Professional Information for MI-VITAMIN® CHILDRENS CHEWS

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® CHILDRENS CHEWS chewable tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each chewable tablet contains:		**% NRV***
Ascorbic acid (Vitamin C)	60 mg	60
Ferrous fumarate	58 mg	
providing Iron (elemental)	10 mg	77
Alpha-tocopherol (Vitamin E)	9 mg	60
Niacin (Vitamin B3)	8 mg	50
Zinc oxide	7 mg	
providing Zinc (elemental)	5 mg	50
Riboflavin (Vitamin B2)	1,3 mg	100
Thiamine (Vitamin B1)	1,1 mg	92
Pyridoxine (Vitamin B6)	0,5 mg	29
Retinol (Vitamin A)	500 µg (1 665 IU)	63
Folic acid	199 µg	50
Potassium iodide	1,7 mg	
providing Iodine (elemental)	100 µg	67
Phylloquinone (Vitamin K)	30 µg	25
Sodium selenite	5 mg	
providing Selenium (elemental)	20 µg	36
Cholecalciferol (Vitamin D)	10 µg (400 IU)	67
Cyanocobalamin (Vitamin B12)	1,2 µg	50

*Nutrient Reference Values SA from 37months and older

Excipients with known effects:

Contains sugar (each tablet contains 466 mg sucrose and 52 mg sorbitol).

Contains sweetener (each tablet contains 1 mg acesulfame K and 3 mg sucralose).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablets.

Orange flavoured speckled chewable tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

MI-VITAMIN® CHILDRENS CHEWS is a health supplement formulated for growing children to maintain good health. MI-VITAMIN® CHILDRENS CHEWS contains 11 essential vitamins and 4 added minerals.

4.2 Posology and method of administration

Children 3 – 12 years:

One chewable tablet 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

Prolonged use of chewable tablets containing vitamin C may cause dental erosion and increase the risk of dental caries.

MI-VITAMIN® CHILDRENS CHEWS contains sucrose:

Children with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take MI-VITAMIN® CHILDRENS CHEWS.

Sucrose in chewable tablets may be harmful to teeth.

4.5 Interaction with other medicines and other forms of interaction

Antacid medicines:

Antacid medicines may interfere with the absorption of iron.

It is recommended to separate doses by 2 – 3 hours.

Antibiotics:

MI-VITAMIN® CHILDRENS CHEWS may decrease the absorption of tetracycline or quinolone antibiotics. Doses should be separated by at least 2 – 4 hours.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

MI-VITAMIN® CHILDRENS CHEWS is indicated for use in children 3 – 12 years of age.

4.7 Effects on ability to drive and use machines

MI-VITAMIN® CHILDRENS CHEWS is not likely to affect your child's ability in performing tasks requiring their attention.

4.8 Undesirable effects

MI-VITAMIN® CHILDRENS CHEWS 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® CHILDRENS CHEWS is important. It allows continued monitoring of the benefit/risk balance of MI-VITAMIN® CHILDRENS CHEWS.

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® CHILDRENS CHEWS is a multi-vitamin mineral supplement for growth and development, and the maintenance of good health in children.

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 E is mostly absorbed in the small intestines by passive diffusion and is excreted mainly unchanged via the faeces.
- Vitamin B3 is water-soluble and well absorbed and is excreted mainly via urine.
- 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 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.
- Vitamin B6 is passively absorbed from the upper gastrointestinal tract, converted in the liver to coenzyme pyridoxal phosphate and excreted in the 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.
- 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

Citric acid, silicon dioxide, flavourant.

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.