SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
DERMO-6 1,2 g/100 g, solution for skin application

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Pyridoxine hydrochloride …….…….. 1,2 g
For 100g of solution for skin application.
Alcoholic strength: 60% v/v.
For the complete list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Solution for skin application.

4. CLINICAL DATA

4.1 Therapeutic indications
Supplementary treatment for seborrheic conditions of the skin and scalp.

4.2 Posology and method of administration
Apply locally twice a day with a soaked cotton pad.

4.3 Contraindications
Hypersensitivity to any of the components.

4.4 Special warnings and precautions for use
It is preferable to use the solution on a dry scalp, as application to a damp scalp can cause tingling.

4.5 Interactions with other medicinal products and other forms of interactions
The data available to date do not suggest clinically significant interactions.

4.6 Pregnancy and breast-feeding
In view of data available, this solution can be used by pregnant and breastfeeding women. Do not apply to the breasts during breastfeeding.

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

4.8 Undesirable effects
Due to the presence of alcohol, frequent applications to the skin can cause skin irritation and dryness.

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
Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
PHARMACO-THERAPEUTIC CLASS : FOR LOCAL ANTISEBORRHEIC USE (D. DERMATOLOGY).

5.2 Pharmacokinetic properties
Not documented.

5.3 Preclinical safety data
Not documented.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Alcohol, purified water.

6.2 Incompatibilities
Not relevant.

6.3 Shelf life
3 years

6.4 Special precautions for storage
Store below 25°C.

6.5 Nature and contents of container
200 ml high-density polyethylene bottle, closed with a high density polyethylene stopper.

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)
• 302 960-7: bottle of 200 ml (polyethylene)

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION
Date of first authorisation : 28/05/1996

10. DATE OF REVISION OF THE TEXT
16/09/2011

11. DOSIMETRY

Not relevant.

12.INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not relevant.

PRESCRIPTION AND SUPPLY CONDITIONS

This medicinal product is available without a prescription.