VITALUX® PLUS TR (vitamins and minerals)

Sustained release coated tablets

Core Data Sheet

Version 1.0

Release date: 16-Jan-2012

Table of contents

1 Trade name

VITALUX® Plus Time Release

2 Description and composition

Pharmaceutical form

Sustained release coated tablets

Active substances

Each tablet contains:

Beta-carotene (provitamin A) 10,000 IU, ascorbic acid (vitamin C) 300 mg, d-alpha-tocopheryl acetate (vitamin E) 100 IU, riboflavin 20 mg, selenium (as Hydrolyzed Vegetable Protein, HVP^+, chelate) 50 microgram, zinc (as gluconate) 40 mg, copper (as HVP^+ chelate) 2 mg, lutein 4 mg (supplying 200 microgram zeaxanthin).

Information might differ in some countries.

Excipients

Microcrystalline cellulose, calcium silicate, hydroxypropyl methylcellulose, silicon dioxide, purified stearic acid, magnesium stearate.

Coating: Purified water, titanium dioxide, hydroxypropyl methylcellulose, hydroxypropyl cellulose, polyethylene glycol, caramel colour, polysorbate 80, montan wax, ethyl vanillin, diacetylated monoglycerides, xanthan powder.

Information might differ in some countries.

3 Indications

The vitamins and mineral salts of Vitalux Plus TR are indicated to help in:

- reducing the risk of eyes from developing age-associated macular degeneration [1,2,4].
- protecting the eye from developing cataracts [2-7],
- hypovitaminosis, states where there is a greater need for vitamins and minerals, such as stressful situations, physical exercise, unvaried diet, ageing, treatment with antibiotics, infections, febrile states, diets, states with loss of appetite, chronic alcoholism, and exposure to sunlight.

Vitalux Plus TR could also be used as coadjuvant against changes in corneal epithelium with opacity of the cornea (xerophthalmia) [8,9], and protect against deficient adjustment of vision to darkness [9,10].

4 Dosage and administration

Dosage in adults

One tablet per day

Special populations

Geriatrics (aged 65 years or above)

There is no information suggesting that the dosage needs to be adjusted in the population over 65 years of age.

Pediatrics

Vitalux Plus TR is intended for use in adults only.

Renal impairment

No studies have been performed in patients with renal impairment.

Hepatic impairment

No studies have been performed in patients with hepatic impairment.

Method of administration

The tablet should be taken orally with a glass of water and with a meal.

5 Contraindications

Vitalux Plus TR must not be used in the event of known hypersensitivity to any of the ingredients (active components and excipients).

6 Warnings and precautions

- Discontinue the treatment in the case of hypersensitivity.
- Vitalux Plus TR should not be used in patients with severe impairment of renal function or the presence of renal calculi [15].
- Vitamin E should not be taken when there is an alteration in prothrombin activity and the clotting time [9,15].
- Vitalux Plus TR should not be used with other preparations containing Vitamin A [9,15].
- Smokers should not use multivitamin preparations containing beta-carotene [9,11,15].

7 Adverse drug reactions

As Vitalux Plus TR contains a combination of vitamins and minerals, adverse reactions observed with each of the components may be expected [15].

The following adverse drug reactions have been derived from post-marketing experience with Vitalux Plus TR via spontaneous case reports and literature cases. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency which is therefore categorized as not known.

Local and systemic hypersensitivity, including rare cases of anaphylaxis [13,15] and diarrhoea [14] have been reported with Vitalux Plus TR.

Patients receiving long-term beta-carotene therapy may experience skin discoloration (yellow or orange skin pigmentation) because of accumulation of beta carotene in the skin.

With vitamin C, nausea, vomiting, heartburn, abdominal pain, fatigue, flushing, headache, insomnia and somnolence have been reported [9].

8 Interactions

Interactions to be considered

- Due to the presence of zinc, chelation with tetracyclines may occur. This decreases the absorption of tetracyclines.
- Concurrent use of penicillamine may reduce the absorption of zinc [12].

