ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

VITAMIN E PROVEPHARM 100 mg/2 mL, solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Alpha-tocopherol acetate ……100.00 mg

In a 2 mL ampoule

Excipient(s) with known effect: Polyoxyl 35 Hydrogenated Castor Oil (CREMOPHOR EL)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection (IM).

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

- Vitamin E deficiency, when the oral route is not possible;
- Digestive malabsorption of vitamin E:
  - cystic fibrosis,
  - hepatic cholestasis,
  - pancreatic impairment,
  - other malabsorptions.
- Vitamin E intake by intramuscular injection during elemental enteral feeding.

4.2. Posology and method of administration

Posology

In adults: 100 mg per month by deep IM.

Paediatric population

Children: 5 mg to 10 mg/kg every 15 days by IM or IV combined with lipid emulsions by infusion.

Method of administration

Injectable use.

Do not administer the product subcutaneously (see section 4.8), or by oesophageal catheter.

4.3. Contraindications

Hypersensitivity to the active substance or one of the excipients listed in section 6.1.

4.4. Special warnings and precautions for use

This medicine contains castor oil and can cause severe allergic reactions.

4.5. Interaction with other medicinal products and other forms of interaction

Combinations requiring precautions for use

+ Antivitamin K

Increase in the effect of oral anticoagulants and risk of haemorrhage.

Frequent monitoring of prothrombin level and INR monitoring. Possible adjustment of oral anticoagulant dosage during treatment with vitamin E and after discontinuation.

4.6. Fertility, pregnancy and lactation

Studies performed in animals have not shown any evidence of teratogenic effects, but have revealed foetotoxicity involving intrauterine growth retardation.

Clinically, a few cases of exposed pregnancies do not seem to suggest a malformation of foetotoxic effect of vitamin E. To date, there is nothing to confirm that a deficiency or overdose of vitamin E during pregnancy can have maternal or foetal repercussions.

VITAMIN E PROVEPHARM can be prescribed during pregnancy and breast-feeding, if necessary.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

The injectable VITAMIN E PROVEPHARM solution contains Polyoxyl Hydrogenated Castor Oil (CREMOPHOR) as solubiliser. This can lead to abrupt falls in blood pressure and anaphylactoid reactions. To reduce these risks as much as possible, administer the product by deep intramuscular injection only.

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 the national reporting system: [French] National agency for safety of medicines and healthcare products (ANSM) and network of Regional Pharmacovigilance Centres - Internet site: www.signalement-sante.gouv.fr.

4.9. Overdose

No cases of overdose have been reported. An overdose of vitamin E may lead to gastrointestinal disorders (diarrhoea, abdominal pains).

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: OTHER VITAMIN PREPARATIONS, ATC: A11HA03

(A: digestive tract and metabolism).

5.2. Pharmacokinetic properties

Distribution

In the blood, vitamin E is found almost completely bound to beta-lipoproteins.

It is distributed on all tissues; it crosses the placental barrier with difficulty (1/5).

Quinone-like metabolites (very similar to coenzyme Q) have been found in the tissues.

Elimination

70% of the dose is eliminated by the liver, the remainder is transformed mainly into glycuronide and excreted through the kidneys.

5.3. Preclinical safety data

Not completed.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Polyoxyl 35 Hydrogenated Castor Oil (CREMOPHOR EL), glycerol, phenol, water for injections.

6.2. Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3. Shelf life

3 years

After opening: the product must be used immediately.

6.4. Special precautions for storage

Store at a temperature not exceeding 25°C.

6.5. Nature and contents of container

2 mL ampoule (brown type I glass); box of 5 ampoules.

2 mL ampoule (brown type I glass); box of 6 ampoules.

2 mL ampoule (brown type I glass); box of 12 ampoules.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

PROVEPHARM
22 RUE MARC DONADILLE
13013 MARSEILLE, FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

- 34009 356 532 3 9: 2 mL in ampoule (brown glass). Box of 5 ampoules
- 34009 356 534 6 8: 2 mL in ampoule (brown glass). Box of 6 ampoules
- 34009 573 115 1 3: 2 mL in ampoule (brown glass). Box of 12 ampoules

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28/10/1997

Date of latest renewal: {DD month YYYY}

10. DATE OF REVISION OF THE TEXT

04/2019

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

GENERAL CLASSIFICATION FOR SUPPLY

List I