SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
A 313 50 000 IU, soft capsule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Vitamin A synthetic (concentrate of) – oily form* …… 50 000 UI
For a soft capsule of 213 mg.
*As vitamin A palmitate at 1 000 000 IU/g.
For the complete list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Soft capsule.

4. CLINICAL DATA

4.1 Therapeutic indications
Curative treatment of vitamin A deficiency.

4.2 Posology and method of administration
RESERVED FOR ADULTS AND CHILDREN OVER 8 YEARS OF AGE.
Oral use.
1 to 2 capsules daily for 10 days until reconstitution of normal hepatic stock, without extending the treatment needlessly in order to avoid a chronic intoxication (see section 4.9).
The capsules should be swallowed with a glass of water as such.

4.3 Contraindications
- Hypersensitivity to any of the components,
- Lipid absorption disorders,
- Chronic malabsorption,
- Associated therapy interfering with vitamin A absorption.

This drug is generally not recommended for use while breastfeeding (see section 4.6).

4.4 Special warnings and precautions for use
This medication contains sorbitol. Its use is not recommended in patients with fructose intolerance.
Due to the presence of sorbitol, this medication may cause a moderate laxative effect.
To avoid any overdose, it is important to consider the total doses of vitamin A in case of association of several treatments with this vitamin.

4.5 Interactions with other medicinal products and other forms of interactions
Contraindicated associations
+ CYCLINS
If intake is 10 000 IU/day or more: risk of intracranial hypertension.
+ RETINOIDS
Risk of symptoms suggestive of hypervitaminosis A.

4.6 Pregnancy and breast-feeding

Pregnancy

Vitamin A is teratogenic in animals in several species.

In humans, cases of foetal malformations have been reported. Nevertheless, the absence of reliable epidemiologic studies and the low effectiveness of isolated notifications do not provide definitive concluding of this malformation risk.

In consequence, high doses of vitamin A are to be prescribed during pregnancy only in cases of severe deficiency.

Breast-feeding

The use during pregnancy is unadvised because of the risk of overdose of the new-born.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Every undesirable effect is susceptible of being a manifestation of an overdose and has to be followed by the stop of the treatment.

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 Medicines and Health Products Safety (Ansm) and network of Regional Pharmacovigilance Centres. Web site : www.ansm.sante.fr.

4.9 Overdose

Clinical signs resulting from the excessive administration of vitamin A (doses over 150 000 IU): digestive disorders, headaches, intracranial hypertension (manifesting in the new-born by the bombing of the fontanel), papillary oedema, psychiatric disorders, irritability, convulsions, retarded general desquamation.

Clinical signs of chronic vitamin A overdose (risk of chronic intoxication with prolonged vitamin A intake at supraphysiologic doses in a non-deficient subject) : intracranial hypertension, cortical hyperostosis of long bones and premature epiphyseal closure. The diagnosis is generally based on the observations of sensitive or painful subcutaneous inflammations in the limbs extremities. Radiographies show a periosteal thickening of the diaphyseal portion of the ulna, the fibula, the clavicles and the ribs.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic class : VITAMIN A, Code ATC A11CA01
(A : digestive system and metabolism)

Vitamin A is a fat-soluble vitamin. It plays an important role in the formation of retinal purple (needed to adapt vision when light decreases), in cell multiplication and epithelial and tissue trophicity.

5.2 Pharmacokinetic properties

Gastrointestinal absorption of vitamin A in the small intestine is related to that of fats.

Hepatic storage is important (at 90%) and it is mostly in the form of retinyl esters. Vitamin A is linked to RBPP (retinol binding plasmatic protein) formed by the liver.

Elimination is through urinary and faecal routes as derivatives.

5.3 Preclinical safety data
Not documented.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Cod liver oil, gelatin, glycerol, sorbitol 70% (non-crystallising), purified water.

6.2 Incompatibilities
Not relevant.

6.3 Shelf life
2 years.

6.4 Special precautions for storage
Store at a temperature not exceeding 25 ºC and protected from light.

6.5 Nature and contents of container
Polystyrene bottle containing 30 soft capsules and closed with a low density polyethylene cap.

6.6 Special precautions for disposal and handling
No special requirements.

7. MARKETING AUTHORISATION HOLDER
PHARMA DEVELOPPEMENT
CHEMIN DE MARCY
58800 CORBIGNY - FRANCE

8 . MARKETING AUTHORISATION NUMBER (S)
- 300 006-4 or 3400930000649 :30 capsules in bottle (polystyrene).

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION
Date of first authorisation : 07/07/1997

10. DATE OF REVISION OF THE TEXT
30/04/2014

11. DOSIMETRY
Not relevant.

12.INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS
Not relevant.

PRESCRIPTION AND SUPPLY CONDITIONS
List I