

Professional Information for MI-VITAMIN® PREGNANCY

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

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

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE: MI-VITAMIN® PREGNANCY capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each capsule contains:		% NRV*
Ascorbic acid (Vitamin C)	60 mg	60
Ferrous fumarate	123 mg	
providing Iron (elemental)	24 mg	185
Niacin (Vitamin B3)	18 mg	113
Alpha-tocopherol (Vitamin E)	15 mg	100
Zinc oxide	13 mg	
providing Zinc (elemental)	10 mg	100
Pantothenic acid (Vitamin B5)	6 mg	120
Pyridoxine (Vitamin B6)	1,9 mg	112
Riboflavin (Vitamin B2)	1,4 mg	108
Thiamine (Vitamin B1)	1,4 mg	117
Copper gluconate	8 mg	
providing Copper (elemental)	1,15 mg	128
Retinol (Vitamin A)	800 µg (2 664 IU)	100
Folic acid	500 µg	125
Potassium iodide	2 mg	
providing Iodine (elemental)	150 µg	100
Phylloquinone (Vitamin K)	55 µg	46
Sodium selenite	12 mg	
providing Selenium (elemental)	50 µg	91
Biotin (Vitamin H)	30 µg	100
Cholecalciferol (Vitamin D)	5 µg (200 IU)	33
Cyanocobalamin (Vitamin B12)	2,6 µg	108

* Nutrient Reference Values SA from 37months and older

Excipients with known effects:

Contains sugar (each capsule contains 1,35 mg sucrose).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules.

Pink-mauve hard gelatine capsule containing cream and black speckled powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

MI-VITAMIN® PREGNANCY is a supplement formulated for women during and after pregnancy to maintain good health.

MI-VITAMIN® PREGNANCY contains 13 essential vitamins and 5 added minerals.

4.2 Posology and method of administration

Take one capsule daily after food, or as directed by your healthcare provider.

Do not exceed the recommended dosage.

4.3 Contraindications

Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 2 or 6.1.

4.4 Special warnings and precautions for use

MI-VITAMIN® PREGNANCY contains sucrose:

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take MI-VITAMIN® PREGNANCY.

4.5 Interaction with other medicines and other forms of interaction

Anticoagulant or antiplatelet medicines:

Vitamin K, as in MI-VITAMIN® PREGNANCY, may decrease the effect of oral anticoagulant medicine and caution is advised.

Antacid medicines:

Antacid medicines may interfere with the absorption of iron. It is recommended to separate doses by 2 – 3 hours.

4.6 Fertility, pregnancy and lactation

MI-VITAMIN® PREGNANCY is indicated for use during and after pregnancy and during lactation.

4.7 Effects on ability to drive and use machines

MI-VITAMIN® PREGNANCY is unlikely to affect the ability to drive and use machines. Caution is advised when driving a vehicle or operating machinery until the effects of MI-VITAMIN® PREGNANCY are known.

4.8 Undesirable effects

MI-VITAMIN® PREGNANCY is generally well tolerated.

Immune system disorders:

Less frequent: hypersensitivity

Nervous system disorders:

Frequent: headache

Vascular disorders:

Frequent: flushing

Gastrointestinal disorders:

Frequent: nausea, vomiting, heartburn, abdominal cramps, diarrhoea, abdominal pain, gastrointestinal irritation, constipation, dyspepsia, gastritis, metallic taste

Skin and subcutaneous tissue disorders:

Less frequent: dermatitis

Frequency unknown: pruritis

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of MI-VITAMIN® PREGNANCY is important. It allows continued monitoring of the benefit/risk balance of MI-VITAMIN® PREGNANCY. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>

4.9 Overdose

See section 4.8.

In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: D 34.12 Multiple substance formulation

Pharmacotherapeutic group: Vitamins, other combinations

ATC code: A11JB

Mechanism of action:

MI-VITAMIN® PREGNANCY is a multi-vitamin mineral supplement for the maintenance of good health.

5.2 Pharmacokinetic properties

- Vitamin C is readily absorbed from the gastrointestinal tract and is widely distributed in the body. The main route of elimination is through urine.
- Iron absorption is variable and is enhanced by the presence of ascorbic acid. Most of the iron absorbed is incorporated into haemoglobin and is mostly excreted in the faeces.
- Vitamin B3 is water-soluble and well absorbed and is excreted mainly via urine.
- Vitamin E is mostly absorbed in the small intestines by passive diffusion and is excreted mainly unchanged via the faeces.
- Zinc is a biologically essential trace element that is absorbed in the small intestines, and is distributed in the body in skeletal muscle and bone. It is mainly excreted through the faeces.
- Vitamin B5 is an essential B vitamin. It is absorbed from the small intestines and widely distributed through the body. About 70 % is excreted unchanged in the urine, and 30 % in the faeces.
- Vitamin B6 is passively absorbed from the upper gastrointestinal tract, converted in the liver to coenzyme pyridoxal phosphate and excreted in the urine.
- Vitamin B2 is readily absorbed from the gastrointestinal tract and is widely distributed in the body. It is excreted in the urine
- Vitamin B1 is a water-soluble B-vitamin and is absorbed by the proximal part of the small intestines. It occurs in the body as the metabolically active form thiamine diphosphate and is excreted in the urine.
- Copper is absorbed from the small intestines and rapidly taken up by the liver and incorporated into caeruloplasmin. It is excreted via bile into faeces, with small amounts excreted in urine.
- Vitamin A is a fat-soluble vitamin that is readily absorbed from the gastrointestinal tract and is excreted in the bile or urine.
- Folic acid is rapidly absorbed from the gastrointestinal tract, mainly the jejunum, and enters portal circulation where it is converted to the metabolically active form 5-methyltetrahydrofolate in the plasma and liver. It is excreted mainly in the urine.
- Iodine is an essential nutrient in the human body. It is absorbed through the stomach and duodenum and converted to iodide. Iodine is excreted mainly in the urine, with small amounts excreted in faeces, sweat and saliva.
- Vitamin K is a fat-soluble compound and is absorbed into the lymphatic system. It is transported in the plasma and metabolised in the liver. 30 – 40 % is eliminated in the bile, with 15 % excreted in the urine.
- After absorption from the gastrointestinal tract, selenium is incorporated into the enzyme glutathione peroxidase. It is excreted mainly in the urine.
- Biotin is completely absorbed after oral administration and is bound to plasma proteins. It is excreted in the urine as unmetabolised biotin or as metabolites.
- Vitamin D is a fat-soluble vitamin. It is well absorbed and requires hydroxylation in the body to form the active metabolite, calcitriol. Excretion occurs mainly through the bile and faeces, with small amounts appearing in urine.
- Vitamin B12 is an essential water-soluble vitamin. It is absorbed in the terminal ileum and is mainly stored in the liver.

5.3 Preclinical safety data

None.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose, silicon dioxide.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C.

Keep bottle tightly closed.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

30 or 60 tablets in a round white plastic tub, with a white plastic screw on lid, containing a Patient Information Leaflet. Tub may be inserted into a cardboard carton (retail sale only).

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

LeBasi Pharmaceuticals (Pty) Ltd.

San Domenico Unit 6

10 Church Street

Durbanville, Cape Town 7551

Marketed by:

At Life Products South Africa (Pty) Ltd.

Bryanston Ridge Office Park, Block B

13A Bruton Road

Corner Main & Bruton Roads

Bryanston, Gauteng, South Africa

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

Will be allocated by SAHPRA upon registration.