SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
A 313 200 000 UI POUR CENT, ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Synthetic vitamin A (concentration of) – oily form …… 200 000 UI
For 100g of ointment.
For the complete list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Ointment.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Adjunctive treatment of irritant dermatitis.

4.2 Posology and method of administration
Apply topically 1 or 2 times per day.

4.3 Contraindications
- History of hypersensitivity to any of the components.
- Infected skin diseases.
- Oozing dermatitis.

4.4 Special warnings and precautions for use
The risk of hypervitaminosis A cannot be excluded in the case of prolonged application.
Systemic effects (risk of hypervitaminosis) are to be feared when the topical application is repeated over a large area, under occlusion or thick layer, on an injured skin (in particular burned), on a mucous membrane, a skin of a premature baby and an infant or young child due to the surface/weight ratio and the spontaneous occlusion effect due to folds and diapers.

4.5 Interactions with other medicinal products and other forms of interactions
Not relevant.

4.6 Pregnancy and breast-feeding
Pregnancy:
• Orally :
at high doses, the absence of epidemiological studies prevents a conclusion on the reality of the malformative risk. It is therefore not recommended to exceed 5000 IU per day (recommended daily intake).
• By dermal route :
The systemic passage of vitamin A from this topical form is negligible.
There are currently not enough exposed pregnancies to assess a possible effect of vitamin A administered dermally.

Therefore, the use of this drug should be considered during pregnancy only if necessary, avoiding simultaneous use of another drug containing vitamin A.

Breastfeeding:
Do not apply to the breasts while breastfeeding because of the risk of ingestion of the product by the newborn.

4.7 Effects on ability to drive and use machines
Not relevant.

4.8 Undesirable effects
Possible local allergic reaction to any of the components.
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
Systemic passage has not been studied under the abnormal conditions of use described in Section 4.4. Special warnings and precautions for use.
The appearance of signs of hypervitaminosis A (nausea, headache, dizziness, dry skin, fatigue) should lead to discontinuation of treatment.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
SKIN PROTECTION
(D. Dermatology)

5.2 Pharmacokinetic properties
Systemic passage of retinol under normal conditions of use is considered negligible.

5.3 Preclinical safety data
Not documented.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Macrogol 400, macrogol 4000, polysorbate 80.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
30 months.

6.4 Special precautions for storage
Store at a temperature not exceeding 25°C.

6.5 Nature and contents of container
50 g in tube (Aluminium coated with an epoxyphenolic internal varnish) closed with a cap (Polypropylene).

6.6 Special precautions for disposal and handling
No particular requirements.

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

8. MARKETING AUTHORISATION NUMBER (S)
- 300 014-7: 50 g in tube (Aluminium).

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION
Date of first authorisation : 12/03/1998

10. DATE OF REVISION OF THE TEXT
17/08/2009

11. DOSIMETRY
Not relevant.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS
Not relevant.

PRESCRIPTION AND SUPPLY CONDITIONS
This medicinal product is available without a prescription.