IGLÜ RAPID RELIEF GEL
(lidocaine hydrochloride, aminoacridine hydrochloride)

PL 00173/0406

UKPAR

TABLE OF CONTENTS

IGLÜ RAPID RELIEF GEL
(lidocaine hydrochloride, aminoacridine hydrochloride)

PL 00173/0406

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Diomed Developments Limited a Marketing Authorisation (licence) for the medicinal product Iglu Rapid Relief Gel (PL 00173/0406) on 27th May 2009. This is a medicine available on the General Sales List (GSL), and can be purchased at pharmacies, supermarkets and other retail outlets without the supervision of a pharmacist.

Iglu Rapid Relief Gel contains two active ingredients; lidocaine hydrochloride (a local anaesthetic) and aminoacridine hydrochloride (an antiseptic).

Iglu Rapid Relief Gel is a treatment for fast, effective relief of pain from common mouth ulcers, sore gums and denture rubbing. The product is a pale yellow paste, which forms a smooth, flexible and adhesive protective gel coating when it becomes wet on contact with saliva inside the mouth. The product works by forming a gel coating to protect the sensitive and delicate area of the mouth lining as it heals. Iglu Rapid Relief Gel also works by stopping pain (through the action of lidocaine hydrochloride) and by preventing infection (through the action of aminoacridine hydrochloride).

This application is a duplicate of a previously granted application for Iglu Gel (PL 00173/0186), held by Diomed Developments Limited, and authorised on 7th March 2001. The test and reference products are identical.

No new or unexpected safety concerns arose from this application and it was therefore judged that the benefits of using Iglu Rapid Relief Gel outweigh the risk; hence a Marketing Authorisation has been granted.

IGLÜ RAPID RELIEF GEL
(lidocaine hydrochloride, aminoacridine hydrochloride)

PL 00173/0406

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted Diomed Developments Limited a Marketing Authorisation for the medicinal product Iglu Rapid Relief Gel (PL 00173/0406) on 27th May 2009. The product is available through general supply (GSL).

This application was submitted as a simple abridged 'informed consent' application according to article 10c of Directive 2001/83/EC (as amended), cross-referring to Iglu Gel (PL 00173/0186, Diomed Developments Limited, authorised 7th March 2001). The originator product is Medijel Gel (PL 00133/5000R, D D D Limited, authorised 14th April 1989).

Iglu Rapid Relief Gel is indicated for fast, effective relief from the pain of common mouth ulcers, soreness of gums and denture rubbing.

The product is strongly mucoadhesive, thereby localising the active ingredients in a depot over the site(s) of application and forming a physical barrier to protect the sensitive and delicate underlying lesion as it heals. Iglu Rapid Relief Gel contains the active ingredients, lidocaine hydrochloride and aminoacridine hydrochloride.

Applied topically to mucous membranes, lidocaine hydrochloride produces rapid, local and superficial anaesthesia which lasts for up to 30 minutes. Its mode of action is to prevent initiation of nerve impulses. Aminoacridine hydrochloride acts as a broad spectrum antiseptic by disrupting microbial metabolic pathways.

The active ingredients are readily absorbed through mucous membranes. Both are rapidly metabolised, even when swallowed. This, and the low doses involved, means that systemic effects are very unlikely.

No new data were submitted nor was it necessary for this simple application, as the data are identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no PAR was generated for it.

PHARMACEUTICAL ASSESSMENT

LICENCE NUMBER:	PL 00173/0406
PROPRIETARY NAME:	Iglu Rapid Relief Gel
ACTIVE INGREDIENT/S:	lidocaine hydrochloride & aminoacridine hydrochloride
COMPANY NAME:	Diomed Developments Limited
E.C. ARTICLE:	Article 10c of Directive 2001/83/EC (as amended)
LEGAL STATUS:	GSL

1. INTRODUCTION

This is a simple abridged application, submitted under Article 10c of Directive 2001/83/EC (as amended) for Iglu Rapid Relief Gel. The proposed MA holder is 'Diomed Developments Ltd., T/A Dermal Laboratories, Tatmore Place, Gosmore, Hitchin, Herts SG4 7QR'.

