

Derbac M

Liquid

Malathion 0.5% Cutaneous Emulsion

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet, you may need to read it again.
- Ask your pharmacist if you need more information or advice
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 weeks.

What is in this leaflet:

1. What Derbac M Liquid is and what it is used for
2. What you need to know before you use Derbac M Liquid
3. How to use Derbac M Liquid
4. Possible side effects
5. How to store Derbac M Liquid
6. Contents of the pack and other information

1. What Derbac M Liquid is and what it is used for

Derbac M Liquid is a liquid emulsion containing the active ingredient Malathion. It is used for the eradication of head lice, pubic lice and their eggs and for the treatment of scabies in adults, the elderly and children aged 6 months and over. As Derbac M does not contain alcohol, it may be more suitable for those with asthma or eczema.

2. What you need to know before you use Derbac M Liquid

Do not use Derbac M liquid:

- If you are allergic to Malathion or any of the other ingredients of this medicine listed in section 6
- Do not use on infants less than 6 months old unless your doctor tells you to.

Warnings and Precautions:

- Prolonged or repeated use with this product should be avoided
- It should not be used more than once a week and for not more than 3 consecutive weeks
- If you are a healthcare professional treating a large number of patients, then wear protective plastic or rubber gloves
- Avoid contact with the eyes
- Use this medicine only on your skin
- Do not use on broken or secondarily infected skin
- This product should not be swallowed. If ingested, contact a doctor or hospital immediately
- This product contains methylhydroxybenzoate (E218) and propylhydroxybenzoate (E216) which may cause allergic reactions (possibly delayed)
- If you have sensitive skin, test a small area before use
- If you suffer with asthma consult a doctor or pharmacist before use

Pregnancy and Breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this product.

3. How to use Derbac M Liquid

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor if you are not sure. Should a member of your family need treatment check other members of your family for live lice with a detector comb and treat if necessary.

Adults, the elderly and children aged 6 months and over:

For treatment of head lice:

- Apply sufficient liquid to **dry** hair to ensure that no part of the scalp is left uncovered. Work into the hair spreading the liquid evenly from root to tip.
- Leave the hair to dry naturally in a warm but well ventilated room.

- After 12 hours, or the next day, if preferred, shampoo hair in the normal way.
- Rinse the hair and comb whilst wet to remove dead lice and eggs (nits) using a nit comb.
- The treatment should be repeated after 7 days.

For treatment of Crab (pubic) lice:

- Apply 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 1 hour before washing but preferably leave on overnight. Wash off in the usual manner.
- The treatment should be repeated after 7 days.

For treatment of Scabies:

- Apply to the entire skin surface
- In adults it may not be necessary to apply above the neck. If used in children under the age of 2 years, a thin film of the liquid should be applied to 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.
- The 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:

- Do not use on children under 6 months unless your doctor tells you to.

If you accidentally swallow the liquid or get it in your eyes:

Only use this medicine on your skin. Protect the eyes at all times by covering the eye area with a towel. If liquid enters the eyes, wash out with plenty of water. If accidentally swallowed, contact your doctor or pharmacist immediately.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- Skin irritation and allergic reactions have been reported, including severe allergic reactions which cause difficulty in breathing or dizziness, or swelling of the face, throat and eyes
- Chemical burns have also been reported

If you feel you are reacting badly to this medicine in any way, or notice any other side effects not listed in this leaflet, seek medical advice straight away.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. (See details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom: Yellow Card Scheme, Vigilance and Intelligence Research Group, Vigilance and Risk Management of Medicines, MHRA, 4.M, 151 Buckingham Palace Road, London SW1W 9SZ Tel: +44 (0) 800 731 6789 Website: www.mhra.gov.uk/yellowcard E-mail: yellowcard@mhra.gov.uk

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

5. How to store Derbac M Liquid

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label and carton.
- Do not store above 25°C and protect from light
- Store in the original container
- Do not throw away medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Derbac M Liquid Contains

The active substance of Derbac M Liquid is Malathion. It contains 0.5% by weight. The other ingredients in Derbac M Liquid are: methylhydroxybenzoate (E218), propylhydroxybenzoate (E216), emulsifying wax, potassium citrate, citric acid, perfume HT52 and water.

What Derbac M Liquid looks like and the contents of the pack

Derbac M Liquid is a white, creamy, perfumed liquid contained in amber glass bottles of 50 and 200ml.

Marketing Authorisation Holder and Distributer:

G R Lane Health Products Ltd., Sisson Road, Gloucester GL2 0GR, UK. Tel: +44 (0)1452 524012 Email: info@laneshealth.com

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Manufacturer:


Laboratoires Chemineau, 93 Route de Monnie, 37210 Vouvray, France

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575004 Derbac M PIL V4
Date: 15/9/17
Amends author: SM
Brief Description: MHRA changes
Size: 160mm x 210mm
Colours:  Black