

iglü^{gel}

mouth ulcer treatment

lidocaine hydrochloride 0.66% w/w,
aminoacridine hydrochloride 0.05% w/w

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

Keep this leaflet. You may need to read it again. Ask your doctor, dentist or pharmacist if you need more information or advice. You must contact a doctor or dentist if your symptoms worsen or do not improve. If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor, dentist or pharmacist.

In this leaflet:

1. What Iglü Gel is and what it is used for
2. Before you use Iglü Gel
3. How to use Iglü Gel
4. Possible side effects
5. How to store Iglü Gel
6. Further information

1. WHAT IGLÜ GEL IS AND WHAT IT IS USED FOR

- Iglü Gel is a treatment for fast, effective relief of pain from common mouth ulcers, sore gums and denture rubbing.
- The product, which at first looks like a pale yellow paste, forms a smooth, flexible and adhesive protective gel coating when it becomes wet on contact with saliva inside the mouth.
- Iglü Gel is suitable for use by **adults, the elderly and children over 7 years of age**.
- The product works in three ways:
 - by forming a gel coating to protect the sensitive and delicate area of the mouth lining as it heals, and
 - by the actions of its two **active ingredients**, lidocaine hydrochloride and aminoacridine hydrochloride, which work by:
 - stopping pain (lidocaine hydrochloride is a local anaesthetic), and
 - preventing infection (aminoacridine hydrochloride is an antiseptic).

2. BEFORE YOU USE IGLÜ GEL

Do not use Iglü Gel if you are **allergic (hypersensitive)** to lidocaine hydrochloride, aminoacridine hydrochloride or any of the other ingredients of Iglü Gel listed in Section 6.

Take special care when using this product:

- Apply it sparingly.
- Keep the product away from your eyes.

Using other medicines

Iglü Gel is not known to affect, or to be affected by, any other medicines.

Pregnancy and breast-feeding

It is unclear whether this product is safe for use during pregnancy and breast-feeding. The potential risks are unknown. If in doubt, ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machinery

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

3. HOW TO USE IGLÜ GEL

Only use Iglü Gel for localised application inside the mouth for the conditions it is recommended for.

For adults, the elderly and children over 7 years of age:

- Wash your hands before and after use.
- If you are treating several ulcers, repeat steps 1 to 3 below for each one:
 1. Use a clean tissue to gently remove excess moisture/saliva from the ulcer area.
 2. Squeeze a **small** quantity of Iglü onto a clean, **dry** finger tip or cotton bud, and then apply it directly to the ulcer using a single, gentle wiping action (avoid dabbing).
 3. At first, the product may seem quite pasty and sticky, but after contact with saliva, the product will form a flexible and adhesive gel coating over and around the ulcer area.

- Re-apply the gel, following steps 1 to 3 above, as necessary for each ulcer. The aim is to keep the ulcer area(s) protected with a coating of gel. As a guide, each application should normally last for an hour or more, although, on occasions, eating or drinking may make it necessary to re-apply the gel. In some cases, Iglü may remain in place for several hours, as it has strong adhesive properties.
- Do not apply excessive amounts of the gel, and avoid applying gel to the back of the tongue and throat area.
- If you are treating sores caused by rubbing from false teeth/dentures etc, avoid using Iglü at the same time (e.g. use the gel at night or when not wearing dentures).

If the gel accidentally gets into the eyes it may cause irritation. If it gets into the eyes, rinse immediately with plenty of water and continue rinsing for 10 to 15 minutes, holding the eyelids well apart. If rinsing one eye, take care to avoid washing product into the other eye. If irritation persists, contact a doctor.

If you use too much Iglü Gel overdose of the active ingredients is unlikely to occur because of the low concentrations used and the small pack size. Overdose may make swallowing difficult due to the loss of feeling. This may increase the risk of food or drink going down the wrong way. Generalised numbness of the mouth may also lead to biting the inside of your mouth when eating. Excessive overdose may also lead to generalised side effects. If you experience any of the following, **seek urgent medical attention;** nervousness, drowsiness, breathing problems or low blood pressure.

If you occasionally forget to use Iglü Gel do not worry, just carry on using it when you remember.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Iglü Gel can cause side effects, although not everybody gets them. On rare occasions, hypersensitivity reactions to lidocaine hydrochloride and aminoacridine hydrochloride can occur, involving wheezing or shortness of breath. Seek urgent medical attention if you experience these symptoms. If you experience any other symptoms not mentioned in this leaflet, stop using the product and tell your doctor, dentist or pharmacist.

Overdose can also lead to other side effects (see section above: **If you use too much Iglü Gel**).

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 IGLÜ GEL

- Keep out of the reach and sight of children.
- Do not use Iglü Gel 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 tightly after use.
- Moisture coming into contact with the nozzle of the tube may cause the gel to thicken and block the opening. If this happens, carefully clear it using a clean pin.
- 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 Iglü Gel contains:

The **active ingredients** are lidocaine hydrochloride (0.66% w/w) and aminoacridine hydrochloride (0.05% w/w).

The **other ingredients** are carbomer, hydroxypropylcellulose, white soft paraffin, liquid paraffin and peppermint oil.

What Iglü Gel looks like and contents of the pack

- Although classified as a gel, when squeezed from the tube the product looks like a thick, pale yellow paste. It forms a flexible and adhesive gel coating when it becomes wet on contact with saliva inside the mouth.
- The product has a peppermint odour and is available in plastic tubes containing 8g.

The Marketing Authorisation holder is:

Diomed Developments Ltd, Tatmore Place, Gosmore, Hitchin, Hertfordshire, SG4 7QR, UK.

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

The Distributor is: DDD Ltd, 94 Rickmansworth Road, Watford, Hertfordshire, WD18 7JJ, UK.

This Patient Information Leaflet was last revised in June 2015.

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: Iglü Gel, 00173/0186.

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