

MULTI MUNE SYRUP

PROFESSIONAL INFORMATION

Complementary Medicine: Health Supplement D 34.12 Multiple substance formulation

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the dief.

SCHEDULING STATUS: SO

1. NAME OF THE MEDICINE

2 OLIAI ITATIVE AND OLIANTITATIVE COMPOSITION

Each 5 ml syrup contains:

Ascorbic acid (Vitamin C)	32,00 mg
Zinc gluconate (providing 3,59 mg elemental Zinc)	25,00 mg
Iron amino acid chelate 20 %	12,00 mg
(providing 2,40 mg elemental Iron)	, ,
Pantothenic acid (Vitamin B5)	2,50 mg
Nicotinamide (Vitamin B3)	2,20 mg
D-α-tocopherol (Vitamin E as DL-α-tocopheryl acetate)	1,99 mg
Copper amino acid chelate 10 %	0,70 mg
(providing 70,00 μg elemental Copper)	
Retinol (as Vitamin A acetate)	870,00 μg
Thiamine (Vitamin B1)	118,00 µg
Riboflavin (Vitamin B2)	110,00 µg
Biotin (Vitamin H)	110,00 µg
Cholecalciferol (Vitamin D3)	14,50 µg
Cyanocobalamin (Vitamin B12)	1,30 µg

Preservatives: sodium benzoate 0 046 % m/v

Contains artificial sweetener (2,5 g sorbitol and 2 mg xylitol) per 5 ml syrup.

Sugar free

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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Cherry berry flavoured, honey coloured syrup.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BIOGEN MULTI MUNE SYRUP contains vitamins and minerals that may help support your child's immune and general wellbeing.

4.2 Posology and method of administration

SHAKE THE BOTTLE WELL BEFORE USE

Children 1 - 3 years: 2.5 ml once daily.

Children 4 - 12 years: 5 ml once daily.

Children 13 years and older: 7.5 ml once daily.

4.3 Contraindications:

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

4.4 Special warnings and precautions for use

Do not exceed the recommended dose. Large doses of vitamin C may cause diarrhoea and other gastrointestinal

4.5 Interaction with other medicines and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Safety in fertility, pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

BIOGEN MULTI MUNE SYRUP is not likely to cause drowsiness. However, patients should take caution when driving a vehicle or operating machinery requiring their attention, until they know how BIOGEN MULTI MUNE SYRUP will affect them

4.8 Undesirable effects

When taken at the recommended dose, undesirable effects are unlikely to occur.

Reporting of suspected adverse reactions

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

4.9 Overdose

In the event of an overdose, side effects can be precipitated and/or be of increased severity (see section **4.8**). Treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

Category and class:

D 34.12 Multiple substance formulation

5.1 Pharmacodynamic properties

Vitamin A contributes to the maintenance of evesight, skin, membranes and immune function.

Vitamin C is an antioxidant and helps in the development and maintenance of bones, cartilage, teeth and gums, as well as connective tissue formation.

Vitamin D helps in the development and maintenance of bones and teeth and helps in the absorption and use of calcium and phosphorous.

Vitamin E contributes to the protection of cells from oxidative stress.

Vitamin B1 and vitamin B3 helps the body to metabolise carbohydrates, fats and proteins and contributes to normal

Vitamin B2 and vitamin B5 helps the body to metabolise carbohydrates, fats and proteins and contributes to tissue formation

Vitamin B12 contributes to normal red blood cell formation

Riotin helps the body to metabolise carbohydrates, fats and proteins

Copper helps to produce and repair connective tissue and form red blood cells.

Iron helps to form red blood cells and helps in their proper function.

Zinc helps to maintain immune function and good health in growing children.

5.2 Pharmacokinetic properties

The vitamins and minerals in BIOGEN MULTI MUNE SYRUP are well absorbed from the gastro-intestinal tract and are widely distributed to all tissues in the body.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cherry berry essence flavour, citric acid monohydrate, purified water, sodium benzoate (preservative), sodium carboxymethylcellulose, sorbitol, xvlitol.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

24 Months.

6.4 Special precautions for storage

Store at or below 25 °C and protect from moisture.

6.5 Nature and contents of container

White 200 ml PET bottle with a white tamper-evident screw on cap in an outer carton. Pack size: 200 ml.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

PhytoHealthcare (Pty) Ltd 49 New Road Block C Midrand 1685

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

This leaflet was last revised in February 2021.