

DIOMED WART GEL
PL 00173/0401

UKPAR

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DIOMED WART GEL
PL 00173/0401

LAY SUMMARY

The MHRA granted Diomed Developments Limited a Marketing Authorisation for the medicinal product Diomed Wart Gel (PL 00173/0410) on 19th January 2009. This pharmacy-only medicine (P) is used to treat warts, verrucas, corns and calluses.

The active ingredients, salicylic acid and lactic acid, are well-established substances. In combination, they are routinely used in the treatment of warts, verrucas, corns and calluses. When applied onto the skin the salicylic acid acts by achieving a slow, painless destruction of the thickened upper layer of skin. The other active ingredient, lactic acid enhances the activity of salicylic acid as well as having antiseptic properties.

This application is identical to a previously granted application for Salatac Gel (PL 00173/0046, granted to the same marketing authorisation holder), approved on 23rd February 1989.

No new or unexpected safety concerns arose from this simple application and it was, therefore, judged that the benefits of applying Diomed Wart Gel outweigh the risks; hence a Marketing Authorisation has been granted.

**DIOMED WART GEL
PL 00173/0401**

SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Diomed Wart Gel (PL 00173/0401) to Diomed Developments Limited on 19th January 2009. The product is a pharmacy-only medicine.

The application was submitted as a simple abridged application according to Article 10c of Directive 2001/83/EC, cross-referring to the originator product Salatac Gel (Diomed Developments Limited, PL 00173/0046), approved on 23rd February 1989.

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 Public Assessment Report (PAR) has been generated for it.

The product contains the active ingredients salicylic acid and lactic acid which are used to treat warts, verrucas, corns and calluses.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 00173/0401

PROPRIETARY NAME: Diomed Wart Gel

ACTIVE(S): Salicylic acid, lactic acid

COMPANY NAME: Diomed Developments Limited

E.C. ARTICLE: Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC

LEGAL STATUS: P

1. INTRODUCTION

This is a simple, informed consent application for Diomed Wart Gel submitted under Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC. The proposed MA holder is Diomed Developments Limited, Tatmore Place, Gosmore, Hitchin, Herts, SG4 7QR, UK.

The application cross-refers to Salatac Gel, approved on 23rd February 1989 to the same marketing authorisation holder Diomed Developments Limited. The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed name of the product is Diomed Wart Gel. The product has been named in line with current requirements.

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

The product contains salicylic acid 12% w/w and lactic acid 4% w/w. It is to be stored in 5 g and 8 g membrane sealed, epoxy resin-lined, collapsible aluminium tubes with flower pot cap and/or HDPE nozzle applicator and overcap, as appropriate. The proposed shelf-life (36 months in an unopened container) and storage conditions (“Highly flammable- keep away from flames. Do not store above 25°C.”) are consistent with the details registered for the cross-reference product.

2.3 Legal status

On approval, the product will be available as Pharmacy-only medicines (P).

2.4 Marketing authorisation holder/Contact Persons/Company

Diomed Developments Limited, Tatmore Place, Gosmore, Hitchin, Herts, SG4 7QR, UK.

The QP responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers

The proposed manufacturing sites are consistent with those 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. This is consistent with the cross-reference product.

3. EXPERT REPORTS

The applicant has included detailed expert reports in Module 2 of the application. Signed declarations and copies of the experts' CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE

See 2.1 for details of the proposed product name. The appearance of the product is identical to the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS

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

6. PATIENT INFORMATION LEAFLET/CARTON

PIL

The patient information leaflet has been prepared in-line with the details registered 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 test shows that the patients/users are able to act upon the information that it contains.

Carton

The proposed artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation the applicant has also included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS

The data submitted with the application are acceptable. A Marketing Authorisation should be granted.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.

CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for an application of this type.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

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

PRECLINICAL

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

EFFICACY

Salicylic acid and lactic acid are well known drugs and have been routinely used in the treatment of warts, verrucas, corns and calluses for many years. This application is identical to previously granted application for Salatac Gel (PL 00173/0046).

No new or unexpected safety concerns arise from this application.

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

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 salicylic acid and lactic acid is considered to have demonstrated the therapeutic value of the product. The risk benefit is therefore considered to be positive.

