



Mucoadhesive, malleable orthodontic brace gel

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

Keep this leaflet. You may need to read it again.

Ask your orthodontist or dentist if you need more information or advice.

You must contact your orthodontist or dentist if your symptoms worsen, do not improve, or if you notice any side effect not listed in this leaflet.

### In this leaflet:

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

### 1. WHAT IGLÜ PROTECT IS AND WHAT IT IS USED FOR

- Iglü Protect helps prevent and relieve mouth sores and ulcers caused by dental braces.
- In contact with saliva inside the mouth, Iglü Protect forms an adhesive, malleable and protective coating over and around protruding areas of dental braces to help prevent them damaging adjacent soft tissue. It also forms a coating over mouth sores and ulcers to protect damaged areas as they heal.
- Iglü Protect is suitable for use by **adults, the elderly and children over 7 years of age**.
- Iglü Protect is non-medicated. Its mouldable adhesive gel works by providing physical protection.
- It has a mild minty flavour.

### 2. BEFORE YOU USE IGLÜ PROTECT

**Do not use** Iglü Protect if you are **allergic (hypersensitive)** to any of the ingredients listed in Section 6.

**It is very important** that you tell your orthodontist or dentist if you have a mouth ulcer that lasts for more than 3 weeks or keeps coming back, particularly if there is

any doubt as to whether it was caused by your brace (i.e. is unexplained). National guidance suggests urgent referral in the case of persistent ulcers, to exclude the rare possibility of oral cancer, which can benefit from early diagnosis and treatment.

### Take special care when using this product:

- Do not apply excessive amounts.
- Keep the product away from your eyes.

### Interactions

Iglü Protect may be used at the same time as medicines. However, it is generally inadvisable to apply it at the same time as any other product used inside the mouth.

### Eating and drinking

There is no need to remove Iglü Protect before eating and drinking. However, bear in mind that it may be necessary to re-apply it afterwards and preferably after cleaning the teeth.

### Pregnancy and breast-feeding

This product can be used during pregnancy and by breast-feeding mothers. The ingredients have been in widespread use in 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 IGLÜ PROTECT

Iglü Protect is designed for personal use. Do not share it with other people. Only use Iglü Protect for localised application inside the mouth. It should be applied to problem areas of the brace, ideally after thorough tooth brushing, and/or to any sore areas or

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ulcers inside the mouth. For best results, start using at the first sign of any soreness.

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

1. Wash your hands before and after use.
2. Squeeze a suitable amount (see 3 below) onto a clean, **dry** finger tip or cotton bud, and then apply it directly to the problem area(s) of the brace and/or any sore areas inside the mouth using a single, gentle wiping action (avoid dabbing).
3. When applying it to problem area(s) of the brace, the aim is to apply enough gel to form a localised coating over and around the brace parts as well as the teeth underneath the brace and the adjacent gum or cheek area. It may take a few tries to find the right amount for you. However, care should be taken to avoid applying excessive amounts which may dislodge and feel uncomfortable.
4. At first, the product may seem quite pasty and sticky, but after wetting with saliva, it will form a thick, adhesive and malleable gel. You may find it helpful to use the tip of your tongue to gently form it into a smooth coating over any protruding parts of the brace.
5. Re-apply as required to keep the problem area(s) protected with a smooth coating. As a guide, each application may remain in place for up to several hours unless removed by eating, drinking or brushing, in which case the product is best re-applied after brushing the teeth/braces. If necessary, repeat applications can be made between cleaning sessions.
6. Do not apply to the back of the tongue and throat area.
7. Carry on using the product in this way until you can see your orthodontist or dentist.
8. Iglü Protect is not intended for more than a few days' continuous use. If your condition does not improve, or you think your brace has been damaged or needs adjusting, see your orthodontist or dentist.

### **If the gel accidentally 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 Protect**

It may feel unpleasant in the mouth. If this occurs, the product can easily be removed from the teeth and brace by ordinary cleaning with a

toothbrush. Any excess attached to the soft lining of the mouth will slowly disperse by itself. If you have any further questions on the use of this product, ask your orthodontist or dentist.

## **4. POSSIBLE SIDE EFFECTS**

As for all products, side effects can occur although not everybody gets them. Some people may dislike the feel or texture of the product inside the mouth. If you experience any undesirable effects, stop using the product and if you have any concerns, tell your orthodontist or dentist.

## **5. HOW TO STORE IGLÜ PROTECT**

- Keep out of the sight and reach of children, particularly young children because the cap may pose a choking hazard.
- Do not use Iglü Protect after the use by date shown on the seal of the tube and on the carton. The use by 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 product to thicken and block the opening. If this happens, carefully clear it using a clean pin.

## **6. FURTHER INFORMATION**

### **What Iglü Protect contains:**

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

### **What Iglü Protect looks like and contents of the pack**

- When squeezed from the tube the product looks like a thick white or off-white paste. It forms a mouldable, flexible and adhesive gel coating when it becomes wet on contact with saliva inside the mouth.
- The product has a mild minty flavour and is available in plastic tubes containing 10 g.

### **Iglü Protect is distributed by**

DDD Ltd, Watford, Herts, WD18 7JJ, UK, for  Diomed Developments Ltd, Hitchin, Herts, SG4 7QR, UK, owners of 'Iglü' Registered Trademark.

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Consult Instructions for Use



Batch Code



Use-by Date



Manufacturer

