

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Bayer Multivitamin & Mineral Film Coated Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains:

Ascorbic acid (vitamin C) 500 mg

Thiamine nitrate 14.57 mg
Corresponding to 15 mg thiamine hydrochloride

Riboflavin 15 mg

Nicotinamide 50 mg

Pantothenic acid 23 mg
In form of calcium pantothenate (25 mg)¹⁾

Pyridoxine hydrochloride 10 mg

Cyanocobalamin 0.01 mg

Folic acid 0.4 mg

Biotin 0.15 mg

Calcium carbonate 244 mg
In form of calcium carbonate¹⁾

Magnesium carbonate, heavy 122 mg
In form of magnesium carbonate, heavy²⁾

Magnesium 115 mg
In form of magnesium oxide, light²⁾

Zinc 32 mg
In form of zinc citrate trihydrate³⁾

¹⁾ Total calcium content 100 mg

²⁾ Total magnesium content 100 mg

³⁾ Total zinc content 10 mg

Excipients:

Lactose 90 mg
as lactose monohydrate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film coated tablet.

Oblong, biconvex, light orange or greyish orange, odourless or almost odourless tablet. Size: 19 mm x 8.8 mm.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Deficiency and increased requirement of vitamin C and B vitamins.

Deficiency and increased requirement of Zinc.

4.2 Posology and method of administration

Adults and adolescents: 1 film-coated tablet daily.

The recommended daily dose of one tablet per day must not be exceeded.

This medicinal product is not recommended for children below 11 years.

4.3 Contraindications

Known allergy or hypersensitivity to the active substances or to any of the excipients in Bayer Multivitamin & Mineral Film Coated Tablets. Hypercalcemia. Hypermagnesemia. Nephrolithiasis/urolithiasis. Hemochromatosis.

Ascorbic acid should not be given to patients with hyperoxaluria, reduced renal function or deficiency of glucose-6-phosphate dehydrogenase.

4.4 Special warnings and precautions for use

The yellow discolouration of the urine after taking Bayer Multivitamin & Mineral Film Coated Tablets is due to its content of Vitamin B2 (riboflavin).

Bayer Multivitamin & Mineral Film Coated Tablets do not contain any fat-soluble vitamins. One Bayer Multivitamin & Mineral Film Coated Tablet contains the maximum daily dose of vitamin B6 (pyridoxine). The recommended daily dose of one tablet per day must not be exceeded.

The levels of calcium (12.5% of the RDA) and magnesium (33.3% of the RDA) in Bayer Multivitamin & Mineral contribute to the recommended daily intake, but the intake of Bayer Multivitamin & Mineral as the only source of calcium and magnesium cannot be regarded as sufficient for the treatment of calcium and/or magnesium deficiencies, or for therapeutic functions of these elements apart from their role as co-factors in the activation and action of B vitamins.

Bayer Multivitamin & Mineral Film Coated Tablets should only be used for the treatment of vitamin B12 deficiency if the cause is dietary. The medicinal product is not intended for use in patients with atrophic gastritis, disorder of the ileum or pancreas and gastro-intestinal malabsorption of vitamin B12 or intrinsic factor deficiency.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take Bayer Multivitamin & Mineral Film Coated Tablets.

One Bayer Multivitamin & Mineral Film Coated Tablet contains 25 mg of mannitol, 94mg of lactose monohydrate and 13.44 mg of polydextrose, corresponding to 0.02 diabetic exchange and an energy value of 0.143 kcal (EU). Thus, Bayer Multivitamin & Mineral Film Coated Tablets can be administered to diabetes patients.

Patients receiving any other medication or those under medical care should consult a physician before taking this medicinal product.

4.5 Interaction with other medicinal products and other forms of interaction

Vitamin C (ascorbic acid) may interfere with some tests for glucose in the urine. Therefore, the administration of ascorbic acid (vitamin C) should be interrupted several days before such tests are performed.

At doses exceeding 5 mg, vitamin B6 (pyridoxine) neutralises levodopa activity in Parkinson disease patients. However, no such antagonism is observed when levodopa is administered in combination with a decarboxylase inhibitor (such as benserazide or carbidopa).

The vitamin B1 antagonists thiosemicarbazone and 5-fluorouracil neutralise the effect of vitamin B1.

Antacids inhibit the resorption of vitamin B1.

Neomycin, aminosalicic acid and H2-blockers can reduce the gastrointestinal absorption of vitamin B12.

Acetylsalicylic acid reduces the absorption of ascorbic acid by about a third.

Oral contraceptives can lower serum levels of vitamin B 12, folic acid, pyridoxine and ascorbic acid.

Some patients treated with deferoxamine and 500 mg Vitamin C daily have shown a deterioration in left ventricular function (often transitory).

4.6 Pregnancy and lactation

No indications exist that the nutrients contained in Bayer Multivitamin & Mineral have any adverse effects on pregnancy or on the health of the foetus/newborn child at the recommended dose of one tablet per day. However, Bayer Multivitamin & Mineral should be administered in pregnancy only when clinically indicated.