DIOMED WART GEL
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STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation application on 19 th December 2007.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 14 th January 2008.
3	Following assessment of the application the MHRA requested further information relating to the quality dossier on 28 th October 2008.
4	The applicant responded to the MHRA's requests, providing further information on 17 th November 2008.
5	The application was determined on 19 th January 2009.

**DIOMED WART GEL
PL 00173/0401**

STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome

DIOMED WART GEL
PL 00173/0401

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Diomed Wart Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Salicylic Acid 12.0% w/w

Lactic Acid 4.0% w/w

For full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Gel

Clear, colourless, collodion-like wart GEL

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the topical treatment of warts, verrucas, corns and calluses.

4.2 Posology and method of administration

For adults, children and the elderly. For cutaneous use only.

Diomed Wart Gel should be applied once daily. The gel should be applied once every night.

Treatment can take up to twelve (12) weeks for resistant lesions to disappear, and it is necessary to persevere with the treatment.

1. Every night, soak the affected site in warm water for 2 to 3 minutes.
2. Dry thoroughly with the patient's own towel.
3. Carefully apply one or two drops of the gel to the lesion and allow to dry over its surface. Take care to avoid spreading on to surrounding normal skin. No adhesive plaster is necessary.
4. The following evening, carefully remove and discard the elastic film formed from the previous application, and reapply the gel. Occasionally, if removal of the elastic film proves difficult, carefully reapply the gel directly over it and allow to dry. This should help thicken the film to assist removal. If necessary, such re-application may be made on two or three successive days.
5. Once a week, gently rub away the treated surface using an emery board, as provided, or pumice stone used only for this purpose, before re-applying the gel.
6. The wart, verruca, corn or callus may take up to twelve (12) weeks to disappear and it is important to persevere with the treatment.
7. At the end of treatment, if the elastic film is difficult to remove, it may be allowed to remain on the skin until it sheds.

4.3 Contraindications

Not to be used on or near the face, intertriginous or anogenital regions, or by diabetics or individuals with impaired peripheral blood circulation.

Not to be used on moles or on any other skin lesions for which the gel is not indicated.

Not to be used in cases of sensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Keep away from the eyes, mucous membranes and from cuts and grazes.

The gel should be applied carefully to the wart, verruca, corn or callus only, to avoid possible irritation of surrounding normal skin.

Do not use excessively.

Some mild, transient irritation may be expected, but in cases of more severe or persistent pain/irritation, the treatment should be suspended and/or discontinued. See also Section 4.8.

Avoid inhaling vapour, and keep cap firmly closed when not in use.

Contact with clothing, fabrics, plastics and other materials may cause damage, and should be avoided.

For external use only.

Keep all medicines out of the reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Pregnancy and lactation

No special precautions

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Diomed Wart Gel may be irritant in certain patients, which in rare instances may appear as a temporary blemish on the skin. See also Section 4.4.

4.9 Overdose

Any excessive use of the product could cause irritation of the skin. If this occurs, the gel should be used more sparingly or applied less frequently.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The active ingredients, salicylic acid and lactic acid, are well-established pharmacopoeial substances. In combination, they are routinely used in the treatment of warts, verrucas, corns and calluses for their keratolytic properties.

When applied topically, and in high enough concentrations, salicylic acid acts by achieving a slow, painless destruction of the thickened stratum corneum. It softens and destroys the stratum corneum of the affected tissue by reducing the adhesiveness of the corneocytes while causing the cornified epithelium to swell, soften, macerate and finally desquamate. In the treatment of warts, a mild irritant reaction, which may render the virus more prone to immunologic stimulation or response, may add to the mechanical removal of infected cells. The other active ingredient, lactic acid, enhances the availability of the salicylic acid from the dried collodion, in addition to having antiseptic and caustic properties.

5.2 Pharmacokinetic properties

The product presents 12% salicylic acid and 4% lactic acid in an evaporative collodion-like gel which forms a cohesive and adhesive film on the skin.

The formulation is presented in a collapsible aluminium tube fitted with a special applicator nozzle allowing the formulation to be dispensed precisely to the affected areas only. This minimises the spread of the preparation onto the surrounding healthy skin, which could otherwise lead to inflammation, irritation and poor patient compliance.

The film-forming characteristics of the collodion-like gel vehicle also offer distinct advantages in clinical usage. The gel quickly forms a surface film, well before it dries completely, thereby

prolonging the period during which the keratolytic solution can properly infiltrate and achieve intimate contact with the surface layers of the thickened stratum corneum.

