zyora™ zymag+™

Healthcare for women

**PROFESSIONAL INFORMATION FOR zymag+™**

**COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT**
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

**SCHEDULING STATUS**
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**1. NAME OF MEDICINE**
zymag+™ effervescent tablets

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**
Each effervescent tablet contains:

| | |
|---|---|
| Magnesium carbonate | 1 090 mg |
| providing Magnesium (elemental) | 250 mg |
| Ascorbic acid (Vitamin C) | 200 mg |
| MecobalActive® as methylcobalamin (Vitamin B12) | 50 µg |

*Excipients with known effect:*
Contains sweetener: 16 mg sucralose per tablet.
Contains sugar alcohol: 400 mg sorbitol per tablet.

For a full list of excipients, see section 6.1.

**3. PHARMACEUTICAL FORM**
Effervescent tablets.
Light pink, strawberry flavoured, round flat effervescent tablet, with a bevelled edge.

**4. CLINICAL PARTICULARS**
**4.1. Therapeutic indications**
zymag+™ is a health supplement containing Magnesium, Vitamin C and Vitamin B12 to assist with the reduction of tiredness and fatigue. It also contributes to normal energy-yielding metabolism and functioning of the nervous system.
**4.2. Posology and method of administration**
*Adults and children over 9 years:* Take 1 (one) effervescent tablet daily dissolved in half to a full glass of water.
**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**
- zymag+™ should be used with caution in patients with renal insufficiency.
- Patients on any medication or suffering from any medical condition, should be advised to seek medical advice before starting any new medicine, supplement or remedy.
- zymag+™ contains sugar alcohol (400 mg sorbitol per tablet). The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in zymag+™ may affect the bioavailability of other medicinal products for oral use administered concomitantly. Patients with hereditary fructose intolerance (HFI) should not take zymag+™.
- The recommended daily dosage should not be exceeded without consulting a health care provider.

**Paediatric population**
The safety and efficacy of zymag+™ have not been established in children under the age of 9 years.
**4.5. Interaction with other medicines and other forms of interaction**
*Medicines*
- Concomitant use of zymag+™ with antibiotics (such as tetracyclines) may reduce absorption.
- Concomitant use of zymag+™ with antipsychotics (such as fluphenazine) may contribute to reduced serum concentrations of fluphenazine.

*Laboratory tests*
Absorption of vitamin B12 from the gastrointestinal tract may be reduced by concomitant use of neomycin, aminosalicylic acid, histamine H2-antagonists, omeprazole, and colchicine and serum concentrations of vitamin B12 may be decreased by use of oral contraceptives. Many of these interactions should be considered when performing assays for blood concentrations.
*Food*
Concomitant use with alcohol should be avoided as it may inhibit absorption.
**4.6. Fertility, pregnancy and lactation**
Safety in pregnancy and breastfeeding has not been established. There is no data available on the possible effects on male and female fertility.
**4.7. Effects on ability to drive and use machines**
zymag+™ has no or negligible influence on driving performance or the ability to use machines.
**4.8. Undesirable effects**
zymag+™ is generally well tolerated.
**Gastrointestinal disorders:**
*Less frequent:* gastrointestinal disturbances, such as diarrhoea.
**Skin and subcutaneous tissue disorders:**
*Less frequent:* itching.
**Reporting of suspected adverse reactions**
Reporting suspected adverse reactions after authorisation of zymag+™ is important. It allows continued monitoring of the benefit/risk balance of zymag+™. Health care providers are asked to report any suspected adverse reactions to the South African Health Products Regulatory Authority (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**
In 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**
**5.1. Pharmacodynamic properties**
**Category and class:**
D 34.12 Multiple substance formulation.
zymag+™ is a health supplement containing Magnesium, Vitamin C and Vitamin B12 to assist with the reduction of tiredness and fatigue. It also contributes to normal energy-yielding metabolism and functioning of the nervous system.
**5.2 Pharmacokinetic properties**
Magnesium is absorbed throughout the gastrointestinal tract, is distributed in the skeleton and soft tissue, and excreted primary via the kidneys.
Vitamin C is readily absorbed from the gastrointestinal tract and is widely distributed in the body. The main route of elimination is through the urine.
Vitamin B12 substances bind to intrinsic factor to be actively absorbed from the gastrointestinal tract. Absorption also occurs by passive diffusion. Vitamin B12 is extensively bound to specific plasma proteins. Vitamin B12 is stored in the liver, excreted in the bile, and undergoes extensive enterohepatic recycling. Part of a dose is excreted in the urine. Vitamin B12 diffuses across the placenta and appears in breast milk.

**6 PHARMACEUTICAL PARTICULARS**
**6.1 List of excipients**
Carmoisine red (colourant)
Citric acid anhydrous
Polyethylene glycol
Sodium bicarbonate
Sorbitol
Strawberry flavour
Sucralose.
**6.2 Incompatibilities**
Not applicable
**6.3 Shelf life**
24 months.
Store at or below 25 °C.
**6.4 Special precautions for storage**
Store in a cool, dry place, protected from light.
**6.5 Nature and contents of container**
Tablets are packed in a PP tube with a closure containing a desiccant, packed inside a carton. Available in pack sizes of 10 and 30 effervescent tablets.
**6.6 Special precautions for disposal**
No special requirements.

**7. HOLDER OF CERTIFICATE OF REGISTRATION**
Technikon Laboratories (Pty) Ltd
1073 Anvil Road
Robertville
Florida
1710

**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 June 2021.