

**DERMOL WASH CUTANEOUS EMULSION
PL 00173/0407**

UKPAR

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DERMOL WASH CUTANEOUS EMULSION

PL 00173/0407

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency granted Diomed Developments Limited a Marketing Authorisation (licence) for the medicinal product Dermol Wash Cutaneous Emulsion (PL 00173/0407) on 30th April 2010. This is pharmacy-only medicine.

Dermol Wash Cutaneous Emulsion contains the following active ingredients- liquid paraffin, isopropyl myristate, benzakonium chloride and chlorhexidine dihydrochloride.

Dermol Wash Cutaneous Emulsion is used to treat of dry skin conditions, especially eczema and dermatitis.

This application is similar to the reference product, Dermol 500 Lotion (PL 00173/0051) also licensed to Diomed Developments Limited in January 1991.

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

DERMOL WASH CUTANEOUS EMULSION
PL 00173/0407

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted Diomed Developments Limited a Marketing Authorisation (licence) for the medicinal product Dermol Wash Cutaneous Emulsion (PL 00173/0407) on the 30th April 2010. The product is a pharmacy-only medicine (P) and is a moisturising, protective and antiseptic soap substitute. It helps treat and prevent dry and itchy skin conditions such as occupational hand dermatitis (hand eczema caused by frequent hand-washing, repeated contact with water or chemicals such as cleaning or hair products), eczema, psoriasis (scaly pink patches of skin) and ichthyosis (unusually scaly skin).

This application was submitted as a simple abridged application according to Article 10c of Directive 2001/83/EC, cross-referring to Dermol 500 Lotion (PL 00173/0051) also licensed to Diomed Developments Limited in January 1991.

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 liquid paraffin, isopropyl myristate, benzakonium chloride and chlorhexidine dihydrochloride which are indicated for the management of dry and pruritic skin conditions, especially eczema and dermatitis.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 00173/0407

PROPRIETARY NAME: Dermol Wash Cutaneous Emulsion

ACTIVE(S): Liquid Paraffin, Isopropyl Myristate, Benzakonium Chloride and Chlorhexidine Dihydrochloride

COMPANY NAME: Diomed Developments Limited

E.C. ARTICLE: Article 10c of Directive 2001/83/EC

LEGAL STATUS: P

1. INTRODUCTION

This is a simple, informed consent applications for Dermaol Wash Cutaneous Emulsion submitted under Article 10c of Directive 2001/83/EC. The proposed Marketing Authorisation Holder is Diomed Developments Limited, T/A Dermal Laboratories, Tatmore Place, Gosmore, Hitchin, Hertfordshire, SG4 7QR, UK.

The application cross-refers to Dermol 500 Lotion (Cutaneous Emulsion)-PL 00173/0051, approved on 16th January 1991 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 Dermol Wash Cutaneous Emulsion. The product has been named in line with current requirements.

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

This product contains liquid paraffin (2.5% w/w), isopropyl myristate (2.5% w/w), benzakonium chloride (0.1% w/w) and chlorhexidine dihydrochloride (0.1% w/w). Dermol Wash Cutaneous Emulsion is packaged in bottles composed of high density polyethylene (HDPE) with either a white polypropylene metering pump or a white polypropylene dispensing stopper/screw cap in pack sizes of 50ml, 200ml or 500ml. All primary product packaging complies with Directive 2002/72/EC (as amended). Specifications and Certificates of Analysis for all packaging types used have been provided and are satisfactory.

The proposed shelf-life is 30 months for an unopened container and, for pack sizes greater than 250ml, 18 months once in-use for pack sizes greater than 250ml. Storage conditions are consistent with the details registered for the cross-reference product.

2.3 Legal status

The product will be available as a pharmacy-only medicine (P).

2.4 Marketing authorisation holder/Contact Persons/Company

Diomed Developments Limited, T/A Dermal Laboratories, Tatmore Place, Gosmore, Hitchin, Hertfordshire, SG4 7QR, UK

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

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 specifications are in-line with the details registered for the cross-reference product.

2.9 Drug substance specification

The proposed drug substance specifications are consistent with the details registered for the cross-reference product.