Furthermore, even when the film appears to have dried completely, the inclusion of the non-evaporative lactic acid ensures that a proportion of the salicylic acid remains in solution within the vehicle, thus permitting continued release of the keratolytic, which may otherwise be entrapped within the collodion-like film.

Systemic absorption of salicylic acid or lactic acid after application of the recommended daily dose of one or two drops of the preparation to small, circumscribed areas is exceedingly unlikely.

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Camphor

Pyroxylin

Ethanol (96%)

Ethyl Acetate

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months in unopened container

6.4 Special precautions for storage

Highly flammable - keep away from flames.

Do not store above 25°C.

6.5 Nature and contents of container

5 g and 8 g membrane sealed, epoxy resin-lined, collapsible aluminium tubes with flower pot cap and/or HDPE nozzle applicator and overcap, as appropriate.

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Diomed Developments Limited

T/A Dermal Laboratories

Tatmore Place, Gosmore

Hitchin, Herts, SG4 7QR, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00173/0401

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

DIOMED WART GEL

PL 00173/0401

PATIENT INFORMATION LEAFLET

PACKAGE LEAFLET *Information for the user*

Diomed™ Wart Gel

12.0% w/w salicylic acid, 4.0% w/w lactic acid, gel

Please read all of this leaflet carefully before you start using this product.
Keep this leaflet. You may need to read it again.

Ask your doctor or pharmacist if you need more information or advice.

In this leaflet:

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

1. WHAT DIOMED WART GEL IS AND WHAT IT IS USED FOR

- Diomed Wart Gel is a treatment for warts, verrucas, corns and calluses.
 - **Warts and verrucas** are small excessive growths of skin caused by a type of virus. Warts often occur on the fingers, or on the back of the hands. You can recognise the common wart by the rough "cauliflower-like" appearance of the surface. Verrucas occur only on the sole of the foot. They can be painful, and often look like a small white ring of skin with a black dot in the centre. The virus is very infectious. This means that warts and verrucas can grow and spread, particularly if left untreated. The virus can also be transferred from one person to another.
 - **Corns and calluses** are hard, thick pads of skin caused by pressure and friction. They usually occur on the feet due to poorly fitting shoes. They can also occur on the hands.
- Diomed Wart Gel is suitable for use by **adults, children and the elderly**.
- The **active ingredients** in this product are salicylic acid and lactic acid.
- The active ingredients work by:
 - softening the hard skin growth, making it easier to remove with a pumice stone or emery board;
 - they also help kill the virus that causes warts and verrucas.

2. BEFORE YOU USE DIOMED WART GEL

Do not use Diomed Wart Gel if you are allergic (hypersensitive) to salicylic acid, lactic acid or any of the other ingredients of Diomed Wart Gel listed in Section 6.

- Do not use the gel anywhere on or near your face, armpits, breasts, bottom or genital (sex) area.
- Do not use the gel on birthmarks, moles, warts with hairs growing from them, or any other spots.
- Do not use the gel if you are diabetic or suffer from poor blood circulation to your hands or feet.

Take special care when using this product:

- If you are unsure whether you have a wart, verruca, corn or callus that is suitable for treatment with Diomed, ask your doctor or pharmacist before starting treatment.
- Apply the gel **carefully**, to the wart, verruca, corn or callus **only**, by squeezing the tube **very gently**.

- take care **not** to apply the gel to surrounding healthy skin, especially on young children's delicate skin, because this may cause irritation;
- do not apply excessive amounts of gel.
- Keep the gel away from your eyes, nose, and mouth, and from broken skin, cuts and grazes.
- **Avoid spillage** as this may cause damage to you, your clothing and your possessions (see Section 4):
 - do not fold the tube because this may damage it and make it leak.
- The product is volatile and highly flammable. Do not use it near flames or ignition sources (eg burning cigarettes or anything else that might ignite it).
- Avoid inhaling the vapour from the gel.

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 DIOMED WART GEL

Use it only on warts, verrucas, corns and calluses on sites for which it is recommended.

Before you use this tube of gel for the first time, open it as follows:

- Find a suitable surface, in case of accidental spillage.
- Hold the tube upright, with the cap uppermost and the base resting on a suitable surface.



