

**DOUBLEBASE EMOLLIENT WASH GEL
PL 00173/0402**

UKPAR

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**DOUBLEBASE EMOLLIENT WASH GEL
PL 00173/0402**

LAY SUMMARY

The MHRA granted Diomed Developments Ltd (trading as Dermal Laboratories) a Marketing Authorisation (licence) for the medicinal product Doublebase Emollient Wash Gel (PL 00173/0402) on 08 September 2008. This product is available through pharmacies for the treatment of dry or chapped skin conditions that may also be itchy, red and sore such as eczema and other types of dermatitis, psoriasis, elderly pruritus and ichthyosis.

Doublebase Emollient Wash Gel contains the active ingredients isopropyl myristate and liquid paraffin which are emollients.

This application is a duplicate of a previously granted application for Doublebase Emollient Shower Gel (Diomed Developments Ltd), as such, these products can be used interchangeably.

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

**DOUBLEBASE EMOLLIENT WASH GEL
PL 00173/0402**

SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a Marketing Authorisation for the medicinal product Doublebase Emollient Wash Gel to Diomed Developments Ltd (trading as Dermal Laboratories) on 08 September 2008. The product is available through pharmacies.

The application was submitted as a simple abridged application according to article 10c of Directive 2001/83/EC as amended, referring to Doublebase Emollient Shower Gel (Diomed Developments Ltd), approved on 06 December 2004.

No new data were submitted nor were any necessary for this simple application since the data are identical to that of the previously granted reference product. As the reference product was granted prior to the introduction of current legislation, a Public Assessment Report (PAR) has not been generated for it.

The product contains the active ingredients isopropyl myristate and liquid paraffin which encourage rehydration and softening of dry skin by forming an occlusive barrier within the skin surface. Doublebase Emollient Wash Gel is indicated for the regular first-line treatment and prophylaxis of dry or chapped skin conditions which may also be pruritic or inflamed.

PHARMACEUTICAL ASSESSMENT

COMPOSITION

The product is formulated as a gel containing 15% w/w of each of the active pharmaceutical ingredients isopropyl myristate and liquid paraffin. The excipients present are glycerol, carbomer, sorbitan laurate, triethanolamine, phenoxyethanol, cetomacrogol 1000 and purified water.

Doublebase Emollient Wash Gel is presented in a HDPE bottle with a polypropylene/silicone valve cap and HDPE hooked overcap in a pack size of 200g.

DRUG SUBSTANCES

Isopropyl myristate and Liquid paraffin

The proposed manufacturing sites are consistent with those registered for the reference product and evidence of GMP compliance has been provided.

DRUG PRODUCT

Other ingredients

All excipients used in the manufacture of the gel are routinely tested for compliance with current relevant international standards.

No excipients used contain material of animal or human origin.

Manufacture

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

Finished product specification

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

Stability

Finished product stability data support the proposed shelf-life of 24 months with storage conditions "Do not store above 25°C. Do not freeze."

Bioequivalence/bioavailability

A bioequivalence study was not required for this application.

SPC, PIL and Labels

The SPC and labels are pharmaceutically acceptable.

A patient information leaflet (PIL) has been submitted to the MRHA along with a bridging report which refers to the results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC performed on the PIL of a similar product. The results indicate that the applicant's PIL

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.

CONCLUSION

It is recommended that a Marketing Authorisation should be granted for this application.

PRECLINICAL ASSESSMENT

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

CLINICAL ASSESSMENT

As this is a duplicate application for Doublebase Emollient Shower Gel, no new clinical data have been supplied and none are required.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for this application are consistent with those previously assessed for the 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

This application is identical to the previously granted application for Doublebase Emollient Shower Gel in which the applicant provided clinical data.

No new or unexpected safety concerns arise from this application.

The SPC, PIL and labelling are satisfactory and consistent with that for the 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 reference product. Clinical experience with isopropyl myristate and liquid paraffin is considered to have demonstrated the therapeutic value of the compounds. The risk benefit is therefore considered to be positive.

**DOUBLEBASE EMOLLIENT WASH GEL
PL 00173/0402**

STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the Marketing Authorisation application on 22 May 2008.
2	Following standard checks and communication with the applicant, the MHRA considered the application valid on 28 May 2008.
3	The application was determined on 08 September 2008.

