ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

VITAMIN A PROVEPHARM 100,000 IU /2 mL, solution for injection (I.M.)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Retinol palmitate (Vitamin A)…… 100,000 IU

in one ampoule

Excipient(s) with known effect: Polyoxyl 40 Hydrogenated Castor Oil (CREMOPHOR RH 40), sodium benzoate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection (I.M.).

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Vitamin A deficiency, when the oral route is not possible;

Digestive malabsorption of vitamin A: cystic fibrosis, hepatic cholestasis, pancreatic impairment, other malabsorptions.

Vitamin A intake during elemental enteral feeding.

4.2. Posology and method of administration

Posology

In adults: 100,000 IU per month.

Paediatric population

Children: 50,000 IU per month or 100,000 IU every 2 months, in cases of hepatic cholestasis.

Method of administration

Deep intramuscular use.

4.3. Contraindications

- Hypersensitivity to the active substance or to one of the excipients mentioned in section 6.1.
- Intestinal occlusion.

4.4. Special warnings and precautions for use

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

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

Due to the presence of benzoic acid (or sodium benzoate), this medicine can irritate the skin, eyes and mucous membranes.

Paediatric population

Due to the presence of benzoic acid (or sodium benzoate), this medicine can increase the risk of jaundice in new-borns.

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

Contraindicated combinations

+ CYCLINES

For intake of 10,000 IU/d or more: risk of intracranial hypertension.

+ RETINOIDS

Risk of symptoms suggestive of hypervitaminosis A.

4.6. Fertility, pregnancy and lactation

Pregnancy

Vitamin A is teratogenic in animals on several species.

In human, cases of foetal malformation have been reported with high doses (25,000 IU/day). However, to date, the lack of reliable epidemiological study and the low number of isolated reports prevent any definitive conclusion about the reality of this malformation risk.

Furthermore, hypovitaminosis A in pregnant women leads to malformations in children.

Consequently, VITAMIN A PROVEPHARM will only be administered during pregnancy if there is proven deficiency.

Breast-feeding

At high dose, there is a risk of overdose in new-borns. Consequently, breast-feeding is not recommended while undergoing treatment with VITAMIN A PROVEPHARM.

4.7. Effects on ability to drive and use machines

VITAMIN A PROVEPHARM has no effect on the ability to drive and use machines.4.8. Undesirable effects

The injectable VITAMIN A PROVEPHARM solution contains Polyoxyl Hydrogenated Castor Oil 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

Acute poisoning: 1,000,000 IU in adults.

The clinical symptoms are digestive and neurological:

- Nausea, vomiting, diarrhoea.
- Headaches, vertigo, vision disorders, incoordination.

At very high dose: faintness, anorexia, flaking from skin and mucous membranes.

Paediatric population

Acute poisoning: more than 100,000 IU in children

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: VITAMIN A, ATC code: A11CA01.

5.2. Pharmacokinetic properties

Distribution

The bioavailability of VITAMIN A PROVEPHARM after intramuscular injection is approximately 50%–70%.

Vitamin A is mainly stored in the liver (90%).

Elimination

Vitamin A is excreted in the faeces and urine (as derivative products).

5.3. Preclinical safety data

Not completed.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Polyoxyl 40 Hydrogenated Castor Oil (CREMOPHOR RH 40), hydrochloric acid, sodium benzoate, alpha-tocopherol, water for injections.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

18 months.

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.

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 356 530 0 0: 2 mL ampoule (brown glass); box of 5 ampoules.
- 34009 356 531 7 8: 2 mL ampoule (brown glass); box of 6 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

12/2018

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

GENERAL CLASSIFICATION FOR SUPPLY

List I