONS:

It is recommended that you always follow dosage directions and discontinue use should you notice or experience any undesirable side effects or are hypersensitive to any of the ingredients.

Effects on ability to drive and use machines

Fefol Multi-Preg is not likely to impair your ability to drive vehicles or operate machinery. However do take care if you take **Fefol Multi-Preg** until you know how it will affect you.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF TREATMENT

Treatment is symptomatic and supportive.

IDENTIFICATION:

22 minims soft opaque capsule with a red colour.

PRESENTATION:

Fefol Multi-Preg soft gelatine capsules are packed in blister strips in an outer cardboard carton.

STORAGE INSTRUCTIONS:

Store at or below 25 °C in a dry place. Protect from light. KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NO:

To be allocated.

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

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DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

15 May 2014



PRO-PRINT (PTY) LTD
THE PROFESSIONALS IN PRINT

REPRO

Date: 14th February 2017
Operator: Elizabeth Choudree
Customer: KCP Products cc
Product Name: Fefol Multi-Preg Soft Capsules Leaflet
Product Code: --
Dimensions: 150 x 260 mm
Fold Size: 150 x 33 mm
Font Size: 6 point Helvetica Condensed
Colours: (1) Black
--
Barcode: --
Pharmacode: (Ref. 13) 001
Stock: 50 gsm Aviator
Proof Status: 1st (First)
Proof read by: _____

Reset: **Alterations:** **Disk/Possie:**

No alterations – proceed as soon as possible

Note alterations – Further proof is required

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