**DOUBLEBASE EMOLLIENT WASH GEL
PL 00173/0402**

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

Date submitted	Application type	Scope	Outcome

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Doublebase Emollient Wash Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Isopropyl Myristate	15% w/w
Liquid Paraffin	15% w/w

For full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Gel

White opaque GEL.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A highly emollient and protective hydrating base for regular first-line treatment and prophylaxis of dry or chapped skin conditions which may also be pruritic (itchy) or inflamed. Doublebase Emollient Wash Gel may also be used as an adjunct to other topical treatments.

4.2 Posology and method of administration

For adults, the elderly and children, who normally shower. For cutaneous use only. Use regularly and as often as necessary.

Doublebase Emollient Wash Gel may be applied before, during or after showering, with or without a normal cleanser (according to personal preference), to help prevent the drying and irritant effects of normal showering.

Doublebase Emollient Wash Gel can be used in one or more of the following ways:

- Before showering, apply the gel to dry skin areas using a few gentle strokes.
- During showering, apply the gel using a gentle washing action, rinse off any

excess and pat the skin dry using a soft towel (avoid rubbing as this can irritate the skin). If a cleanser is to be used, apply the emollient gel afterwards.

- After showering, apply the gel to dry skin areas, using a few gentle strokes across the skin in the same direction as hair growth. If necessary, allow time for any excess to soak in. Do not rub vigorously.

4.3 Contraindications

Do not use in cases of known sensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Take care not to slip in the bath or shower. Surfaces that have been in contact with the product should be cleaned with a proprietary detergent.

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

No special precautions.

4.8 Undesirable effects

Although Doublebase Emollient Wash Gel has been specially formulated for use on dry, problem or sensitive skin, local skin reactions can occur in rare cases. In this event, treatment should be discontinued.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: D02A, emollients and protectives.

The oily ingredients, isopropyl myristate and liquid paraffin, encourage rehydration and softening of dry skin by forming an occlusive barrier within the skin surface, thus reducing drying from evaporation of water that diffuses from the underlying layers.

5.2 Pharmacokinetic properties

Because Doublebase Emollient Wash Gel is designed to deliver the emollient ingredients into the stratum corneum when gently applied to areas of dry skin, it is relatively non-greasy despite its high oil content.

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

Glycerol E422

Carbomer

Sorbitan Laurate

Triethanolamine

Phenoxyethanol

Cetomacrogol 1000

Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Do not store above 25°C

Do not freeze.

6.5 Nature and contents of container

HDPE bottle (200g) with polypropylene/silicone valve cap and HDPE hooked overcap.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Diomed Developments Limited

T/A Dermal Laboratories

Tatmore Place

Gosmore

Hitchin

Hertfordshire, SG4 7QR

UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00173/0402

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

08/09/2008

10 DATE OF REVISION OF THE TEXT

08/09/2008

PATIENT INFORMATION LEAFLET

PACKAGE LEAFLET

Information for the user

Doublebase™ Emollient Wash Gel

isopropyl myristate, liquid paraffin

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

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

In this leaflet:

1. What Doublebase Emollient Wash Gel is and what it is used for
2. Before you use Doublebase Emollient Wash Gel
3. How to use Doublebase Emollient Wash Gel
4. Possible side effects
5. How to store Doublebase Emollient Wash Gel
6. Further information
7. General advice on looking after dry skin conditions

1. WHAT DOUBLEBASE EMOLLIENT WASH GEL IS AND WHAT IT IS USED FOR

- Doublebase Emollient Wash Gel is a treatment for you to apply to your skin during your normal showering routine.
- It helps treat dry or chapped skin conditions that may also be itchy, red and sore. Common examples include:
 - psoriasis (scaly, pink patches of skin), elderly pruritus (itchy skin due to ageing), ichthyosis (abnormal scaly skin), various forms of eczema, dermatitis and other dry skin disorders.
- **All age groups who normally shower** can use Doublebase Emollient Wash Gel.
- The **active ingredients** in this product are isopropyl myristate and liquid paraffin. These are known as **emollients**. When used as part of your normal showering routine the product helps to:
 - soften, moisturise and protect your skin by trapping moisture in the skin and restoring the normal protective function of the skin.
 - prevent the skin-drying and irritant effects that can be caused by showering and by the soaps, foaming additives and fragrances used in ordinary shower products.
- This product can be used in addition to any other emollients or treatments your doctor, pharmacist or nurse may have given or prescribed for you to treat your dry skin condition.

