

## Summary of Product Characteristics

- 1. **Name Of The Medicinal Product:**  
Vitamin E Forte Soft Gelatin Capsules.
- 2. **Qualitative And Quantitative Composition**

### Each Capsule Contains:

dl-Alpha Tocopherol Acetate Equivalent to 400 I.U Natural Vitamin E .	400 mg	BP 2018
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### Composition of soft gel. Capsule (Oval 6):

Gelatin bloom (150 -160)	144 mg	BP 2018
Glycerol	40.30 mg	BP 2018
Sorbitol solution 70%	27.84 mg	BP 2018
Propyl paraben	0.072 mg	BP 2018
Methyl paraben	0.144 mg	BP 2018

### 3. Pharmaceutical Form:

Capsules for oral administration

### 4. Clinical Particulars:

#### 4.1 Therapeutic Indications:

Vitamin E capsules is indicated for

- Hyperlipoproteinemias, atherosclerosis and cardiomyopathy.
- Haemolytic anemia.
- Male infertility, habitual abortion and post IUD insertion.
- Epilepsy, Parkinson's disease and larvide dyskinesia.
- Cholestatic liver disease.

#### 4.2 Posology And Method Of Administration:

One capsule daily.

#### 4.3 Contraindications:

Vitamin E is contraindicated in the following conditions:

- Retinitis pigmentosa (RP): Investigators hypothesised that the 400 IU day<sup>-1</sup> dosage of vitamin E may inhibit the absorption or transport of vitamin A, as the participants

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receiving this dosage of vitamin E had significantly decreased serum retinol levels compared with those not receiving vitamin E (Grover and Samson , 2014; Pang et al., 2001)

- Vitamin K deficiency: Vitamin E may exacerbate the effects of Vitamin K deficiency and has been associated with an increased risk of haemorrhagic stroke, and a reduced risk of ischaemic stroke and ischaemic heart disease.

- Oral anticoagulants administration: The action of oral anticoagulants may be increased by concurrent administration of vitamin E. Concurrent vitamin E and warfarin use has been associated with abnormal bleeding, and vitamin E appears to add to aspirin's blood thinning effect. (Bartlett, H., et al., 2005).

- Angioplasty, a heart procedure: vitamin E or other antioxidant vitamins (beta-carotene, vitamin C) should be avoided immediately before and following angioplasty . This may be due to interference with proper healing.

#### • 4.4 Special Warnings And Precautions For Use:

##### • **Precautions:**

□ **Vitamin E** is a natural blood thinner , so it may increase the risk of bleeding, especially if you are taking blood-thinners such as warfarin ,aspirin, or clopidogrel .

□ **Vitamin E** can cause a temporary elevation of blood pressure.

**Vitamin E** in 400 IU per day or higher; may increase the risk of death.

□ **Vitamin E** should not be taken in higher amounts during pregnancy or breastfeeding.

□ Oral administration of large doses (200 mg per day) of a hyperosmolar vitamin E preparation to low-birth weight infants has been associated with the development of necrotizing entero-colitis

#### • 4.5 Interaction With Other Medicinal Products And Other Forms Of Interaction:

Vitamin E may cause the following interactions between the following medications:

□ **Antidepressant medications:** Vitamin E interferes with the absorption of the antidepressant desipramine (Scuntaro et al., 1996).

□ **Antipsychotic medications:** Vitamin E can interfere with the body's absorption of the antipsychotic medication such as chlorpromazine (Soares and McGrath, 2001).

□ **Aspirin:** Because vitamin E can increase the risk of bleeding (Podszun and Frank, 2014).

□ **AZT:** Vitamin E may protect against toxicity and side effects from AZT, a medication used to treat HIV and AIDS (García-de-la-Asunción et al., 2007).

□ **Beta-blockers:** Vitamin E interferes with the body's absorption of propranolol and other beta-blockers include: Acebutolol, Atenolol, Bisoprolol, Carteolol, Metoprolol, Nadolol, and Propranolol.

□ **Cholesterol-lowering medications:**

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- **Bile acid sequestrants:** may reduce how much vitamin E your body absorbs (Sutken et al., 2006).

- **Statins:** Taking a combination of antioxidants, including vitamins E and C, selenium, and beta-carotene, along with niacin and simvastatin (Zocor) seems to keep niacin and Zocor from raising "good" HDL cholesterol (Sutken et al., 2006).

- **Gemfibrozil:** may also reduce vitamin E levels (Sutken et al., 2006).

□ **Cyclosporine:** Vitamin E may interact with cyclosporine, a medication used to treat cancer, making both vitamin E and cyclosporine less effective (Chang et al., 1996).

□ **Chemotherapy drugs:** vitamin E may reduce the effectiveness of chemotherapy drugs, including chlorambucil, busulfan, doxorubicine, carmustine, thiopeta, and cyclophosphamideradicals.

