

Professional Information for MI-VITAMIN® MIXME®

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

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

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE: MI-VITAMIN® MIXME® Vitamin Mineral Powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each 1 g sachet contains:		% RNI*
Ascorbic acid (Vitamin C)	30 mg	100
Ferrous fumarate	56,4 mg	
providing Iron (elemental)	10 mg	100
Niacinamide (Vitamin B3)	6 mg	100
Alpha-tocopherol (Vitamin E)	5 mg TE	100
Zinc gluconate	34,7 mg	
providing Zinc (elemental)	4,1 mg	100
Copper gluconate	4,8 mg	
providing Copper (elemental)	0,56 mg	100
Pyridoxine (Vitamin B6)	0,5 mg	100
Riboflavin (Vitamin B2)	0,5 mg	100
Thiamine (Vitamin B1)	0,5 mg	100
Retinol (Vitamin A)	400 µg (1 332 IU)	100
Folic acid	90 µg	100
Potassium iodide	1,5 mg	
providing Iodine (elemental)	90 µg	100
Sodium selenite	4,7 mg	
providing Selenium (elemental)	17 µg	100
Cholecalciferol (Vitamin D)	5 µg (200 IU)	100
Cyanocobalamin (Vitamin B12)	0,9 µg	100

*Reference Nutrient Intakes based on WHO / UNICEF / WFP Joint Statement Document 6-59 months (2007).

Excipients with known effects:

Contains sugar (0,085 g sucrose per 1 g sachet).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder.

Dry, white speckled powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

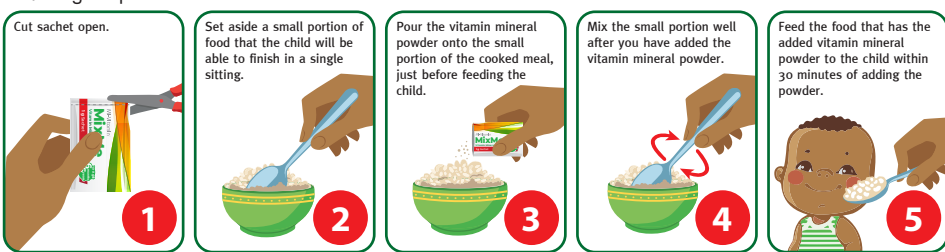
MI-VITAMIN® MIXME® is a multi-vitamin mineral supplement, and antioxidant which is a factor in the maintenance of good health in children 6 months – 5 years of age.

4.2 Posology and method of administration

Use only one (1) sachet per child per day.

Instructions for use:

1. Cut sachet open.
2. Set aside a small portion of food that the child will be able to finish in a single sitting.
3. Pour MI-VITAMIN® MIXME® powder onto the small portion of the cooked meal, just before feeding the child.
4. Mix the small portion well after you have added the MI-VITAMIN® MIXME® powder.
5. Feed the food that has the added MI-VITAMIN® MIXME® powder to the child within half an hour (30 minutes) of adding the powder.



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

Do not exceed the recommended daily dosage.

Hypercalcaemia

Vitamin D should not be given to children with hypercalcaemia. It should be used with caution in infants, who may have increased sensitivity to its effects and patients with renal impairment or calculi, heart disease or who might be at increased risk of organ damage, if hypercalcaemia occurred.

Gastrointestinal disturbances

Large doses vitamins C and E may cause diarrhoea, abdominal pain and other gastrointestinal disturbances. Iron might cause gastrointestinal irritation and exacerbate peptic ulcer disease and ulcerative colitis.

Laboratory tests

Large doses of vitamin B2 result in a bright yellow discolouration of the urine, that may interfere with certain laboratory tests.

Dark or black stools

Iron may darken the colour of the child's faeces, even change it to black.