2. BEFORE YOU USE DOUBLEBASE EMOLLIENT WASH GEL

Do not use Doublebase Emollient Wash Gel if you are **allergic** (hypersensitive) to isopropyl myristate, liquid paraffin or any of the other ingredients of Doublebase Emollient Wash Gel listed in Section 6.

Take special care when using this product:

- it can make your shower tray (or bath surface) slippery, so be careful to avoid slipping over when getting into and out of your shower (eg by using a shower or bath mat).
- after use, clean out the shower tray with a suitable detergent to remove any remaining greasiness (wearing protective gloves to avoid irritating your hands).

Using other medicines

This product is not known to affect, or to be affected by, 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.

3. HOW TO USE DOUBLEBASE EMOLLIENT WASH GEL

This product is only for application to the skin. For maximum benefit you should use the gel whenever you shower.

- To use the product, remove the hooked overcap and attach it to the base of the bottle for hanging in the shower.
- Holding the bottle upside down, gently squeeze the product into the palm of your hand.

For all age groups who normally shower:

You can use Doublebase Emollient Wash Gel in **any** of the following ways (whichever suit you best):

Before showering:

- Apply the gel to the dry areas of the skin, using a few gentle strokes.

During showering:

- Apply the gel using a gentle washing action.
- If you decide to use your normal cleanser in the shower, use Doublebase Emollient Wash Gel afterwards to condition your skin.
- Rinse off any excess (you should still be able to feel the product coating the skin).

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After showering:

- Pat the skin dry with a soft towel (avoid rubbing as this can make dry skin conditions worse).
- Apply the gel to areas of dry skin, using a few gentle strokes to smooth across the skin in the same direction as hair growth (like stroking a cat or dog).
- Allow any excess to soak in.

You may prefer to use your normal soap or shower gel as well as Doublebase Emollient Wash Gel when showering. As a general rule, however, the use of normal soaps and shower gels (even those labelled "moisturising") is best avoided, or at least kept to a minimum.

If you forget to use Doublebase Emollient Wash Gel

Do not worry if you occasionally forget to use it, just carry on using the shower gel as described the next time you shower.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Doublebase Emollient Wash Gel can cause side effects, although not everybody gets them. This product has been specially designed for use on dry or problem skin. However, in rare cases it can cause skin irritation (mild rashes) or allergic skin reactions on extremely sensitive skin. These rare effects tend to occur during or soon after the first few uses.

Stop using this shower gel and **tell** your doctor, nurse or pharmacist:

- if your skin condition seems to look or feel worse.
- if any of the side effects get serious, or you notice any other side effects not mentioned in this leaflet.

If this product is accidentally **swallowed**, its oily ingredients may cause diarrhoea.

If this happens:

- treat the symptoms as you would deal with any case of diarrhoea.
- drink plenty of water.
- **do not attempt to cause vomiting.**

5. HOW TO STORE DOUBLEBASE EMOLLIENT WASH GEL

- Keep out of the reach and sight of children.
- Do not use Doublebase Emollient Wash Gel after the expiry date shown on the container. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Do not freeze the product.
- Replace the hooked overcap in the original position on the top of the bottle during transport.

6. FURTHER INFORMATION**What Doublebase Emollient Wash Gel contains:**

The **active ingredients** are **isopropyl myristate** (15% w/w) and **liquid paraffin** (15% w/w). The **other ingredients** are cetomacrogol, glycerol, carbomer, sorbitan laurate, triethanolamine, phenoxyethanol and purified water.

What Doublebase Emollient Wash Gel looks like and contents of the pack

- The shower gel is available in a plastic bottle containing 200 g. The bottle is fitted with a purple hooked overcap.
- The product is a white, viscous liquid. It contains no dye or fragrance.

The Marketing Authorisation holder is Dermal Laboratories, Hitchin, Herts, SG4 7QR, UK.

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

This leaflet was last approved in April 2008.

