Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Derbac M Liquid 0.5% w/w cutaneous emulsion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The liquid contains 0.5% w/w Malathion.

Also contains methyl parahydroxybenzoate (E218) 0.20% w/w and propyl parahydroxybenzoate (E216) 0.08% w/w.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Emulsion.
Creamy white perfumed emulsion.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

1. For the treatment of severe infestation of the scalp or pubic with lice (T. Pediculosis).
2. For the treatment of scabies.

4.2 Posology and method of administration

For topical external use only

Adults, the elderly and children aged 6 months and over:
As this product does not contain alcohol, it may be more suitable for those with asthma or eczema.

Treatment of head lice
Rub the liquid into the scalp until all the hair and scalp is thoroughly moistened. Leave the hair to dry naturally in a warm but well ventilated room. After 12 hours, or the next day if preferred, shampoo the hair in the normal way.

Rinse the hair and comb whilst wet to remove dead lice and eggs (nits) using the Nit Comb.

Treatment should be repeated after 7 days.

Treatment of crab (pubic) lice
Apply Derbac-M Liquid to the entire skin surface. Pay particular attention to all hairy areas including beards and moustaches. Avoid any other areas above the neck. Leave on for at least one hour before washing but preferably Derbac-M Liquid should be left on overnight. Wash off in the usual manner.

Treatment should be repeated after 7 days.

Treatment of scabies
Apply Derbac-M Liquid to the entire skin surface. In adults it may not be necessary to apply above the neck but children under the age of two years should have a thin film of Derbac-M Liquid applied to the scalp, face and ears, avoiding the eyes and mouth.

Do not wash off or bathe for 24 hours. If hands or any other parts must be washed during this period, the treatment must be reapplied to those areas immediately.

Treatment should be repeated after 7 days.

No special sterilisation of clothing is necessary, ordinary laundering or dry-cleaning with hot-iron pressing are sufficient.

The infestation is cleared by the treatment. However, the itching and rash may persist for up to 7 days. An anti-irritant cream can be applied if necessary.

Family members and close contacts should also be treated simultaneously.

Children aged 6 months and under:
Under medical supervision only.

4.3 Contraindications

1. Hypersensitivity to active ingredients or excipients.
2. Not to be used on infants less than six months old except on medical advice.

4.4 Special warnings and precautions for use

1. The eyes should be well protected during the application and washing of hair.
2. Persons applying this product should wear rubber gloves so that their continued direct contact is avoided.
3. All members of the household of the patients should be treated, preferably simultaneously.
4. The source of infestation should be sought and treated.
5. This product is poisonous if ingested. If accidentally swallowed, contact your local doctor or hospital immediately.
6. Prolonged continued application should be avoided. It should not be used more than once a week and for not more than three consecutive weeks.
7. Keep out of reach of children.
8. Children under the age of 6 months should only be treated under medical supervision.
9. The lotion should not be applied to damaged skin except after medical consultation.
10. This product contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Fertility, pregnancy and lactation

No know effects in pregnancy and lactation. However, as with all medicines, use with caution.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Skin irritation and hypersensitivity reactions have been reported with malathion products. Chemical burns have also been reported.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: http://www.hpra.ie/; E-mail:medsafety@hpra.ie.

4.9 Overdose

It is most unlikely that a toxic dose of Malathion will be ingested. Treatment consists of gastric lavage, assisted respiration and, if necessary in the event of massive ingestion, administration of atropine together with pralidoxime.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Malathion, ATC code: P03AX03.

Derbac M Liquid contains malathion, a widely used organophosphorous insecticide which is active by cholinesterase inhibition. It is effective against a wide range of insects but is one of the least toxic organophosphorous insecticides since it is rapidly detoxified by plasma carboxylesterases.

5.2 Pharmacokinetic properties

Derbac-M Liquid is applied topically to the affected area.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Emulsifying wax
Potassium Citrate
Citric Acid
Perfume HT 52
Purified water

6.2 Incompatibilities

30 months.

6.3 Shelf life

Two and a half years.

6.4 Special precautions for storage

Do not store above 25^{o}C. Store the bottle in the outer carton in order to protect from light.

6.5 Nature and contents of container

Cartoned, clear or amber glass (Ph. Eur. Type III) bottles with polypropylene caps with an HDPE body, HDPE ring and a polyethylene LDPE plug containing either 50, 55, 150, 160, 200 or 210 ml of product.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

LanesHealth (Ireland) Limited
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8 MARKETING AUTHORISATION NUMBER

PA22702/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 July 1993

Date of last renewal: 13 July 2008

10 DATE OF REVISION OF THE TEXT

December 2019