SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Vitamin E Suspension 100mg/ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of suspension contains 500mg of DL-alpha-tocopheryl acetate.

Excipients with known effect:
Each 5ml of suspension contains 1 g of sucrose and 400 mg of polyethoxylated castor oil

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral Suspension

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.

For instructions on dilution of Vitamin E before administration, see section 6.6.

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 Suspension 100 mg/ml may be necessary (see section 4.5).

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 (see section 4.4).

Vitamin E may increase the risk of thrombosis in patients taking oestrogens (see 4.4 above).

4.6 Fertility, 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.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

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 of relevance to the prescriber which are additional to that already in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyethoxylated castor oil
Benzoic acid E210
Sorbic acid
Sucrose
Glycerol
Purified Water

Raspberry flavour containing:
Propylene glycol E1520
Natural flavourings
Purified water.

6.2 Incompatibilities

None.

6.3 Shelf life

Unopened:	Two years.
After first opening:	One month (The product will be stable after opening for the normal duration of treatment providing the cap is replaced after use and the recommended storage conditions on the label are observed).

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

100ml Amber glass bottles with an HDPE child resistant and tamper evident cap with a polypropylene inner and EPE wad.

6.6 Special precautions for disposal

No special requirements.

Vitamin E Suspension may be diluted with Syrup BP but should be used immediately and not stored.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 16853/0117

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

24/08/2016