The reference product is Iglu Gel (PL 00173/0186), held by Diomed Developments Ltd. The test and reference products are identical.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The approved name of the product is Iglu Rapid Relief Gel. The product name is acceptable.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

Iglu Rapid Relief Gel is for local topical use and contains the active ingredients lidocaine hydrochloride 0.66% and aminoacridine hydrochloride 0.05%. Each 1g of gel contains 6.6 mg of lidocaine hydrochloride and 0.5 mg aminoacridine hydrochloride. The finished product is marketed in 3 different types of tube of size 8g, which are fitted with screw caps (tubes and caps are described in the SmPC). The tubes are packaged with the Patient Information Leaflet (PIL) into cardboard outer cartons.

The approved shelf-life (3 years) and storage conditions ('Do not store above 25^{o}C') are consistent with the details registered for the cross-reference product.

2.3 Legal status

The product is a GSL licensed medicine, available by supply through pharmacies, supermarkets and other retail outlets without the need for supervision by a pharmacist.

2.4 Marketing authorisation holder / Contact Persons / Company

The proposed Marketing Authorisation holder is 'Diomed Developments Ltd., T/A Dermal Laboratories, Tatmore Place, Gosmore, Hitchin, Herts SG4 7QR'.

The QP responsible for pharmacovigilance was stated and their CV included.

2.5 Manufacturers

The proposed manufacturing site is consistent with that registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition

The proposed composition is consistent with the details registered for the cross-reference product.

2.7 Manufacturing process

The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

2.8 Finished product / shelf-life specification

The proposed finished product specification is in line with the details registered for the cross-reference product.

2.9 Drug substance specification

The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance

No materials of animal or human origin are included in the product.

3. EXPERT REPORTS

Satisfactory expert reports and curriculum vitae of experts were provided.

4. PRODUCT NAME & APPEARANCE

See 2.1 for details of the proposed product name. The appearance of the product (soft, pale yellow, slightly opalescent oromucosal gel) is consistent with that of the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The approved SmPC is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL) / CARTON

PIL

The patient information leaflet has been prepared in the user tested format and in line with the details registered for the cross-reference product. The approved PIL is satisfactory.

Labelling

Colour mock-ups of the labelling have been provided and are satisfactory. The approved artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements.

7. CONCLUSIONS

The grounds for this application are considered adequate. A Marketing Authorisation was, therefore, granted.

PRECLINICAL ASSESSMENT

This abridged application was submitted as a simple abridged application according to article 10c of Directive 2001/83/EC (as amended).

No new preclinical data have been supplied with this application and none are required for an application of this type. A preclinical expert report has been written by a suitably qualified person and is satisfactory.

CLINICAL ASSESSMENT

This abridged application was submitted as a simple abridged application according to article 10c of Directive 2001/83/EC (as amended).

As this is a duplicate application for PL 00173/0186, no new clinical data have been supplied with the application, and none are required for applications of this type. A clinical expert report has been written by a suitably qualified person and is satisfactory.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for this application are consistent with that previously assessed for the cross-reference product and as such have been judged to be satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type.

EFFICACY

Medicinal products containing the active ingredients; lidocaine hydrochloride and aminoacridine hydrochloride, in a combined formulation, have been available in the UK for much more than ten years. Their use is well established with recognised efficacy and acceptable safety.

This application is identical to the previously granted application for Iglu Gel (PL 00173/0186, Diomed Developments Limited).

No new or unexpected safety concerns arise from this application.

PRODUCT LITERATURE

The approved SmPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The testing shows that patients/users are able to act upon the information that the leaflet contains.

Colour mock-ups of the labelling have been provided and are satisfactory. The approved labelling artwork complies with statutory requirements.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant’s product is identical to the cross-reference product. Extensive clinical experience with lidocaine hydrochloride / aminoacridine hydrochloride combination products is considered to have demonstrated the therapeutic value of this product. The risk: benefit is, therefore, considered to be positive.