2.10 TSE Compliance

None of the excipients used in the product contain materials of animal or human origin. 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 and 2.2 for details of the product appearance. 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.

Cartons and labels

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 this application is acceptable. A Marketing Authorisations 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

Liquid paraffin, isopropyl myristate, benzakonium chloride and chlorhexidine dihydrochloride are well known drugs and have been used in the management of dry and pruritic skin conditions, especially eczema and dermatitis, for many years. This application is similar to the reference product, Dermol 500 Lotion (Cutaneous Emulsion) – PL 00173/0407 granted to the same Marketing Authorisation Holder on 16th January 1991.

No new or unexpected safety concerns arise from this application.

The SmPC, 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 which, in turn, has been shown to be interchangeable with the innovator product. Extensive clinical experience with liquid paraffin, isopropyl myristate, benzakonium chloride and chlorhexidine dihydrochloride is considered to have demonstrated the therapeutic value of the compound. The risk benefit is therefore considered to be positive.

**DERMOL WASH CUTANEOUS EMULSION
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STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation application on 4 th May 2010.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 6 th May 2010.
3	The application was determined on 7 th June 2010.

**DERMOL WASH CUTANEOUS EMULSION
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STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome
04/05/2010	Type IB	To update section 4.2 of the SPC (Posology and method of administration) to emphasise primary use of product as a soap substitute for use a part of patient's normal washing routine at the sink, particularly for hand washing. There are consequential changes made to the PIL and labelling.	Approved

SUMMARY OF PRODUCT CHARACTERISTICS

The UK Summary of Product Characteristics (SmPC) for Dermol Wash Cutaneous Emulsion is as follows:

1 NAME OF THE MEDICINAL PRODUCT

Dermol Wash Cutaneous Emulsion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Liquid Paraffin	2.5% w/w
Isopropyl Myristate	2.5% w/w
Benzalkonium Chloride	0.1% w/w
Chlorhexidine Dihydrochloride	0.1% w/w

Excipient:

Cetostearyl Alcohol	5.0% w/w
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For full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Cutaneous emulsion

White, non-greasy cutaneous emulsion.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

An antimicrobial emollient for the management of dry and pruritic skin conditions, especially eczema and dermatitis. Dermol Wash Cutaneous Emulsion is suitable for direct application and for use as a soap substitute.

4.2 Posology and method of administration

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

For use as a soap substitute

Use as a cleanser at the sink or to wash with in the bath or shower, instead of ordinary soap or shower gel. Pat the skin dry using a soft towel (avoid rubbing as this can irritate the skin).

For application to the skin (eg after washing)

Apply to the affected areas as required.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Avoid contact with the eyes.

The excipient cetostearyl alcohol may on rare occasions give rise to local skin reactions (e.g. contact dermatitis) in sensitive people.

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

Although the product has been specially formulated for use on dry or problem skin, in the unlikely event of a reaction, discontinue treatment.

These reactions are very rare (<1/10,000, based on spontaneous reporting) and may be irritant or allergic in nature. Reactions have been observed occasionally when used excessively as a leave-on application in areas of folded skin such as the anogenital area.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: D02 AX, emollients and protectives.

Bacteria (especially *Staphylococcus aureus*) are implicated in the pathogenesis of inflammatory dry skin conditions such as atopic eczema and dermatitis.

Dermol Wash contains 5% of emollient oils in a non-greasy aqueous system which also contains the well-known and effective antiseptics benzalkonium chloride and chlorhexidine dihydrochloride. Its antimicrobial properties assist in overcoming infection, whether from *Staph aureus*, the pathogen which often complicates eczema and associated pruritus, or secondary infection caused by scratching.

Massaged into the skin, the emollients, liquid paraffin and isopropyl myristate, permit rehydration 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

The active ingredients are presented in an aqueous emulsion system and so are readily absorbed into the stratum corneum when the product is gently massaged over the areas of dry skin. The antiseptic ingredients are in intimate contact with the skin, and as they are in solution, their availability is optimal.

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

Cetostearyl Alcohol
Cetomacrogol 1000
Phenoxyethanol
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf life

30 months in unopened container
In-use - 18 months (container sizes greater than 250 ml)

6.4 Special precautions for storage

Do not store above 25°C.

