Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ephynal Tablets 50 mg.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

D, L-Alpha Tocopherol Acetate	50.0	mg
Used as Vitamin E 5% adsorbate comprising of:		
D, L-Alpha Tocopherol Acetate and	51.5 %	w/w
Silica precipitated FK320	48.5 %	w/w

3 PHARMACEUTICAL FORM

Tablet
White to pale cream coloured cylindrical biconvex tablet imprinted ‘Ephynal 50’ on one face with a single break bar on the other.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the correction of vitamin E deficiency occurring in malabsorption disorders ie:
- Cystic fibrosis
- Chronic cholestasis
- Abetalipoproteinaemia

4.2 Posology and method of adminstration

Posology:
These tablets are for oral administration.

Adults:
For the treatment of malabsorption disorders the following doses should be administered:
Cystic fibrosis 100-200 mg/day
Abetalipoproteinaemia 50-100 mg/kg/day

Elderly:
The adult dose is appropriate.

Children:
For the treatment of cystic fibrosis a dose of 50 mg/day should be given to children less than 1 year and 100 mg/day to children 1 year and over. The adult dosage should be used for the treatment of abetalipoproteinaemia (50-100 mg/kg/day). Infants with vitamin E deficiency which is secondary to chronic cholestasis may be treated with doses of 150-200 mg/kg/day.

4.3 Contraindications

Known hypersensitivity to vitamin E.

4.4 Special warnings 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 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 has been reported to increase the risk of thrombosis in patients predisposed to this condition, including 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

4.8 Undesirable effects

No undesirable effects are known at recommended doses.

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The exact role of Vitamin E in the animal organism has not yet been fully established, though it is known to have many functions. 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

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Starch maize white
Silica precipitated FK320
Sucrose
Lactose monohydrate
Talc Purified
Magnesium stearate
Gelatin

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

5 years

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

Amber glass bottles with aluminium screw caps
or
HDPE bottles with J-closures
Pack sizes: 100

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Bayer PLC
Bayer House
Strawberry Hill
Newbury
Berkshire
RG14 1JA
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 21/68/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1983

Date of last renewal: 1st April 2003

10 DATE OF REVISION OF THE TEXT

July 2005