

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

# TOCOFER

(Vitamin E Capsules U.S.P. 100 mg, 200 mg, 400 mg)

Vitamin E is one of the most important naturally occurring fat-soluble antioxidant vitamins. It is an oil present in plants, particularly wheat germ, rice and cotton seeds, The signs of vitamin E deficiency in humans are muscular weakness, creatinuria and fragile erythrocytes. These signs are reported to disappear after the administration of Tocofer.

## CLINICAL PHARMACOLOGY :

Vitamin E participates in the formation of structures of mesodermal origin and in the maintenance of their function. At the cellular level vitamin E participates in nucleic acid metabolism and in the respiratory chain.

Vitamin E acts as a biological antioxidant, preventing spontaneous oxidation of highly unsaturated compounds to aggressive free radicals, as well as in the formation of carcinogenic nitrosoamines. It diminishes the toxic action of oxygen and improves economy in oxygen utilization.

Owing to its lipophilic properties, vitamin E accumulates in membranes and thereby protects functionally important cell structures, primarily by inhibition of lipid peroxidation. Vitamin E is instrumental in stabilizing the lysosomal, mitochondrial and capillary membranes and thus in maintaining normal erythrocyte resistance. In the same way it helps to increase phagocytosis. Vitamin E deficiency leads, through lipid peroxidation, to the accumulation of lipofuscin, the yellow brown pigment of old age.

It is thought vitamin E brings about redistribution of cholesterol with a rise in HDL cholesterol fraction and a decline in LDL cholesterol fraction.

Administered orally, approximately 20-40% of alpha-tocopherol acetate is absorbed, primarily in the middle portion of the small intestine; this percentage declines, however, with increasing dosage. Optimum absorption is possible only in the presence of biliary and pancreatic juices. In lymph and blood, most vitamin E is bound to the beta-lipoprotein fraction. Elimination is primarily in the feces. Urinary excretion generally accounts for less than 1% of orally ingested vitamin E, part of which is excreted as glucuronic acid conjugates, and part in the form of its metabolites which have virtually no vitamin E activity. The elimination half-life is determined by the duration of administration and the size of the dose. Vitamin E appears in breast milk but it is poorly transferred across the placenta.

## INDICATIONS :

Tocofer Capsules are indicated for the therapeutic management of nocturnal muscle cramps, intermittent claudication and fibrocystic breast disease. They are also useful in minimising the pathological processes leading to atherosclerosis and as a dietary supplement in malabsorption syndromes and in those who are on a diet rich in polyunsaturated fatty acids.

## CONTRAINDICATIONS :

No contraindications to use of vitamin E are known.

## ADVERSE REACTIONS :

Adverse effects are extremely rare after the administration of vitamin E. Relatively large doses of the order of several hundred mg/day have been administered without the appearance of any untoward side effects. Diarrhoea, intestinal cramps, angular stomatitis, lethargy, muscle weakness and thrombophlebitis have been reported after unusually large dosage and they have rapidly reversed after stopping vitamin E administration.

Vitamin E hypervitaminosis is known.

## DRUG INTERACTIONS :

Vitamin E may interfere with the action of iron in correcting iron deficiency anemia.

Hence, iron preparations should preferably be taken 8-12 hrs before or after vitamin E. Very high doses of vitamin E can reinforce the action of anti-coagulants. A regular check on the coagulation parameters is indicated in patients receiving concomitant oral anticoagulant therapy.

## DOSAGE AND ADMINISTRATION :

Various dosage schedules are being used.

Some of the commonly used regimens are :

As a dietary supplement	: 30-100mg daily
Nocturnal muscle cramps	: 400mg daily for 8-12 weeks
Intermittent claudication	: 400mg daily for 12-18 weeks
Fibrocystic breast disease	: 400mg daily for 2-6 months
Atherosclerosis	: 400mg daily.

## PRESENTATION :

Tocofer Capsules are available in blister strips of 10's capsules. Each soft gelatin capsule contains Vitamin E Acetate U.S.P. either 100/200/400 mg



Manufactured by:

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