

4head[®]

90% W/W CUTANEOUS STICK
levomenthol

Please read all of this leaflet carefully before using this product.

This medicine is available without prescription. However, you still need to use it carefully to get the best results from it. Keep this leaflet. You may need to read it again. Ask your doctor or pharmacist if you need more information or advice.

You must contact a doctor or pharmacist if your symptoms worsen or if you get lots of headaches.

If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT 4HEAD IS AND WHAT IT IS USED FOR

- 4head stick is a treatment for headaches that is applied directly to the forehead.
- The **active ingredient** in this product is levomenthol.
- When applied to the forehead the product causes local skin sensations (such as cooling or tingling) at the site of application, followed by an analgesic (painkilling) effect.

2. BEFORE YOU USE 4HEAD

Do not use this product if you are **allergic (hypersensitive)** to levomenthol or any of the other ingredients listed in section 6.

Take special care with this product:

- **Keep it away from sources of heat at all times.** The levomenthol stick may soften or even melt at high temperatures (eg in a car or in the sun on a hot day), leading to a risk of leakage or spillage. Do not attempt to use 4head if the levomenthol stick has changed shape, softened or become flaky.
- **Do not put this product in your mouth or swallow it.**
- Keep it away from your eyes.
- Do not share this product with anyone else.

Using other medicines

4head stick is not known to affect, or be affected by, any other medicines.

Pregnancy and breast-feeding

This product can be used during pregnancy and while breast-feeding. The ingredients have been in widespread use in this and similar preparations for many years, without significant adverse reports. However, safety trials have not been conducted. If you are pregnant and often have headaches, tell your midwife or doctor so that they can advise you. Severe headaches in pregnancy can be a sign of high blood pressure and you should seek urgent advice.

Driving and using machinery

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

3. HOW TO USE 4HEAD

Use only directly on the forehead. Do not swallow.

For adults, the elderly and children:

- Before use, remove both the outer cap and the small inner cap from the top of the dispenser.
- Whilst holding the upper section of the dispenser, twist the base anti-clockwise until the levomenthol stick protrudes from the top.

- Apply the stick gently across the forehead (taking care to avoid the eyes).
- After use, retract the stick into the dispenser and replace both caps.
- Reapply as and when required (unless the skin sensations become too strong).

If the product comes into contact with the eyes or mouth

The product may cause irritation if it comes into contact with the eyes or mouth. If this occurs, rinse the affected site with plenty of water. If rinsing one eye, take care to avoid washing product into the other eye. If irritation persists, seek medical attention.

If the product is accidentally swallowed, go to a hospital Accident & Emergency department straight away, taking this leaflet with you.

Symptoms can include severe tummy pain, sickness, dizziness, drowsiness, impaired co-ordination and unconsciousness. **Emergency stomach washout may be required**, as levomenthol is toxic if swallowed.

If you use too much of this product the skin sensation may become too strong. If this happens, use it less frequently or apply it over a smaller area.

4. POSSIBLE SIDE EFFECTS

Like all medicines, 4head stick can cause side effects, although not everybody gets them. In some rare cases it can cause irritant or allergic skin reactions on extremely sensitive skin. Because the product is volatile (i.e. liable to give off a small amount of vapour), in rare cases it may cause temporary, mild watering of the eyes.

Stop using this product if it feels uncomfortable. If any side effect gets serious, or if you notice any other side effect not mentioned in this leaflet, stop using this product and tell your doctor or pharmacist.

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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE 4HEAD

- Keep out of the sight and reach of children.
- Do not use 4head stick after the expiry date shown on the dispenser and on the carton. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Keep away from sources of heat.
- Always replace both caps after use.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What 4head contains

The **active ingredient** is levomenthol (90% w/w).

The other ingredients are macrogol 20000 and peppermint oil.

What 4head looks like and contents of the pack

The stick is a hard, white to off-white opaque material, with a smooth appearance. The stick is available in a dispenser containing 3.6g. Each dispenser is fitted with an inner and outer cap.

The Marketing Authorisation holder is Diomed Developments Ltd, Tatmore Place, Gosmore, Hitchin, Herts, SG4 7QR, UK.

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

The Distributor is DDD Limited, 94 Rickmansworth Road, Watford, Herts, WD18 7JJ, UK.

This Patient Information Leaflet was last revised in March 2018.

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: 4head, 00173/0193

This is a service provided by the Royal National Institute of Blind People (RNIB).