

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Derbac M Liquid
Prioderm Liquid

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Malathion 0.5% w/w
Also contains methylhydroxybenzoate (E218) and propylhydroxybenzoate (E216).

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Liquid emulsion.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Eradication of head lice, pubic lice and their eggs. 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 Derbac Nit Comb.

Treatment should be repeated after 7 days.

Treatment of crab (pubic) lice

Apply Derbac-M Liquid/Prioderm 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/Prioderm 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/Prioderm 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/Prioderm 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 under 6 months:

Under medical supervision only.

4.3 Contraindications

Known sensitivity to malathion. Not to be used on infants less than 6 months except on medical advice.

4.4 Special warnings and precautions for use

Avoid contact with the eyes. For external use only. Do not use on broken or secondarily infected skin. Keep out of the reach of children. If inadvertently swallowed, a doctor or casualty department should be contacted at once.

When Derbac M Liquid/Prioderm Liquid is used by a school nurse or other health officer in the mass treatment of large numbers of children, it is advisable that protective plastic or rubber gloves be worn.

Continued prolonged treatment with this product should be avoided. It should be used not more than once a week and for not more than 3 consecutive weeks.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Fertility, Pregnancy and lactation

No known 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 such as anaphylaxis, angioedema, and swollen eyes 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 the Yellow Card Scheme website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

It is most unlikely that a toxic dose of malathion will be ingested. Treatment consists of gastric lavage, assisted by 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/Prioderm Liquid contains malathion, a widely used organophosphorus insecticide which is active by cholinesterase inhibition. It is effective against a wide range of insects, but is one of the least toxic organophosphorus insecticides since it is rapidly detoxified by plasma carboxylesterases.

5.2 Pharmacokinetic properties

None stated. Derbac M Liquid/Prioderm Liquid is applied topically to the affected area.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl hydroxybenzoate (E218)

Propyl hydroxybenzoate (E216)

Emulsifying wax
Potassium citrate
Citric acid
Perfume HT 52
Water

6.2 Incompatibilities

None stated.

6.3 Shelf life

Two and a half years unopened.

6.4 Special precautions for storage

Store at or below 25°C. Protect from light.

6.5 Nature and contents of container

Cartoned, clear or amber glass bottles with polyethylene caps with an HDPE body, HDPE ring and an LDPE plug containing either 50, 2 x 50, 55, 100, 150, 200 or 210 ml of product.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

7 MARKETING AUTHORISATION HOLDER

G R Lane Health Products Ltd.

Sisson Road

Gloucester

GL2 0GR

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 01074/0241

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

18/12/2008

10 DATE OF REVISION OF THE TEXT

06/01/2025