- Unscrew and remove the combined white nozzle/cap assembly from the tube.
- Remove the red collar and throw it away.
- Keep the tube upright for 30 seconds.
- Then, without squeezing or over-gripping the tube, and with it still held upright and away from your face:
 - replace the white nozzle/cap assembly onto the screw thread of the tube (taking care to avoid "cross-threading");
 - tighten the nozzle/cap assembly firmly to pierce the top of the tube;
 - briefly loosen the cap (to release any slight pressure in the tube) and then retighten.
- Please note that once in place, a small gap will remain between the base of the nozzle/cap and the top of the tube.

continued...

To use the gel (adults, children and the elderly): Follow these steps **once every day**, usually in the evening. Carry on using the gel in this way until the wart, verruca, corn or callus disappears:

- A. Soak the affected area in warm water for 2 to 3 minutes.
- B. Dry the area thoroughly, using your own towel if you have a wart or verruca (this will help stop the infection spreading to other people).
- C. Taking care to avoid squeezing the tube, remove the protective cap, leaving the nozzle attached to the tube.



- D. **Carefully** apply a thin coating (one or two drops) of the gel to the top of the wart, verruca, corn or callus **only**:
 - avoid the gel spreading to the surrounding healthy skin;
 - allow the gel to dry for a few minutes to form a small white patch that sticks to the treated area and is water resistant;
 - there is no need to cover the treated area with a sticking plaster;
 - always replace the protective cap after use.

- E. **The next evening**, carefully peel or pick off the white patch of dried gel from the wart, verruca, corn or callus:
 - apply fresh gel as described above;
 - if removal of the white patch is difficult, carefully re-apply the gel directly over it and leave it to dry. This will thicken the white patch and make it easier to remove.

- F. **Once every week**, before applying fresh gel, **gently** rub the wart, verruca, corn or callus with the emery board provided, or a pumice stone:
 - if you are treating a wart or verruca, **do not let anyone else use the emery board or pumice stone as the infection may spread to them.**

- G. The length of treatment will vary depending on the size and resistance of the wart, verruca, corn or callus:
 - some may go in a relatively short time;
 - some warts and verrucas can require up to 12 weeks treatment before they disappear;
 - it is important that you do not give up on the treatment until the wart, verruca, corn or callus has disappeared (unless irritation occurs, see section 4 below);
 - if the wart, verruca, corn or callus has not disappeared after twelve weeks of treatment ask your doctor or pharmacist for advice.

- H. At the end of treatment, if the white patch is difficult to remove, you can leave it because it will eventually fall off by itself.

If the gel accidentally gets onto normal skin, wipe it off straight away with a tissue, and, if necessary, wash the area.

If the gel accidentally gets into the eyes or mouth, it may cause damage. Rinse the eyes or mouth with plenty of water. If rinsing one eye, take care to avoid washing product into the other eye. Then seek urgent hospital attention.

If you inhale a lot of the vapour from the gel it may make you feel light-headed. If this happens, get plenty of fresh air.

If you forget to use Diomed Wart Gel
Do not worry if you occasionally forget to use

this product, just carry on using it when you remember.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Diomed Wart Gel can cause side effects although not everybody gets them:

- While the gel is working you may feel a slight tingling sensation and / or some mild tenderness at the treated area. This is usually temporary, and in rare cases may appear as a temporary blemish on the skin.
- If you mistakenly allow the gel to spread onto and remain in contact with areas of normal skin (see precautions in section 2), it may cause irritation.
- If you spill the product on your clothes, fabrics, jewellery or metal and polished surfaces it may damage them permanently.
- **Stop using this product and tell your doctor or pharmacist if:**
 - you experience unacceptable discomfort or if irritation persists, or;
 - any of the side effects get serious, or you notice any other side effects not mentioned in this leaflet.

5. HOW TO STORE DIOMED WART GEL

- Keep out of the reach and sight of children.
- Do not use Diomed Wart 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.
- The product is highly flammable. Keep it away from flames or ignition sources.
- 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 DIOMED WART GEL

What Diomed Wart Gel contains:

The **active ingredients** are salicylic acid (12.0% w/w) and lactic acid (4.0% w/w).

The **other ingredients** are camphor, pyroxylin, ethanol and ethyl acetate.

What Diomed Wart Gel looks like and contents of the pack

The product is a clear colourless gel.

The product is available in a tube containing 8 g of gel. The tube has a special applicator nozzle. Each pack also includes an emery board.