9 Women of child bearing potential, pregnancy, breast-feeding and fertility

Women of child bearing potential

There is no data supporting any special recommendations in women of child-bearing potential.

Pregnancy and breast-feeding

Multivitamin preparations should be used during pregnancy and breast-feeding only as directed by the physician.

Fertility

There is no data available on the effect of Vitalux Plus TR on fertility in humans.

10 Overdosage

Vitalux Plus TR is an antioxidant supplement of vitamins and mineral salts. Overdose may cause hypervitaminosis and mineral toxicity when the intake of the supplement exceeds the Tolerable Upper Intake [15].

Signs and symptoms

Vitamin E at dosages exceeding 300 IU daily may cause nausea, diarrhoea, intestinal cramps, and fatigue. Vitamin C at high doses (i.e. 1 g daily or greater) may cause gastrointestinal disturbances such as diarrhoea [9,15].

Treatment

There is no specific antidote for Vitalux Plus TR. Symptoms of overdose should be treated symptomatically [15].

11 Clinical pharmacology

Pharmacotherapeutic group, ATC

ATC code: A11AA03 multivitamins and other minerals, incl. combinations

Pharmacodynamics (PD)

Vitalux Plus TR is an advanced antioxidant supplement of vitamins and mineral salts, that are involved in cellular protection against the degenerative action of free radicals. The vitamins and mineral salts of Vitalux Plus TR are also essential for optimal cell metabolism. In particular, Vitalux Plus TR combines the vitamins and mineral salts necessary for maximizing vision and health of the eye.

Pharmacokinetics (PK)

No pharmacokinetic data on Vitalux Plus TR is available.

12 Clinical studies

No clinical trials with Vitalux Plus TR have been conducted.

13 Non-clinical safety data

No pre-clinical studies were performed with the combination itself. However, all components of Vitalux Plus TR are well established. At the recommended dosage, preclinical data do not support a special hazard for humans [16].

14 Pharmaceutical information

Incompatibilities

Not applicable

Special precautions for storage

Store below 25°C, in a cool and dry place.

Information might differ in some countries.

Vitalux Plus TR must be kept out of the reach and sight of children.

Instructions for use and handling

Not applicable

15 References

1. Age-related Eye Disease Study Research Group (2001) A randomized, placebo-controlled, clinical trial of high-dose supplementation with vitamins C and E, beta carotene, and zinc for age-related macular degeneration and vision loss. AREDS Report No. 8. Arch Ophthalmol; 119(10):1417-36.

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7. Mares-Perlman JA, Lyle BJ, Klein R, et al (2000) Vitamin supplement use and incident cataracts in a population-based study. Arch Ophthalmol; 118(11):1556-63.

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11. Ommen GS, Goodman GE, Thornquist MD, et al (1996) Effects of a combination of beta carotene and vitamin A on lung cancer and cardiovascular disease. N Eng J Med; 334(18):1150-5.

12. Drug Information for the Health Care Professional. USP DI. 22nd edition. 2002; 2978-9.

Newly added references BPI amendment 09-Feb-2009

13. Clinical Safety Statement – Support the changes in section 4.8 on hypersensitivity of the Basic Prescribing Information (BPI). Novartis Pharma AG. Basel, Switzerland. 03 Feb 09.

14. Clinical Safety Statement – Support the changes in section 4.8 on diarrhoea of the Basic Prescribing Information (BPI). Novartis Pharma AG. Basel, Switzerland. 03 Feb 09.

Newly added references CDS update 16-Jan-2012

15. [Vitalux Plus TR, 2.5 Clinical Overview]. Rationale for changes to Core Data Sheet (CDS) / A full review and update of Safety sections. Novartis. 29-Nov-2011

16. [Vitalux Plus TR, 2.4 Nonclinical Overview]. Rationale for changes to Core Data Sheet (CDS) / Product Information – Nonclinical safety section. Novartis. 29-Nov-2011