

1. Name of the Medicinal Product

1.1 Name of the Medicinal Product

Embassy VIT-E Injection (Tocopheryl Acetate Injection)

1.2. Strength

30mg/ml

1.3. Pharmaceutical Dosage Form

Liquid Injection

2. Qualitative And Quantitative Composition

Qualitative Declaration

Embassy VIT-E Injection contains Tocopheryl Acetate.

Quantitative Declaration

Each ml contains:

Tocopheryl Acetate BP 30mg

Arachis Oil q.s.

3. Pharmaceutical Form

Liquid Injection

4. Clinical Particulars

4.1 Therapeutic Indications

Vitamin E helps maintain good health and has been shown to be beneficial, in helping to act as an antioxidant, be used as an anti-inflammatory, help to prevent and treat disease, and to support the body's immune system. It can also be used to support circulation, promote respiratory health and promote heart health.

4.2 Posology and Method of Administration

The recommended daily intake for adults over 14 is 15 milligrams (or 22.5IU). For adults older than 18 years, pregnant women and breastfeeding women, the maximum dose is 1,000 milligrams daily (or 1500 IU) Or as prescribed by the physician.

Dosage: For IM use only.

4.3 Contraindications

Use in patients with a known hypersensitivity to Vitamin E. Patients with hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

4.4 Special Warning and Precautions for Use

Vitamin E has been reported to increase the risk of thrombosis in patients predisposed to this condition, including patients taking oestrogens. This finding has not been confirmed but should be borne in mind when selecting patients for treatment, in particular women taking oral

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

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

Vitamin E may increase the risk of thrombosis in patients taking oestrogens.

4.6 Fertility, pregnancy and lactation

Pregnancy and lactation

There is no evidence of safety of high doses of vitamin E in pregnancy nor is there evidence of animal work that is free from hazard, therefore do not use in pregnancy especially in the first trimester. Not use during lactation.

Fertility

There is no information on the effects of vitamin E on human fertility

4.7 Effects on Ability to Drive and Use Machines

None known

4.8 Undesirable Effects

Hypertension; myopathy; thrombophlebitis; fatigue, weakness, nausea, headache, dizziness, blurred vision, flatulence, diarrhoea, abdominal pain. Topical: Contact dermatitis.

4.9 Overdose

Overdose symptoms may include stomach pain, nausea, diarrhea, dizziness, headache, tiredness, blurred vision, or tiredness.

5.0 Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Other plain vitamin preparations,

ATC code: A11HA03

The exact role of vitamin E in the animal organism has not yet been established. Vitamin E is known to exert an important physiological function as an antioxidant for fats, with a sparing action on vitamin A, carotenoids and on unsaturated fatty acids. Other work has demonstrated that vitamin E is connected with the maintenance of certain factors essential for the normal metabolic cycle.

5.2 Pharmacokinetic properties

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.

5.3 Preclinical Safety Data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6. Pharmaceutical Particulars

6.1 List of Excipients

- Benzyl Alcohol BP
- Arachis Oil BP

6.2 Incompatibilities

None known.

6.3 Shelf Life

36 Months

6.4 Special Precautions for Storage

Store in a cool and dry place at a temperature not exceeding 30°C. Protect from light.

Keep all medicines out of the reach of children.

6.5 Nature and Contents of Container

10x1ml amber coloured ampoules packed in a unit carton along with patient information leaflet.

6.6 Special Precautions for Disposal and Other Handling

No special requirements.

7. Registrant/Sole Agent

EMBASSY PHARMACEUTICAL & CHEMICALS LTD.

41, Ademola Street, South West Ikoyi,

Lagos, Nigeria, Tel.: 01-2900791

8. Manufacturer

LABORATE PHARMACEUTICALS INDIA LIMITED

51, Industrial Area, Gondpur, Paonta Sahib, Himachal Pradesh (India)

HO: E-11, Indl. Area, Panipat – 132 103 (INDIA)

laborate@laborate.com

9. Date of Revision of Text

To be given after approval of product.