7. GENERAL ADVICE ON LOOKING AFTER DRY SKIN CONDITIONS

- Emollients help soften, moisturise and protect the skin. They play a central role in the treatment and management of dry skin conditions. For maximum effect, they should be applied regularly and as often as needed.
- When bathing, try to use warm, not hot, water and avoid staying in the bath for long periods. This could make dry skin conditions worse.
- Try to avoid using normal soaps or cleansing products (even those labelled "moisturising"). This is because they tend to dry and irritate the skin. Avoid using products containing fragrances, as these can also cause skin problems. You should try to use a fragrance-free emollient "soap substitute" instead. This type of product will not foam or lather but will be better for your dry skin condition.

Breaking the itch-scratch cycle

Some dry skin conditions like eczema and dermatitis are itchy, and can be quite sore. Although scratching relieves the itching for a short while, it further damages the skin. Badly scratched skin easily gets infected. This makes it itchier and the urge to scratch becomes even greater. It is better if scratching can be avoided by reducing the itching. The regular use of emollients or moisturisers can help with this.

- You may find it helpful to contact NHS Direct (tel: 0845 4647) or a patient support group such as the National Eczema Society (tel: 0800 0891122, 8am - 8pm, Mon - Fri) for information about your skin condition.

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:
Doublebase Emollient Wash Gel, 00173/0402.

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

PACKAGE LEAFLET

Information for the user

Doublebase™

Emollient Wash Gel

isopropyl myristate, liquid paraffin

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

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

In this leaflet:

1. What Doublebase Emollient Wash Gel is and what it is used for
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1. WHAT DOUBLEBASE EMOLLIENT WASH GEL IS AND WHAT IT IS USED FOR

- Doublebase Emollient Wash Gel is a treatment for you to apply to your skin during your normal showering routine.
- It helps treat dry or chapped skin conditions that may also be itchy, red and sore. Common examples include:
 - psoriasis (scaly, pink patches of skin), elderly pruritus (itchy skin due to ageing), ichthyosis (abnormal scaly skin), various forms of eczema, dermatitis and other dry skin disorders.
- **All age groups who normally shower** can use Doublebase Emollient Wash Gel.
- The **active ingredients** in this product are isopropyl myristate and liquid paraffin. These are known as **emollients**. When used as part of your normal showering routine the product helps to:
 - soften, moisturise and protect your skin by trapping moisture in the skin and restoring the normal protective function of the skin.
 - prevent the skin-drying and irritant effects that can be caused by showering and by the soaps, foaming additives and fragrances used in ordinary shower products.
- This product can be used in addition to any other emollients or treatments your doctor, pharmacist or nurse may have given or prescribed for you to treat your dry skin condition.

2. BEFORE YOU USE DOUBLEBASE EMOLLIENT WASH GEL

Do not use Doublebase Emollient Wash Gel if you are **allergic** (hypersensitive) to isopropyl myristate, liquid paraffin or any of the other ingredients of Doublebase Emollient Wash Gel listed in Section 6.

Take special care when using this product:

- it can make your shower tray (or bath surface) slippery, so be careful to avoid slipping over when getting into and out of your shower (eg by using a shower or bath mat).
- after use, clean out the shower tray with a suitable detergent to remove any remaining greasiness (wearing protective gloves to avoid irritating your hands).

Using other medicines

This product is not known to affect, or to be affected by, 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.

3. HOW TO USE DOUBLEBASE EMOLLIENT WASH GEL

This product is only for application to the skin. For maximum benefit you should use the gel whenever you shower.

- To use the product, remove the hooked overcap and attach it to the base of the bottle for hanging in the shower.
- Holding the bottle upside down, gently squeeze the product into the palm of your hand.

For all age groups who normally shower:

You can use Doublebase Emollient Wash Gel in **any** of the following ways (whichever suit you best):

Before showering:

- Apply the gel to the dry areas of the skin, using a few gentle strokes.

During showering:

- Apply the gel using a gentle washing action.
- If you decide to use your normal cleanser in the shower, use Doublebase Emollient Wash Gel afterwards to condition your skin.
- Rinse off any excess (you should still be able to feel the product coating the skin).

continued...

After showering:

- Pat the skin dry with a soft towel (avoid rubbing as this can make dry skin conditions worse).
- Apply the gel to areas of dry skin, using a few gentle strokes to smooth across the skin in the same direction as hair growth (like stroking a cat or dog).
- Allow any excess to soak in.

You may prefer to use your normal soap or shower gel as well as Doublebase Emollient Wash Gel when showering. As a general rule, however, the use of normal soaps and shower gels (even those labelled "moisturising") is best avoided, or at least kept to a minimum.