IGLÜ RAPID RELIEF GEL

(lidocaine hydrochloride, aminoacridine hydrochloride)

PL 00173/0406

STEPS TAKEN FOR ASSESSMENT

1 The MHRA received the marketing authorisation application on 11th February 2009

2 Following standard checks and communication with the applicant the MHRA considered the application valid on 16th February 2009

3 The application was determined on 27th May 2009

IGLÜ RAPID RELIEF GEL
(lidocaine hydrochloride, aminoacridine hydrochloride)

PL 00173/0406

STEPS TAKEN AFTER AUTHORISATION

Not applicable

SUMMARY OF PRODUCT CHARACTERISTICS

The UK Summary of Product Characteristics (SmPC) for Iglu Rapid Relief Gel is as follows:

1 NAME OF THE MEDICINAL PRODUCT

Iglu Rapid Relief Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lidocaine Hydrochloride 0.66%w/w
Aminoacridine Hydrochloride 0.05%w/w.

For full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM

Oromucosal Gel
Soft, pale yellow, slightly opalescent oromucosal gel.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For fast, effective relief from the pain of common mouth ulcers, soreness of gums and denture rubbing.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

For use in the mouth.

For adults, children and the elderly.

Apply sparingly, directly to the affected area(s) with a clean finger tip or a cotton wool bud. Re-apply as necessary – the aim being to keep the affected area(s) protected with a thin layer of gel. As a guide, each application should normally last for an hour or more, although eating and/or drinking may necessitate more frequent re-application. In some cases, applications may remain in place for several hours.

4.3 CONTRAINDICATIONS

Do not use in cases of known sensitivity to lidocaine hydrochloride (or other local anaesthetics of the amide-type), aminoacridine hydrochloride or any of the other ingredients.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Keep the product away from the eyes. In case of accidental contact, wash eye immediately with water: keep rinsing for 10 to 15 minutes, holding the eyelids well apart and avoid getting the rinse liquid into the other eye. Consult a doctor if irritation persists.

If symptoms persist consult your doctor or dentist.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

None known.

4.6 PREGNANCY AND LACTATION

Animal studies are insufficient with respect to effects on pregnancy and lactation (see section 5.3). The potential risk for humans is unknown.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

None stated.

4.8 UNDESIRABLE EFFECTS

Rare instances of hypersensitivity reactions to lidocaine and aminoacridine have been reported.

4.9 OVERDOSE

Overdosage is unlikely to be a problem because of the low formulated concentrations. Severe overdosage (e.g. if a large quantity is swallowed) may impair swallowing and this enhances the risk of aspiration. Likewise, generalised numbness of the tongue or buccal membranes may lead to biting trauma when eating. Systemic adverse reactions to excessive overdosage include excitory and depressant effects on the CNS and depressant cardiovascular reactions. Emergency treatment of such systemic side effects should be directed to assuring adequate ventilation and averting convulsions. In the meantime, use of this product should be discontinued.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

ATC code: A01AD, other agents for local oral treatment.
The product is strongly mucoadhesive, thereby localising the active ingredients in a depot over the site(s) of application and forming a physical barrier to protect the sensitive and delicate underlying lesion as it heals.

Applied topically to mucous membranes, lidocaine hydrochloride produces rapid, local and superficial anaesthesia which lasts for up to 30 minutes. Its mode of action is to prevent initiation of nerve impulses.

Aminoacridine hydrochloride acts as a broad spectrum antiseptic by disrupting microbial metabolic pathways.

5.2 PHARMACOKINETIC PROPERTIES

The active ingredients are readily absorbed through mucous membranes. Both are rapidly metabolised, even when swallowed. This, and the low doses involved, means that systemic effects are very unlikely.

5.3 PRECLINICAL SAFETY DATA

There are no preclinical data of relevance, which are additional to those already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Carbomer
Hydroxypropylcellulose (E463)
White Soft Paraffin
Liquid Paraffin
Peppermint Oil

6.2 INCOMPATIBILITIES

None encountered.

6.3 SHELF LIFE

36 months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Do not store above 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER

1) 8 g high density polyethylene (HDPE) tube with HDPE/linear low density polyethylene (LLDPE) nozzle and polypropylene cap

2) 8 g co-extruded HDPE laminate tube with inclined HDPE nozzle and polypropylene cap.