The vitamins and minerals in Bayer Multivitamin & Mineral Film Coated Tablets are excreted into breast milk, but harmful effects on the child are unlikely at therapeutic doses.

4.7 Effects on ability to drive and use machines

Bayer Multivitamin & Mineral has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The most commonly found adverse reactions are mild transient multivitamin/mineral gastrointestinal disturbances, occurring in up to 5% of patients.

Allergic reactions are very rare (<1/10,000). Urticaria, throat swelling and rash have been reported in isolated cases.

Ascorbic acid may cause haemolytic anaemia in certain individuals with a deficiency in glucose-6-phosphate-dehydrogenase.

4.9 Overdose

Cases of overdoses have not been reported. Symptoms of overdose may include gastrointestinal disturbance, such as diarrhoea and abdominal discomfort. The daily administration of over 200 mg of vitamin B6 (pyridoxine) (corresponding to more than 20 tablets of Bayer Multivitamin & Mineral daily) over several months may lead to symptoms of neuropathy.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vitamin B complex with vitamin C and minerals.

ATC code: A 11 E B and A 11 E C.

The vitamin content of the Bayer Multivitamin & Mineral formulation is intended for use in deficiencies and increased requirement states. As a result, the content of the individual vitamins in Bayer Multivitamin & Mineral was formulated above the recommended nutritional Recommended Dietary Allowances (RDAs) which are not intended for therapeutic use. One tablet contains: ascorbic acid 500 mg (RDA = 60 mg), thiamine 15 mg (RDA = 1.4 mg), riboflavine 15 mg (RDA = 1.6 mg), nicotinamide 50 mg (RDA = 18 mg), pyridoxine 10 mg (RDA = 2 mg), cyanocobalamin 0.01 mg (RDA = 0.001 mg), folic acid 0.4 mg (RDA = 0.2 mg), pantothenic acid 23 mg (RDA = 6 mg) and biotin 0.15 mg (RDA = 0.15 mg).

Since the water-soluble vitamins are not stored by the body to any appreciable extent, the supply of water-soluble vitamins might be insufficient in the elderly, during pregnancy and lactation, in persons on diet, during certain chronic diseases, during extensive physical exercise and during long-lasting stress and chronic alcohol abuse. The demand of vitamin C (ascorbic acid) is higher than normal in smokers and in women using oral contraception.

B vitamins are involved in a broad spectrum of cell metabolic reactions, such as synthesis of neurotransmitters.

Vitamin C (ascorbic acid) is a biological antioxidant and plays an important role in the inactivation of free radicals. It is also required for the activity of a number of enzymes involved in hydroxylation reactions and in the metabolism of e.g. cholesterol, bile acids and drugs. Vitamin C (ascorbic acid) enhances the absorption of iron in the intestine, influences folic acid metabolism and leukocyte function. It promotes the formation of connective tissue and is essential for the formulation and function of teeth, bones and capillaries.

Calcium participates in numerous physiological processes, enzyme systems and in nerve transmission, and interacts in many of these processes in a complex way with magnesium and vitamin B6.

Magnesium participates in a variety of reactions including protein catabolism, fatty acid metabolism, sugar oxidation and respiratory reactions.

Zinc is an important trace element in the body and is involved as a catalyst in more than 200 enzymes. It is a natural constituent of many proteins, hormones, neuropeptides and hormone receptors. Amongst others, zinc is directly involved in the synthesis of co-enzymes derived from vitamin B6 (pyridoxine).

5.2 Pharmacokinetic properties

Human health and well-being is naturally dependent on the continuous uptake and management of vitamins and trace elements, and their absorption, distribution, metabolism and elimination are maintained by specific physiological mechanisms. As the Bayer Multivitamin & Mineral Film Coated Tablets are completely dissolved in the gastrointestinal tract a good availability of these compounds is assured.

5.3 Preclinical safety data

At the recommended dose of one tablet per day Bayer Multivitamin & Mineral Film Coated Tablets are devoid of toxic effects.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core:

Lactose monohydrate
Povidone (K90)
Sodium croscarmellose
Mannitol (E421)
Talc
Magnesium stearate

Excipients of cyanocobalamin 0.1% WS:

Sodium citrate
Anhydrous citric acid
Dextrin.

Film Coat

Hypromellose
Fractionated coconut oil
Polydextrose
Titanium dioxide (E171)
Red, yellow and black iron oxide (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

Packages: 10, 30, 60 and 100. Blisters of 10 tablets (PVC/PE/PVDC/ALU).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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United Kingdom

Trading as: Bayer plc, Consumer Care Division

8 MARKETING AUTHORISATION NUMBER

PA 0021/061/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 November 1998

Date of last renewal: 23 November 2008

10 DATE OF REVISION OF THE TEXT

February 2009