□ **Tamoxifen:** Vitamin E when taken along with tamoxifen, reduced its side effect. made the anti-cancer action of the tamoxifen stronger. (Podszun and Frank, 2014)

□ **Warfarin :** Taking vitamin E at the same time as other blood-thinners can increase the risk of bleeding (Podszun and Frank, 2014).

□ **Orlistat :** It may prevent the absorption of vitamin E (McDuffie et al., 2002).

#### 4.6 Pregnancy And Lactation:

-Vitamin E is likely safe when taken by mouth in recommended daily amounts during breast-feeding.

-When used in the recommended daily amount, vitamin E is possibly safe for pregnant women. There has been some concern that taking vitamin E supplements might be harmful to the fetus when taken in early pregnancy (Boskovic et al, 2005).

#### • 4.7 Effects On Ability To Drive And Use Machines:

Not applicable

#### • 4.8 Undesirable Effects:

##### 1. Adverse effect:

Greater dose more than 300 Units a day and long-term use may results in the following side effects:

##### 1.1. Gastrointestinal

Gastrointestinal side effects associated with oral doses greater than 300 units daily have rarely included nausea, diarrhea, and intestinal cramps.

##### 1.2. Hematologic

Hematologic side effects associated with oral doses greater than 300 units daily have rarely included thrombophlebitis.

##### 1.3. Ocular

Ocular side effects associated with oral doses greater than 300 units daily have rarely included blurred vision.

##### 1.4. Dermatologic

Dermatologic side effects associated with oral doses greater than 300 units daily have rarely included rash. Dermatologic side effects associated with topical application of vitamin E have included growth of white hair at site of alopecia and contact dermatitis.

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### 1.5. Genitourinary

Genitourinary side effects associated with oral doses greater than 300 units daily have rarely included gonadal dysfunction and breast soreness.

Endocrine side effects associated with oral doses greater than 300 units daily have rarely included decrease in serum thyroxine and triiodothyronine.

### 1.7. Metabolic

Metabolic side effects associated with oral doses greater than 300 units daily have rarely included creatinuria, increased serum creatinine kinase, increased serum cholesterol and triglycerides and increased urinary estrogens and androgens.

### 1.8. Other

Other side effects may include fatigue, emotional disturbances, weakness, and headache. (Meyers et al., 1996)

(<http://www.drugs.com/sfx/nutr-e-sol-side-effects.html>).

### • 4.9 Overdose:

Occurrence of vitamin E overdose is rare, However high doses of alphatocopherol supplements can cause hemorrhage and interrupt blood coagulation in animals, and in vitro data suggest that high doses inhibit platelet aggregation (Sesso et al., 2008).

### 5. Pharmacological Properties:

Vitamin E Forte Soft Gelatin is regarded as the most recommended concentrated preparation of natural alpha tocopherol, which is recognized the most active form of tocopherol.

Alpha tocopherol is considered the major lipid soluble antioxidant, protecting lipids in body tissues from peroxidative damage. In particular, it protects polyunsaturated fatty acids (PUFA) within biological membrane phospholipids or in plasma low density lipoproteins.

The medical trials and epidemiological studies have provided evidence that high blood levels of alpha tocopherol as anti-oxidant may thwart the incidence of atherosclerosis, congestive cardiomyopathy, Cholestatic liver disease, carcinogenesis and neurological problems associated with abetalipoproteinemia.

Also, the administration of high levels of high levels of alpha tocopherol has important role in the treatment of Haemolytic anemia.

Alpha tocopherol, also influence hormonal processes and fertility. In addition, the anti-inflammatory effect of alpha tocopherol is useful for habitual abortion and post IUD insertion

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## 6. Pharmaceutical Particulars:

### 6.1 List Of Excipients :

No excipient added.

### 6.2 Incompatibilities:

- All soft gelatin capsule Components comply with their BP or USP Pharmacopoeia monograph.
- None of the excipients contains materials of animal or human origin.
- No genetically modified organisms (GMO) have been used in the preparation of these products.
- No incompatibilities with the excipients or packaging materials have been shown during research of pre-formulation and formulation studies and nor during manufacturing processing and stability.

### 6.3 Shelf Life

3 years

### 6.4 Special Precautions For Storage:

No special precaution for storage

Store in a dry place at temperature not exceeding 30° C.

### 6.5 Nature And Contents Of Container:

Carton box containing 2 (Aluminum- PVC) strips each of 10 capsules and inner leaflet.

### 6.6 Special Precautions For Disposal And Other Handling:

Keep out of reach of children

### 7. Marketing Authorization Holder:

Arab Company for Pharmaceuticals & Medicinal Plants (Mepaco – Medi food) Egypt.

### 8. Marketing Authorization Number(S)

Reg. No: 1742/1997

Reg. No: 24576/2006

### 9. Date Of First Authorization/Renewal Of The Authorization:

Reg. No: 1742/1997

Authorization date: 05/01/1997

Reg. No: 24576/2006

Authorization date: 13/06/2006



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Dr. / Mohamed Eldegwy

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Operating Under Law 43 Issued 1974 - Commercial Register No. 866 - Capital 400 EGP Million

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