3) 8 g enamelled, internally lacquered, aluminium tube with membrane seal and spiked polyethylene screw cap

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Diomed Developments Ltd.
T/A Dermal Laboratories
Tatmore Place
Gosmore
Hitchin
Herts
SG4 7QR

8 MARKETING AUTHORISATION NUMBER(S)

PL 00173/0406

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27/05/2009

10 DATE OF REVISION OF THE TEXT

27/05/2009

PRODUCT INFORMATION LEAFLET

PACKAGE LEAFLET Information for the user

iglü® rapid relief 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 RAPID RELIEF GEL IS AND WHAT IT IS USED FOR

- Iglü Rapid Relief 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 Rapid Relief Gel is suitable for use by **adults, the elderly and children (excluding infants and babies).**
- 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 RAPID RELIEF GEL

Do not use Iglü Rapid Relief Gel if you are **allergic (hypersensitive)** to lidocaine hydrochloride, aminoacridine hydrochloride or any of the other ingredients of Iglü Rapid Relief 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 Rapid Relief 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 RAPID RELIEF GEL

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

For adults, the elderly and children (excluding infants and babies):

- 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 Rapid Relief Gel 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)

ED10/09/3

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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 Rapid Relief Gel may remain in place for several hours, as it has strong adhesive properties.

- Do not apply excessive amounts of the gel.
- If you are treating sores caused by rubbing from false teeth/dentures etc, avoid using Iglü Rapid Relief Gel 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 Rapid Relief Gel it is unlikely to be a problem because of the low concentration of the active ingredients 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 Rapid Relief 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 Rapid Relief 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.

If your symptoms persist, tell your doctor, dentist or pharmacist.

Overdose can also lead to other side effects (see **If you use too much Iglü Rapid Relief Gel** in Section 3).

5. HOW TO STORE IGLÜ RAPID RELIEF GEL

- Keep out of the reach and sight of children.
- Do not use Iglü Rapid Relief 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 waste water 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 Rapid Relief 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 Rapid Relief 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, fitted with nozzles and caps.

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 approved in February 2009.

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 Rapid Relief Gel, 00173/0406.

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

ED10/09/3

Alternative PIL (identical apart from manufacturer details)

PACKAGE LEAFLET Information for the user

iglü® rapid relief 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 RAPID RELIEF GEL IS AND WHAT IT IS USED FOR

- Iglü Rapid Relief 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 Rapid Relief Gel is suitable for use by **adults, the elderly and children (excluding infants and babies).**
- 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 RAPID RELIEF GEL

Do not use Iglü Rapid Relief Gel if you are **allergic (hypersensitive)** to lidocaine hydrochloride, aminoacridine hydrochloride or any of the other ingredients of Iglü Rapid Relief 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 Rapid Relief 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 RAPID RELIEF GEL

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

For adults, the elderly and children (excluding infants and babies):

- 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 Rapid Relief Gel 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)

ED10T-4

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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 Rapid Relief Gel may remain in place for several hours, as it has strong adhesive properties.

- Do not apply excessive amounts of the gel.
- If you are treating sores caused by rubbing from false teeth/dentures etc, avoid using Iglü Rapid Relief Gel 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 Rapid Relief Gel it is unlikely to be a problem because of the low concentration of the active ingredients 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 Rapid Relief 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 Rapid Relief 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.

If your symptoms persist, tell your doctor, dentist or pharmacist.

Overdose can also lead to other side effects (see **If you use too much Iglü Rapid Relief Gel** in Section 3).

5. HOW TO STORE IGLÜ RAPID RELIEF GEL

- Keep out of the reach and sight of children.
- Do not use Iglü Rapid Relief 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 waste water 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 Rapid Relief 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 Rapid Relief 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, fitted with nozzles and caps.

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

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

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Please be ready to give the following information: Iglü Rapid Relief Gel, 00173/0406.

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

ED10T-4

LABELLING

Tube carton

Tube label

For fast, effective relief of pain from common mouth ulcers, sore gums and denture rubbing

Directions: For use in the mouth. For full details, please read and retain the accompanying patient information leaflet.

Distributed by DDD Ltd, Watford, Herts, WD18 7JJ, UK,
on behalf of 'iglü' Registered Trademark and Product Licence holder,
Diomed Developments Ltd, Hitchin, Herts, SG4 7QR, UK.

Batch No. and Expiry Date on crimp

ED7/09/1
PL 00173/0406

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