MI-VITAMIN® MIXME® contains sucrose:

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

4.5 Interaction with other medicines and other forms of interaction

The following medicines should be used with caution when used in combination with MI-VITAMIN® MIXME®:

- Chloramphenicol can delay or interrupt the reticulocyte response to supplemental vitamin B12 in some children. Monitor blood counts closely if this combination cannot be avoided.
- Zinc, as in MI-VITAMIN® MIXME®, might decrease cephalosporin levels by chelating with cephalosporin in the gut and preventing its absorption. Patients should be advised to take MI-VITAMIN® MIXME® 3 hours after cephalosporin.
- Copper chelates penicillamine, decreasing its absorption. Separate dose times by at least 2 hours.

4.6 Fertility, pregnancy and lactation

MI-VITAMIN® MIXME® is only indicated for the use in children 6 months to 5 years of age.

Safety during pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

MI-VITAMIN® MIXME® powder is a multi-vitamin mineral supplement which is usually well tolerated with no side effects, when taken correctly. However, MI-VITAMIN® MIXME® may cause serious side effects, if taken in large doses. Children should not take more than the recommended daily dosage.

Immune system disorders:

Less frequent: hypersensitivity

Nervous system disorders:

Less frequent: headache

Vascular disorders:

Frequent: flushing

Gastrointestinal disorders:

Frequent: nausea, vomiting, heartburn, abdominal pain and cramps, gastrointestinal obstruction, diarrhoea, dyspepsia, gastric irritation, gastritis

Less frequent: intestinal cramps, constipation

Skin and subcutaneous tissue disorders:

Less frequent: rash, itching, dermatitis

General disorders and administration site conditions:

Frequent: fatigue

Less frequent: weakness

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of MI-VITAMIN® MIXME® is important. It allows continued monitoring of the benefit/risk balance of MI-VITAMIN® MIXME®. 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.

Treatment is 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® MIXME® is a multi-vitamin mineral supplement containing 15 essential vitamins and minerals that are often missing in the diets of children. MI-VITAMIN® MIXME® supplies the daily requirements for optimal health and development of children 6 months – 5 years of age.

5.2 Pharmacokinetic properties

- Vitamin A is a fat-soluble vitamin. It contributes to the maintenance of eyesight, skin, membranes, immune function and the development and maintenance of night vision. Vitamin A also contributes to the development and maintenance of bones and teeth.
- Vitamin D is a fat-soluble vitamin. It helps in the development and maintenance of bones and teeth, the absorption and use of calcium and phosphorus.
- Vitamin E is fat-soluble vitamin and an antioxidant, which prevent the formation of free radicals.
- Vitamin B1, B2, B3 and B6 is water-soluble vitamins, which help to metabolise carbohydrates, fats and proteins. It also contributes to normal growth.
- Folic acid helps the body to metabolise proteins and to form red blood cells.
- Vitamin C is a water-soluble vitamin, an antioxidant and maintains immune function. It helps to metabolise fats and proteins, helps with the development and maintenance of bones, cartilage, teeth and gums, connective tissue formation and in wound healing.
- Iron is a trace mineral, a component of red blood cells and helps in their proper function.
- Zinc is an essential trace element, which helps in connective tissue formation, the maintenance of healthy skin, metabolism of carbohydrates, fats and proteins and to maintain immune function.
- Copper is an essential trace mineral, which helps to produce and repair connective tissue and to form red blood cells.
- Selenium is an essential trace mineral and antioxidant.
- Iodine is a trace element and essential nutrient which contributes to the normal production of thyroid hormones and normal thyroid function.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maltodextrin, Silicon dioxide, Tri-calcium phosphate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C.

Protect from moisture and direct sunlight.

Do not use after the expiry date, indicated on the soft foil pouch / bottom of the carton box and sachets.

6.5 Nature and contents of container

Carton box or soft foil pouch containing 30 x 1 g sachets, with a Patient Information Leaflet.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

DSM Nutritional Products South Africa (Pty) Ltd.

16 Brewery Street

Isando

1600

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.