Replace cap after use.

6.5 Nature and contents of container

High density polyethylene bottle (50, 200 or 500 ml) with either a white polypropylene metering pump or a white polypropylene dispensing stopper/screw cap.

6.6 Special precautions for disposal

No special requirements.

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 00173/0407

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORIZATION

30/04/2010

10 DATE OF REVISION OF THE TEXT

07/06/2010

DERMOL WASH CUTANEOUS EMULSION

PL 00173/0407

PATIENT INFORMATION LEAFLET

PACKAGE LEAFLET

Information for the user



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

1. WHAT DERMOL WASH IS AND WHAT IT IS USED FOR

- Dermol Wash is a moisturising, protective and antiseptic soap substitute for you to use whenever you wash. It has been developed for use instead of soaps (bars and liquids) and cleansers, both of which may irritate dry skin.
- Dermol Wash can also be used as a leave on treatment, re-applied after washing and drying.
- It helps treat and prevent dry and itchy skin conditions. Common examples include:
 - occupational hand dermatitis (due to frequent hand-washing, or repeated contact with water or chemicals such as cleaning or hair products)
 - eczema and other types of dermatitis
 - psoriasis (scaly, pink patches of skin)
 - elderly pruritis (itchy skin due to ageing)
 - ichthyosis (unusually scaly skin)
- All age groups can use Dermol Wash, including babies.
- The active ingredients in this product are isopropyl myristate and liquid paraffin (which are emollients), and benzalkonium chloride and chlorhexidine dihydrochloride (which are antimicrobials).
- This soap substitute is specially designed to be non-foaming and is fragrance free. When used as part of your normal washing routine, it helps to:
 - cleanse, soften, moisturise and protect your skin by trapping in moisture and restoring the normal protective function of the skin
 - prevent the skin-drying and irritant effects that can be caused by washing and by the soaps, foaming additives and fragrances used in ordinary cleansing products
 - combat bacteria present on your skin that can make eczema worse
 - prevent infection caused by scratching itchy skin
 - prevent 'flare-ups' of your skin condition
- 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 DERMOL WASH

Do not use Dermol Wash if you are allergic (hypersensitive) to isopropyl myristate, liquid paraffin, benzalkonium chloride and chlorhexidine dihydrochloride or any of the other ingredients of Dermol Wash listed in Section 6.

Take special care when using this product:

- Avoid getting it in the eyes, especially when using it on the face.
- If you decide to use this product to wash with in the bath or shower, it can make the surface slippery, so:
 - be careful to avoid slipping over when getting into and out of your shower or bath (eg by using a shower or bath mat);
 - after use, clean out the bath/shower tray with a suitable detergent to remove any remaining greasiness (wearing protective gloves to avoid irritating your hands).
- For patients with very sensitive skin, it is generally a good idea to start any new treatment on a small test area first, in case any side effect occurs (see Section 4 overleaf). This is especially important when treating the face or young children. Thereafter, treatments may be applied more generously, as required.

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 whilst 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.

Important information about one of the ingredients of Dermol Wash

The product contains cetostearyl alcohol. This ingredient may cause local skin reactions (eg contact dermatitis) in a small number of sensitive people. If you have been told by your doctor that you are sensitive to cetostearyl alcohol, please talk to your doctor before using this product.

3. HOW TO USE DERMOL WASH

This product is only for application to the skin. Use this product as part of your normal washing routine, instead of your ordinary soap (bar or liquid) or cleanser. For maximum benefit you should use it whenever you wash (including routine hand washing).

Before using this product, turn the top of the pump dispenser anti-clockwise to unlock it.

- Wash with this product in the same way as you would with any liquid soap.
- Use it with a gentle washing action. The product will not foam or lather as you wash.

- Rinse off (you should still be able to feel the product coating the skin).
 - Pat the skin dry with a soft towel (avoid rubbing as this can make dry skin conditions worse).
- You can also use Dermal Wash as a leave-on treatment, by re-applying it after washing and drying.

- Gently smooth the product into the dry skin areas. If necessary, allow time for any excess to soak in. Do not rub the skin vigorously.
- If you are applying another product to the same areas of skin as Dermal Wash, try to avoid mixing the two products. You can do this by applying the treatments alternately, leaving enough time to allow the previous product to soak in.

If you forget to use Dermal Wash

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

If the product gets into the eyes

The product may cause irritation if it gets into the eyes. Rinse the eyes with plenty of water. If rinsing one eye, take care to avoid washing product into the other eye. If irritation persists, seek medical advice.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Dermal Wash can cause side effects, although not everybody gets them.

This product has been specially designed for use on dry or problem skin areas anywhere on the body, but in some very rare cases it can cause local skin reactions (involving redness, irritation and/or itching). Reactions may occasionally occur if used excessively as a leave-on application in areas of folded skin such as the groin area.

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

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

If you swallow Dermal Wash

If you accidentally swallow the product and you then feel unwell, seek medical attention.

Do not attempt to cause vomiting.

5. HOW TO STORE DERMOL WASH

- Keep out of reach and sight of children.
- Do not use Dermal Wash after the expiry date shown on the container and carton. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- After using the product it is advisable to turn the top of the pump dispenser clockwise to lock it.

6. FURTHER INFORMATION

What Dermal Wash Cutaneous Emulsion contains:

The active ingredients in this product are isopropyl myristate (2.5% w/w), liquid paraffin (2.5% w/w), benzalkonium chloride (0.1% w/w) and chlorhexidine dihydrochloride (0.1% w/w). The other ingredients are cetostearyl alcohol, cetomacrogol 1000, phenoxyethanol and purified water.

What Dermal Wash looks like and contents of the pack

- The product is a white, non-greasy emulsion (lotion) that contains no dye or fragrance.
- The product is available in a plastic bottle with a pump dispenser containing 200 ml of lotion. (50 ml packs are also available to medical and allied professions.)

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 October 2009.

7. GENERAL ADVICE ON LOOKING AFTER DRY SKIN CONDITIONS

- Try to avoid using normal soaps or shower 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.
- 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.
- 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.
- **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 to 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: Dermal Wash Cutaneous Emulsion, 00173/0407.

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

PACKAGE LEAFLET

Information for the user



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

1. WHAT DERMOL WASH IS AND WHAT IT IS USED FOR

- Dermol Wash is a moisturising, protective and antiseptic soap substitute for you to use whenever you wash. It has been developed for use instead of soaps (bars and liquids) and cleansers, both of which may irritate dry skin.
- Dermol Wash can also be used as a leave on treatment, re-applied after washing and drying.
- It helps treat and prevent dry and itchy skin conditions. Common examples include:
 - occupational hand dermatitis (due to frequent hand-washing, or repeated contact with water or chemicals such as cleaning or hair products)
 - eczema and other types of dermatitis
 - psoriasis (scaly, pink patches of skin)
 - elderly pruritis (itchy skin due to ageing)
 - ichthyosis (unusually scaly skin)
- All age groups can use Dermol Wash, including babies.
- The active ingredients in this product are isopropyl myristate and liquid paraffin (which are emollients), and benzalkonium chloride and chlorhexidine dihydrochloride (which are antimicrobials).
- This soap substitute is specially designed to be non-foaming and is fragrance free. When used as part of your normal washing routine, it helps to:
 - cleanse, soften, moisturise and protect your skin by trapping in moisture and restoring the normal protective function of the skin
 - prevent the skin-drying and irritant effects that can be caused by washing and by the soaps, foaming additives and fragrances used in ordinary cleansing products
 - combat bacteria present on your skin that can make eczema worse
 - prevent infection caused by scratching itchy skin
 - prevent 'flare-ups' of your skin condition
- 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 DERMOL WASH

Do not use Dermol Wash if you are allergic (hypersensitive) to isopropyl myristate, liquid paraffin, benzalkonium chloride and chlorhexidine dihydrochloride or any of the other ingredients of Dermol Wash listed in Section 6.

Take special care when using this product:

- Avoid getting it in the eyes, especially when using it on the face.
- If you decide to use this product to wash with in the bath or shower, it can make the surface slippery, so:
 - be careful to avoid slipping over when getting into and out of your shower or bath (eg by using a shower or bath mat);
 - after use, clean out the bath/shower tray with a suitable detergent to remove any remaining greasiness (wearing protective gloves to avoid irritating your hands).
- For patients with very sensitive skin, it is generally a good idea to start any new treatment on a small test area first, in case any side effect occurs (see Section 4 overleaf). This is especially important when treating the face or young children. Thereafter, treatments may be applied more generously, as required.

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 whilst 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.

Important information about one of the ingredients of Dermol Wash

The product contains cetostearyl alcohol. This ingredient may cause local skin reactions (eg contact dermatitis) in a small number of sensitive people. If you have been told by your doctor that you are sensitive to cetostearyl alcohol, please talk to your doctor before using this product.

3. HOW TO USE DERMOL WASH

This product is only for application to the skin. Use this product as part of your normal washing routine, instead of your ordinary soap (bar or liquid) or cleanser. For maximum benefit you should use it whenever you wash (including routine hand washing).

Before using this product, turn the top of the pump dispenser anti-clockwise to unlock it.

- Wash with this product in the same way as you would with any liquid soap.
- Use it with a gentle washing action. The product will not foam or lather as you wash.

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- Rinse off (you should still be able to feel the product coating the skin).
- Pat the skin dry with a soft towel (avoid rubbing as this can make dry skin conditions worse). You can also use Dermal Wash as a leave-on treatment, by re-applying it after washing and drying.
- Gently smooth the product into the dry skin areas. If necessary, allow time for any excess to soak in. Do not rub the skin vigorously.
- If you are applying another product to the same areas of skin as Dermal Wash, try to avoid mixing the two products. You can do this by applying the treatments alternately, leaving enough time to allow the previous product to soak in.

If you forget to use Dermal Wash

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

If the product gets into the eyes

The product may cause irritation if it gets into the eyes. Rinse the eyes with plenty of water. If rinsing one eye, take care to avoid washing product into the other eye. If irritation persists, seek medical advice.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Dermal Wash can cause side effects, although not everybody gets them.

This product has been specially designed for use on dry or problem skin areas anywhere on the body, but in some very rare cases it can cause local skin reactions (involving redness, irritation and/or itching). Reactions may occasionally occur if used excessively as a leave-on application in areas of folded skin such as the groin area.

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

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

If you swallow Dermal Wash

If you accidentally **swallow** the product and you then feel unwell, seek medical attention.

Do not attempt to cause vomiting.

5. HOW TO STORE DERMOL WASH

- Keep out of reach and sight of children.
- Do not use Dermal Wash after the expiry date shown on the container and carton. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- After using the product it is advisable to turn the top of the pump dispenser clockwise to lock it.

6. FURTHER INFORMATION

What Dermal Wash Cutaneous Emulsion contains:

The **active ingredients** in this product are **isopropyl myristate** (2.5% w/w), **liquid paraffin** (2.5% w/w), **benzalkonium chloride** (0.1% w/w) and **chlorhexidine dihydrochloride** (0.1% w/w). The **other ingredients** are cetostearyl alcohol, cetomacrogol 1000, phenoxyethanol and purified water.

What Dermal Wash looks like and contents of the pack

- The product is a white, non-greasy emulsion (lotion) that contains no dye or fragrance.
- The product is available in a plastic bottle with a pump dispenser containing 200 ml of lotion. (50 ml packs are also available to medical and allied professions.)

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

The Manufacturer is Fleet Laboratories Ltd, 94 Rickmansworth Road, Watford, Herts, WD18 7JJ, UK.

This leaflet was last approved in October 2009.

7. GENERAL ADVICE ON LOOKING AFTER DRY SKIN CONDITIONS

- Try to avoid using normal soaps or shower 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.
- 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.
- 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.
- **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 to 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: Dermal Wash Cutaneous Emulsion, 00173/0407.

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

DERMOL WASH PL 00173/0407

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CARTON



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CARTON



dermol 50ml emulsion carton - 48mm x 48mm x 68mm
 barcode 334 place
 barcode 331 place
 barcode 3265 place
 barcode guide only. do not print

LABEL