If you forget to use Doublebase Emollient Wash Gel

Do not worry if you occasionally forget to use it, just carry on using the shower gel as described the next time you shower.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Doublebase Emollient Wash Gel can cause side effects, although not everybody gets them. This product has been specially designed for use on dry or problem skin. However, in rare cases it can cause skin irritation (mild rashes) or allergic skin reactions on extremely sensitive skin. These rare effects tend to occur during or soon after the first few uses.

Stop using this shower gel and **tell** your doctor, nurse or pharmacist:

- if your skin condition seems to look or feel worse.
- if any of the side effects get serious, or you notice any other side effects not mentioned in this leaflet.

If this product is accidentally **swallowed**, its oily ingredients may cause diarrhoea.

If this happens:

- treat the symptoms as you would deal with any case of diarrhoea.
- drink plenty of water.
- **do not attempt to cause vomiting.**

5. HOW TO STORE DOUBLEBASE EMOLLIENT WASH GEL

- Keep out of the reach and sight of children.
- Do not use Doublebase Emollient Wash Gel after the expiry date shown on the container. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Do not freeze the product.
- Replace the hooked overcap in the original position on the top of the bottle during transport.

6. FURTHER INFORMATION

What Doublebase Emollient Wash Gel contains:

The **active ingredients** are **isopropyl myristate** (15% w/w) and **liquid paraffin** (15% w/w). The **other ingredients** are cetomacrogol, glycerol, carbomer, sorbitan laurate, triethanolamine, phenoxyethanol and purified water.

What Doublebase Emollient Wash Gel looks like and contents of the pack

- The shower gel is available in a plastic bottle containing 200 g. The bottle is fitted with a purple hooked overcap.
- The product is a white, viscous liquid. It contains no dye or fragrance.

The Marketing Authorisation holder is Dermal Laboratories, Hitchin, Herts, SG4 7QR, UK.

The Manufacturer is Fleet Laboratories Limited, 94 Rickmansworth Road, Watford, Hertfordshire, WD18 7JJ, UK.

This leaflet was last approved in April 2008.

7. GENERAL ADVICE ON LOOKING AFTER DRY SKIN CONDITIONS

- Emollients help soften, moisturise and protect the skin. They play a central role in the treatment and management of dry skin conditions. For maximum effect, they should be applied regularly and as often as needed.
- When bathing, try to use warm, not hot, water and avoid staying in the bath for long periods. This could make dry skin conditions worse.
- Try to avoid using normal soaps or cleansing products (even those labelled "moisturising"). This is because they tend to dry and irritate the skin. Avoid using products containing fragrances, as these can also cause skin problems. You should try to use a fragrance-free emollient "soap substitute" instead. This type of product will not foam or lather but will be better for your dry skin condition.

Breaking the Itch-scratch cycle

Some dry skin conditions like eczema and dermatitis are itchy, and can be quite sore. Although scratching relieves the itching for a short while, it further damages the skin. Badly scratched skin easily gets infected. This makes it itchier and the urge to scratch becomes even greater. It is better if scratching can be avoided by reducing the itching. The regular use of emollients or moisturisers can help with this.

