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EVITOL®

TABLETS

Composition

Each tablet contains:

Active Ingredient
dl-alpha-Tocopherol acetate 100 mg or 200 mg (Vitamin E)

Other Ingredients
Microcrystalline cellulose, silicon dioxide, hydrogenated vegetable oil, povidone, gelatin, sucrose*, maize starch, sodium alumino-silicate.

* *Each Evitol 100 mg tablet contains 9.4 mg sucrose*.
* *Each Evitol 100 mg tablet contains 1.74 mg sodium.*

* *Each Evitol 200 mg tablet contains 18.8 mg sucrose.*
* *Each Evitol 200 mg tablet contains 3.5 mg sodium.*

Mechanism of Action

Vitamin E is a fat-soluble intracellular antioxidant. It plays an important role in preventing oxidation of essential cellular constituents, thereby preventing the formation of toxic oxidation products, such as the peroxides formed from unsaturated fatty acids. These lipid peroxides are known to damage cell membranes.

Vitamin E deficiency plays a significant role in the pathogenesis of hemolytic anemia in premature infants. Its antioxidant property is important for the maintenance of red cell viability. It is also quite likely that vitamin E deficiency predisposes to the development of retrolental fibroplasia in premature infants exposed to higher oxygen tensions than those of the intrauterine environment.

The need of the body for vitamin E is considerably increased by diets that contain foods rich in polyunsaturated fatty acids. This explains vitamin E deficiency in infants fed on formulas rich in such fatty acids. This deficiency is corrected by the administration of vitamin E. In fact, it has been shown that levels of vitamin E rise much slower in artificially-fed infants than in those who are breastfed.

Human atheromatous lesions contain lipid peroxides. Furthermore, patients with intermittent claudication show a raised red cell malonyldialdehyde, a secondary product of lipid peroxidation. These factors point to the presence of lipid peroxides being an integral factor in the pathogenesis of intermittent claudication. By virtue of its biological antioxidant properties, Evitol is a valuable adjunct in the treatment of intermittent claudication in occlusive arterial disease of the leg.

There are also a number of other clinical conditions in which successful treatment with vitamin E has been reported. However, the mechanism of its action in these conditions is still obscure.

Vitamin E is absorbed from the gastrointestinal tract. Most of the vitamin appears in the lymph and is then widely distributed to all tissues. Most of the dose is slowly excreted in the bile and the remainder is eliminated in the urine as glucuronides of tocopheronic acid or other metabolites.

Indications

Vitamin E supplement.

Supplement for the correction of Vitamin E deficiency associated with malabsorption disorders, cystic fibrosis, chronic cholestasis and abetali- poproteinemia.

Supplement to diets rich in polyunsaturated fatty acids.

Prevention of hemolytic anemia and retrolental fibroplasia in low birth-weight premature infants.

Contraindications

Known hypersensitivity to vitamin E, or to any other ingredient of the preparation.

Warnings

Use in Pregnancy

There is no evidence of the safety of high doses of vitamin E in pregnancy, nor is there evidence from animal work that it is free from hazard. Therefore, do not use this drug in pregnancy, particularly in the first trimester.

Use in Lactation

No information is available on the excretion of vitamin E in breast milk. Therefore, it is recommended not to administer this drug to nursing mothers.

Adverse Reactions

Diarrhea and abdominal pain may occur with doses greater than 1 g/day.

Large doses {greater than 300 IU *(135 mg potency)*/day} have rarely caused intestinal cramps, fatigue, weakness, headache, blurred vision, rash, gonadal dysfunction, creatinuria, increased serum creatine kinase, increased serum cholesterol and triglycerides, increased urinary estrogens and androgens, and decreased serum thyroxine and triiodothyronine. These effects disappear after discontinuing the vitamin.

Precautions

Vitamin E has been reported to increase the risk of thrombosis in patients who are predisposed to this condition, including patients taking estrogens (see also Drug Interactions). This finding has not been confirmed but should be borne in mind when selecting patients for treatment, in particular women taking oral contraceptives containing oestrogen.

A higher incidence of necrotising enterocolitis has been noted in lower weight premature infants (less than 1.5kg) treated with vitamin E.

Drug Interactions

Vitamin E/Oral Anticoagulants*:* Vitamin E may interfere with vitamin K-dependent clotting factors. In patients on oral anticoagulant therapy who receive vitamin E concomitantly, the hypoprothrombinemic effects may be increased, possibly with bleeding. Therefore these patients should be observed closely for signs of an excessive hypoprothrombinemic response to oral anticoagulants, and coagulation indices monitored during concurrent administration of vitamin E. Lower anticoagulant doses may be required.

Vitamin E/Estrogens: Vitamin E may increase the risk of thrombosis in patients taking estrogens.
Vitamin E/ Vitamin A: Vitamin A absorption, utilization and storage may be increased.
Vitamin E/Cholesterol Lowering Agents (e.g.: Colestipol, Cholestyramine, Gemfibrozil): These agents may decrease the absorption of vitamin E upon concomitant administration.
Vitamin E/Orlistat: Orlistat may decrease the absorption of fat-soluble vitamins, including vitamin E. It is therefore recommended that at least 2 hours elapse between doses of orlistat and vitamin E.

Dosage and Administration

Latest trends in vitamin E therapy favor high doses and prolonged treatment.

Adults

The usual dose is 200-400 mg daily. Larger doses up to 800 mg daily may be administered. In chronic diseases, treatment should be continued for at least 3 months.

Children

Up to half the adult dose.

Overdosage

Transient gastrointestinal disturbances have been reported with doses greater than 1 g/day. Where necessary, general supportive measures should be employed.

Storage

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

Registration Numbers:
Evitol tablets 100 mg: 027.65.21671.00
Evitol Tablets 200 mg: 036.20.22048.00

Manufacturer

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