1.4.1 Prescribing information (Summary of Product Characteristics)

1. NAME OF THE MEDICINAL PRODUCT

EVA VIT 400

(Vitamin E Capsules USP 400 IU)

1.1 Qualitative and quantitative composition

Each soft gelatin capsule contains:

Vitamin E USP 400 IU

(as dl- alpha Tocopheryl acetate)

1.2 Pharmaceutical dosage form

Soft gelatin capsule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2. 1 Qualitative composition

Batch Size: 5, 00,000 Capsules

S. No.	Ingredients	Specifica -tion[1]	Overage -s %	Qty per capsule (mg)	Qty per batch (kg)	Therapeutic Category
Fill Materials						
1	Vitamin E (dl- Alpha Tocopheryl acetate)	USP	5%	420.000	210.000	Antioxidant
2	Refined Soya Oil	BP	--	29.910	0.023	Diluent
3	Butylated Hydroxyanisole	BP	--	0.045	0.023	Antioxidant
4	Butylated Hydroxytoluene	BP	--	0.045	14.955	Antioxidant
Shell Materials[2]						
5	Gelatin[3]	BP	--	136.157	68.079	Gelling agent
6	Glycerol	BP	--	36.306	18.153	Plasticizer
7	Liquid Sorbitol (Non-crystallizing)	BP	--	24.204	12.102	Plasticizer
8	Methyl Hydroxybenzoate	BP	--	0.817	0.409	Preservative
9	Propyl Hydroxybenzoate	BP	--	0.082	0.041	Preservative
10	Quinoline Yellow WS	IH	--	0.417	0.209	Colouring Agent
11	Brilliant Blue FCF	IH	--	0.017	0.009	Colouring Agent
12	Purified Water	BP		22.000	11.000	Solvent

Abbreviation:

USP : United States Pharmacopoeia

BP : British Pharmacopoeia

IH : In- House Specification

Note:

1 – Current Pharmacopoeial monographs are implied.

[2]In the batch formula excess material is added to compensate process loss. Process loss due to sticking of gel mass on gelatin melting tank, Gelatin holding tank, Gel mass discharge pipe, spread box retention and gelatin net wastage.

3 – Gelatin is derived from Bovine free from Skulls, Spinal Cord and Vertebrae. Country of Origin – India

- **Description of accompanying reconstitution diluent(s) :** Not Applicable
- **Type of container and closure used for the dosage form and accompanying reconstitution diluent, if applicable :** Not Applicable

3. PHARMACEUTICAL FORM

Green coloured oblong shaped transparent soft gelatin capsules containing pale yellow viscous oily liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the correction of Vitamin E deficiency occurring in malabsorption disorders ie. cystic fibrosis, chronic cholestasis and abetalipoproteinaemia.

4.2 Posology and method of administration

Route of administration: For oral use.

Adults (including the elderly)

For the treatment of malabsorption disorders the following doses should be administered:

Cystic fibrosis	100-200mg/day
Abetalipoproteinaemia	50-100mg/kg/day

Children

For the treatment of cystic fibrosis a dose of 50mg/day should be given to children less than 1 year and 100mg/day to children 1 year and over.

The adult dosage should be used for the treatment of abetalipoproteinaemia (50-100mg/kg/day).

Infants with vitamin E deficiency which is secondary to chronic cholestasis may be treated with doses of 150-200mg/kg/day.

4.3 Contraindications

Use in patients with a known hypersensitivity to Vitamin E.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.4 Special warnings and precautions for use

Vitamin E has been reported to increase bleeding tendency in vitamin-K deficient patients or those taking anticoagulant treatments, it is therefore recommended to monitor the prothrombin time and international normalised ratio (INR) to detect any changes in haemostasis. A possible adjustment of the dose of anticoagulants during and after treatment with Vitamin E capsules 100 mg/cap may be necessary

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 necrotising 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 haemorrhage in patients taking anticoagulants.

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

4.6 Pregnancy and lactation

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 in pregnancy especially in the first trimester. No information is available on excretion in breast milk, therefore it is advisable not to use during lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Diarrhoea and abdominal pain may occur with doses greater than 1g daily.

4.9 Overdose

Transient gastro-intestinal disturbances have been reported with doses greater than 1g daily and where necessary, general supportive measures should be employed.

5. 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

6- PHARMACEUTICAL PARTICULARS:

6.1 List of Excipients

S.No	Ingredients	Specification
1.	Refined Soya Oil	BP
2.	Butylated Hydroxyanisole	BP
3.	Butylated hydroxytoluene	BP
4.	Gelatin	BP

S.No	Ingredients	Specification
5.	Glycerol	BP
6.	Liquid Sorbitol (Non-crystallising)	BP
7.	Methyl Hydroxybenzoate	BP
8.	Propyl Hydroxybenzoate	BP
9.	Quinoline Yellow WS	IH
10.	Brilliant Blue FCF	IH
11.	Purified Water	BP

6.2 Incompatibilities : None.

6.3 Shelf life : 24 months

6.4 Special precautions for storage:

Store below 30°C. Protect from light and moisture.

Keep out of reach of children.

6.5 Nature and contents of container

a) **Type of package**

Blister pack

b) **Nature and packaging material**

– 3x10's Blister pack

7- Marketing Authorization Holder:

8-Marketing Authorization Numbers:

9- Date of first Authorization/renewal of the Authorization:

10 - Date of Revision of the text: