ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

DERMOBACTER, solution for cutaneous application

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzalkonium chloride solution.....0.985 g
Quantity corresponding to benzalkonium chloride .....0.500 g

Chlorhexidine digluconate solution.....1.065 g
Quantity corresponding to chlorhexidine digluconate .....0.200 g
For 100 ml of solution for cutaneous application.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for cutaneous application.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Cleansing and adjuvant treatment of skin disorders and mucous membranes primarily of bacterial origin or liable to become suprainfected.

Note: antiseptic agents do not sterilise: they temporarily reduce the number of micro-organisms.

4.2 Posology and method of administration

Posology
The solution can be used pure or diluted once or twice a day for 7 to 10 days.

Method of administration
- Pure use: application on the skin.
- Diluted use $1/10^{th}$: application on the mucous membranes. The diluted solution must be prepared immediately before use and must not be stored.

The application should **always be followed by careful rinsing**.

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6..
- Do not apply on the eyes, ears.
- This product must not penetrate the auditory canal, particularly in case of eardrums perforation, nor, as a general rule, come into contact with nervous tissue or meninges.
- This preparation must not be used to disinfect medical or surgical equipment.

4.4 Special warnings and precautions for use

External use.

Although cutaneous resorption is very slight, the risk of systemic effects cannot be excluded. Such effects are particularly likely if the antiseptic is applied to a large surface, to a damaged skin (burnt in particular), mucous membranes or the skin of premature infant or neonate (because of the surface/weight ratio and the occlusive effect of nappies on the buttock).

Microbial contamination is possible as soon as the packaging of an antiseptic product is opened.

The use of chlorhexidine solutions, both alcohol based and aqueous, for skin antisepsis prior to invasive procedures has been associated with chemical burns in neonates. Based on available case reports and the published literature, this risk appears to be higher in preterm infants, especially those born before 32 weeks of gestation and within the first 2 weeks of life.

Remove any soaked materials, drapes or gowns before proceeding with the intervention. Do not use excessive quantities and do not allow the solution to pool in skin folds or under the patient or drip on sheets or other material in direct contact with the patient. Where occlusive dressings are to be applied to areas previously exposed to DERMOBACTER, care must be taken to ensure no excess product is present prior to application of the dressing.

4.5 Interaction with other medicinal products and other forms of interaction

Combinations not recommended
The simultaneous or successive use of anionic antiseptics should be avoided.

4.6 Fertility, pregnancy and lactation

Breast-feeding
Do not apply the solution to the breasts during breast-feeding.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Dry skin and mucosal dryness sensation , which is attenuated by careful rinsing.
Slight skin irritation during the first applications.
Possibility of contact dermatitis.
Chemical burns in neonates (frequency unknown).

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: Agence nationale de sécurité du médicament et des produits de santé (ANSM - French Health Products Safety Agency) and Regional Pharmacovigilance Centers - Website: www.ansm.sante.fr.

4.9 Overdose

No overdose case has been reported. However, an excessive use may result in an exacerbation of side effects. In addition, a systemic absorption cannot be excluded in case of extended application or under occlusive dressings.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: ANTISEPTIC (D. Dermatology), ATC Code: D08AC52.

Combination of benzalkonium chloride, quaternary ammonium and chlorhexidine digluconate, an antiseptic in the family of biguanides.

Broad-spectrum bactericidal antiseptic, active *in vitro* on Gram +, Gram – germs, as well as on *Candida Albicans*.

Rapid activity after a contact period of 1 minute.

There is only a slight loss of activity in the presence of proteins and exudate.

5.2 Pharmacokinetic properties

Absorption
Chlorhexidine and benzalkonium chloride exhibit virtually no cutaneous absorption.

5.3 Preclinical safety data

Not documented.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Betaine cocoalkyldimethyl 30% solution, poloxamer 188, hydroxyethylcellulose, citric acid monohydrate, sodium citrate, purified water.

6.2 Incompatibilities

Incompatible with anionic compounds.

6.3 Shelf life

2 years.

The diluted solution should be prepared immediately before use and must not be stored.

6.4 Special precautions for storage

Do not store above 25°C.

For storage conditions after dilution of the medicinal product, see section 6.3.

6.5 Nature and contents of container

125 ml, 300 ml or 1000 ml in bottle (brown PVC) with a stopper (white PE).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

LABORATOIRE INNOTECH INTERNATIONAL
22 AVENUE ARISTIDE BRIAND
94110 ARCUEIL

8. MARKETING AUTHORISATION NUMBER(S)

- 34009 348 407 9 1: 125 ml in bottle (PVC)
- 34009 348 408 5 2 : 300 ml in bottle (PVC)
- 34009 348 409 1 3 : 1000 ml in bottle (PVC)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 November 1998
Date of latest renewal: 19 August 2009

10. DATE OF REVISION OF THE TEXT

20 February 2018

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

GENERAL CLASSIFICATION FOR SUPPLY
Medicinal product not subject to medical prescription.