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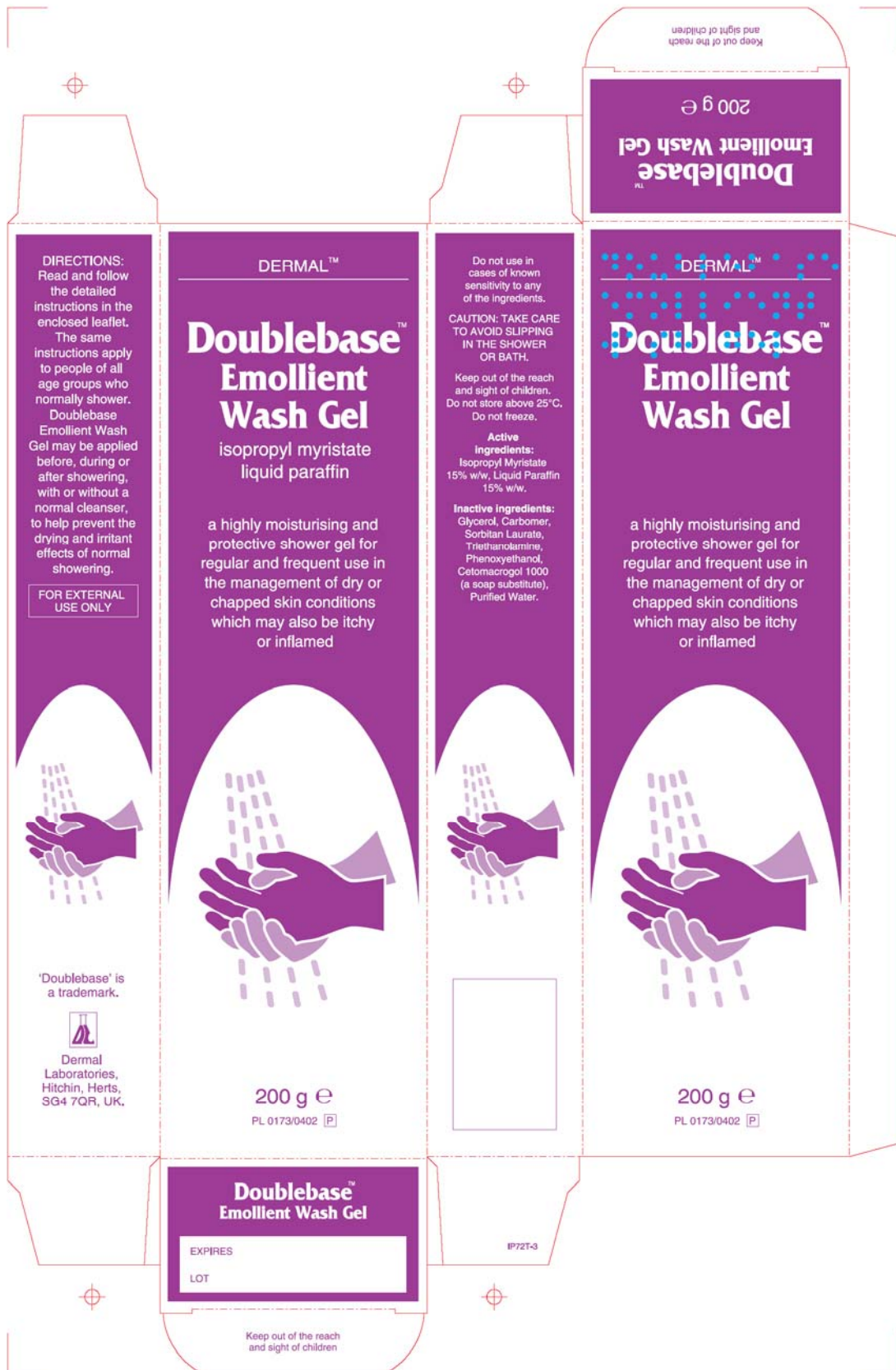
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Please be ready to give the following information:

Doublebase Emollient Wash Gel, 00173/0402.

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

LABELLING



Doublebase™ Emollient Wash Gel

isopropyl myristate
liquid paraffin



a highly moisturising and protective shower gel for regular and frequent use in the management of dry or chapped skin conditions which may also be itchy or inflamed

200 g e

PL 0173/0402 P

FOR EXTERNAL USE ONLY

IP70T-3

DIRECTIONS: Read and follow the detailed instructions in the accompanying leaflet. The same instructions apply to people of all age groups who normally shower. Doublebase Emollient Wash Gel may be applied before, during or after showering, with or without a normal cleanser, to help prevent the drying and irritant effects of normal showering.

Do not use in cases of known sensitivity to any of the ingredients.

CAUTION: TAKE CARE TO AVOID SLIPPING IN THE SHOWER OR BATH.

Keep out of the reach and sight of children.

Do not store above 25°C.

Do not freeze.

Active ingredients:

Isopropyl Myristate 15% w/w
Liquid Paraffin 15% w/w

Inactive ingredients: Glycerol, Carbomer, Sorbitan Laurate, Triethanolamine, Phenoxyethanol, Cetomacrogol 1000 (a soap substitute), Purified Water.

'Doublebase' is a trademark.

Dermal Laboratories, Hitchin, Herts, SG4 7QR, UK.

EXPIRES

LOT

IP71T-1