



DermaX[®]

Therapeutic Shampoo

benzalkonium chloride 0.5% w/w

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, pharmacist or nurse has told you. Keep this leaflet. You may need to read it again. Ask your doctor, pharmacist or nurse if you need more information or advice. If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4. You must talk to a doctor if your skin condition is not improving or if it feels worse after 4 weeks.

In this leaflet:

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

1. WHAT DERMAL THERAPEUTIC SHAMPOO IS AND WHAT IT IS USED FOR

- Dermax Therapeutic Shampoo is a treatment for dry, scaly scalp conditions such as:
 - seborrhoeic eczema / seborrhoeic dermatitis (patches of red, scaly, itchy skin), and;
 - pityriasis capitis (severe dandruff).
- Dermax Therapeutic Shampoo is for use by **adults, the elderly and children.**
- The **active ingredient** in this product is benzalkonium chloride. It works by;
 - loosening the scales from the scalp and lifting them from the hair, and;
 - acting as a mild antiseptic to combat the micro-organisms that can make these scalp conditions worse.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE DERMAL THERAPEUTIC SHAMPOO

Do not use Dermax Therapeutic Shampoo if you are **allergic (hypersensitive)** to benzalkonium chloride or any of the other ingredients of Dermax Therapeutic Shampoo listed in section 6.

Warnings and precautions

Take special care when using this product: Keep the undiluted shampoo, and the lather, away from the eyes.

In case of irritation, or if there is no improvement after 4 weeks, or the scalp condition seems to look or feel worse, discontinue treatment and tell your doctor, pharmacist or nurse. Dermax Therapeutic Shampoo contains 5mg of sodium benzoate in each gram of shampoo. Sodium benzoate (E 211) may cause local irritation. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

Other medicines and Dermax Therapeutic Shampoo

This product is not known to affect, or to be affected by, any other medicines.

Pregnancy and breast-feeding

This product can be used during pregnancy and whilst breast-feeding. The ingredients have been in widespread use in this and similar preparations for many years, without reports of problems. However, safety trials have not been conducted.

Driving and using machinery

Using this product is not known to affect your ability to drive or use machinery.

3. HOW TO USE DERMAL THERAPEUTIC SHAMPOO

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Use Dermax Therapeutic Shampoo only to treat the scalp conditions that it is intended for.

Use as a shampoo until the scalp looks and feels better or as recommended by your doctor, pharmacist or nurse. Dermax can be used daily if required, reducing frequency of use to once or twice a week as your condition improves. Thereafter, occasional use may be necessary.

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For adults, the elderly and children:

- Wet the hair thoroughly.
- Apply a sufficient amount of shampoo to produce a rich lather (approximately a quantity the size of a fifty pence piece for short hair, adjusting up depending on length/thickness of hair).
- With the tips of the fingers, massage in thoroughly.
- Remove as much lather as possible with the hands (this is important as it will take the scales with it).
- Rinse out.
- If necessary, repeat the steps above.
- Rinse the hair thoroughly under running water, then dry as normal.

If the shampoo gets into the eyes

The product, or the lather, may cause irritation if it gets into the eyes. If it gets into the eyes, rinse with plenty of water. If rinsing one eye, take care to avoid washing product into the other eye. If irritation persists, tell your doctor or pharmacist.

If you use more Dermal Therapeutic Shampoo than you should

Do not worry if you use too much shampoo, simply rinse hair under running water and continue as instructed above.

If you forget to use Dermal Therapeutic Shampoo

Do not worry if you occasionally forget to use this product, just carry on using it when you remember.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

If there is no improvement after 4 weeks, or if your scalp condition seems to look or feel worse, discontinue use of the product and consult your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Dermal Therapeutic Shampoo can cause side effects, although not everybody gets them. This product has been specially designed for use on dry or problem skin, but in some rare cases it can cause irritant or allergic skin reactions on extremely sensitive skin. These rare effects tend to occur during or soon after the first few uses.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DERMAL THERAPEUTIC SHAMPOO

- Keep this medicine out of the sight and reach of children.
- Always replace the cap tightly after use.
- Keep the bottle in the outer carton.
- Do not store the product above 25°C.
- Do not use this medicine after the expiry date which is stated on the bottle and carton after EXP. The expiry date refers to the last day of that month.
- Do not throw away any unused medicines via wastewater or household waste. Ask your pharmacist how to throw away any of medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Dermal Therapeutic Shampoo contains:

The active ingredient is **benzalkonium chloride** (0.5% w/w).

The **other ingredients** are coconut oil, dilute hydrochloric acid, lauryldimonium hydroxypropyl hydrolysed collagen (contains phenoxyethanol and potassium sorbate), macrogol lauryl ether (4), sodium benzoate, sodium chloride, sodium lauryl ether sulfate (contains sodium hydroxide as a pH adjuster) and purified water.

What Dermal Therapeutic Shampoo looks like and contents of the pack

- The product is a clear, colourless to pale yellow viscous shampoo.
- It is available in white plastic bottles containing 250ml fitted with dispensing caps. (25ml bottles are also available to medical and allied professionals.)

The Marketing Authorisation Holder is Dermal Laboratories, Tatmore Place, Gosmore, Hitchin, Herts, SG4 7QR, UK.

The Manufacturer is Aeropak, Viking Road, Great Yarmouth, NR31 0NU, UK.

This leaflet was last revised in December 2023.

To listen to or request a copy of this leaflet in Braille, large print or audio, please call free of charge: 0800 198 5000 (UK only).

Please be ready to give the following information: Dermal Therapeutic Shampoo, 00173/0198. This is a service provided by the Royal National Institute of Blind People (RNIB).