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 Agent in Ireland is Cahill May Roberts, Pharmapak, Chapelizod, Dublin 20.

This Leaflet was last approved in November 2008.

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: Diomed, PL 00173/0401.

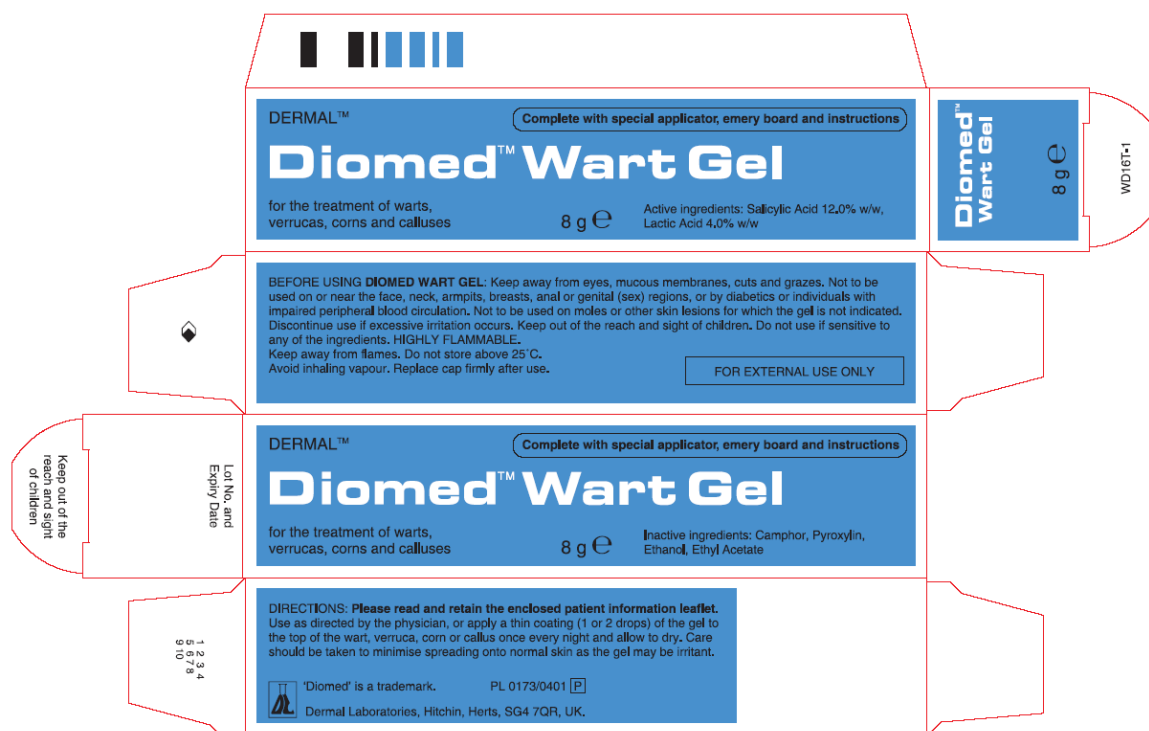
This is a service provided by the Royal National Institute of Blind People (RNIB).

WD18F2

**DIOMED WART GEL
PL 00173/0401**

LABELLING

CARTONPACK SIZE-8G



Label

BEFORE USING DIOMED WART GEL: Keep away from eyes, mucous membranes, cuts and grazes. Not to be used on or near the face, neck, armpits, breasts, anal or genital regions, or by diabetics or individuals with impaired peripheral blood circulation. Keep out of the reach and sight of children. Do not use if sensitive to any of the ingredients.

HIGHLY FLAMMABLE.

FOR EXTERNAL USE ONLY

Keep away from flames. Do not store above 25°C. Avoid inhaling vapour. Replace cap firmly after use. Expiry Date and Lot No. on crimp. Dermal Laboratories, Hitchin, Herts, SG4 7QR, UK,

PL 0173/0401 [P]

Diomed™ Wart Gel

for the treatment of warts, verrucas, corns and calluses

Active ingredients:
Salicylic Acid 12.0% w/w
Lactic Acid 4.0% w/w

8 g e

DIRECTIONS:
Read and retain the accompanying patient information leaflet. Use as directed by the physician, or apply a thin coating (1 or 2 drops) once every night.

WD15T-1