PACKAGE LEAFLET: INFORMATION FOR THE USER

Happinger BALM 0.3% w/w levomenthol ointment

Please read all of this leaflet carefully before you start 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 do not improve after 10 to 14 days. 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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I. WHAT HAPPINOSE IS AND WHAT IT IS USED FOR

- Happinose is a soothing balm for application in and around the nose to relieve congestion (blocked nose) associated with the common cold, catarrh, head colds and hay fever.
- If you wish to, you may also massage it onto the lips, throat, chest and between the shoulders.
- Happinose is suitable for use by adults, the elderly and children over
 5 years old.
- The active ingredient in this product is levomenthol.
- When inhaled, the levomenthol produces a cooling sensation in the nasal passages, helping to relieve the symptoms of congestion. The lubricating ointment base also helps to soothe irritated skin around the nose.

2. BEFORE YOU USE HAPPINOSE

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

Do not use it on children under the age of 5 years.

Take special care with this product:

- Keep the product away from the eyes.
- Wash hands after use.

Using other medicines

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 while 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 HAPPINOSE

Use it only in and around the nose, on the lips, throat, chest and between the shoulders. **Before you use this tube for the first time, open it as follows:**

Unscrew the cap, turn it upside down and use the sharp point in the top of the cap to pierce the tube membrane.

For adults:

- Blow the nose.
- Using the little finger, carefully apply **up to I cm** of Happinose in and around each nostril, and then inhale through the nose.

- You may also gently massage the ointment onto the lips, throat, chest and between the shoulders.
- Re-apply every 4 hours or as required.
- Wash hands after use.
- If your symptoms last for longer than 10 to 14 days, tell your doctor or pharmacist.

For children, 10 years and over:

Follow the above instructions for adults, but using $up\ to\ {1\!\!/}_2\ cm$ of ointment in and around each nostril.

Children, between 5 to 9 years:

Follow the above instructions for adults, but using **up to** ¼ **cm** of ointment in and around each nostril.

If the ointment accidentally gets into the eyes, it may cause irritation. If this happens, rinse the eyes 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 forget to use Happinose

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

4. POSSIBLE SIDE EFFECTS

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

In some rare cases, irritant or allergic skin reactions (involving itching, swelling and redness) may occur on extremely sensitive skin.

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

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 HAPPINOSE

- Keep out of the reach and sight of children.
- Do not use Happinose after the expiry date shown on the fold of the tube and on the carton. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Always replace the cap 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 ABOUT HAPPINOSE

What Happinose contains:

The active ingredient is levomenthol (0.3% w/w).

The **other ingredients** are cineole (eucalyptol), geranium oil, white soft paraffin, and light liquid paraffin.

What Happinose looks like and contents of the pack

The product is a translucent ointment.

The product is available in aluminium tubes containing 14 g and fitted with screw caps. 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, WDI8 7JJ, UK.

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:

Happinose Ointment, 00173/0177.

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