DOUBLEBASE BATH ADDITIVE

PL 00173/0200

UKPAR

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DOUBLEBASE BATH ADDITIVE

PL 00173/0200

LAY SUMMARY

The MHRA granted Diomed Developments Limited a Marketing Authorisation (licence) for the medicinal product Doublebase Bath Additive (PL 00173/0200) on 28th March 2006. This medicine is used for the symptomatic relief of contact dermatitis, atopic dermatitis, senile pruritus (itchy dry skin), ichthyosis and related dry skin disorders. This medicinal product is available over the counter from pharmacies and non-pharmacy outlets.

Doublebase Bath Additive contains the active ingredients Liquid Paraffin and Acetylated Wool Alcohols which are emollients and soothe, smooth and hydrate the skin.

This application is a duplicate of a previously granted application for Dermalo bath Emollient (PL 00173/0182) held by Diomed Developments Ltd.

No new or unexpected safety concerns arose from this simple application. It was, therefore, judged that the benefits of using Doublebase Bath Additive outweigh the risks. Hence a Marketing Authorisation has been granted.

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Doublebase Bath Additive (PL 00173/0200) to Diomed Developments Ltd on 28th March 2006. This medicinal product is available as General Sales List (GSL).

The application was submitted according to article 10.1(a)(i) of Directive 2001/83/EC, cross-referring to Dermalo Bath Emollient (PL 00173/0182), which was granted a marketing authorisation on 14th February 2000.

No new data was submitted nor was it necessary for this simple application, as the data is 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 was generated for it.

The product contains the active ingredients Liquid Paraffin and acetylated wool alcohols which are emollients and soothe, smooth and hydrate the skin. Doublebase Bath Additive is indicated for the symptomatic relief of contact dermatitis, atopic dermatitis, senile pruritus, ichthyosis and related dry skin disorders.

PHARMACEUTICAL ASSESSMENT

1 Introduction

1.1 Legal Basis

The applicant claims essential similarity, under article 10.1(a)(i) of Directive 2001/83/EC, to the reference product, Dermalo Bath Emollient, PL 00173/0182, held by the applicant and granted 14th February 2000.

1.2 Legal Status

The legal status of the product is GSL.

1.3 Letters of Access

Since the applicant holds the cross reference product, it is taken that the applicant has access to all data supporting the application and that they have Part II or Module 3 in their possession.

The proposed and reference products are identical except for the Product Name.

A letter confirming that the proposed finished product manufacturer is prepared to manufacture the product on the applicant's behalf has been provided.

2 Overall Summaries (OS)

The Quality, Preclinical and Clinical OSs provided confirm the proposed product is identical with the reference product in all particulars. The OSs have been signed. The CVs of the Experts are acceptable.

3 Module 1

3.1 Product Name

The product name has been changed from the reference product, PL 00173/0182 Dermalo Bath Emollient, to Doublebase Bath Additive. This is the only name for the product.

3.2 Summary of Product Characteristics

The SPC is in line with the reference product and current SPC guidelines.

3.3 Patient Information leaflet

The proposed product uses a combined label/PIL, in line with the reference product.

Full colour mock ups have been provided for the 50ml and 500ml bottles. For these bottle sizes, the combined label/PILs are in line with the SPC and MHRA labelling and PIL guidelines.

Currently it is planned to launch this new product only in 50 ml and 500 ml packs. Therefore, full colour mock-ups of the labels/PILs for the 200 ml and 1000 ml packs are not available. The applicant has committed to submitting the appropriate full scale colour

mock-ups of the proposed label/PIL for assessment should it be decided to launch either of these pack sizes in the future.

3.4 Marketing Authorisation Application (MAA) Form

The MAA form is satisfactory

3.4.1 TSE

Section 2.6.2 of the MAA form states that none of the ingredients are of animal or human origin. This is in line with the reference product. The product is therefore Annex III according to MCA letter dated 7 July 2000.

3.5 Part IC: Additional Data Requirements

Finished Product Specification (FPS)
The FPS is in line with the reference product. The FPS does not comply with BP/Ph Eur and NfG. Assay tests for the active substances are missing. Given the nature of the active substances, it is unlikely that assay methods exist; therefore omission of assay is acceptable.

Method of manufacture
The method of manufacture and batch size are in line with the reference product.

Drug Substance Specification (DSS)
Full DSSs for both drug substances have been provided.

4 Conclusion

A product license may be granted for this product.

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 PL 00173/0182, no new clinical data have been supplied and none are required.

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 and acetylated wool alcohols have been used to treat the symptoms of dry skin conditions for many years. The data supplied with this application is identical to the previously approved marketing authorisation for Dermalo Bath Emollient (PL 00173/0182).

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 Liquid Paraffin and acetylated wool alcohols is considered to have demonstrated the therapeutic value of the product. The risk benefit is therefore considered to be positive.

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STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the marketing authorisation application on 01/04/2005.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 13/04/2005.
3	Following assessment of the application the MHRA requested further information on 28/07/2005 and 12/01/2006.
4	The applicant responded to the MHRA's requests, providing further information on 19/10/2005 and 23/03/2006.
5	The application was determined on 28/03/2006

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STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome

DOUBLEBASE BATH ADDITIVE

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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Doublebase Bath Additive

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Liquid Paraffin	65.0% w/w
Acetylated Wool Alcohols	5.0% w/w

For excipients see Section 6.1.

3 PHARMACEUTICAL FORM

BATH ADDITIVE

Dye- and fragrance-free colourless to straw coloured clear oily liquid

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of contact dermatitis, atopic dermatitis, senile pruritus, ichthyosis and related dry skin disorders.

4.2 Posology and method of administration

Adults, including the elderly:

Add 15 to 20 ml (1½ to 2 capfuls) to a standard bath of water (8 inch depth). Immerse and cover the affected areas with the bath water and soak for 10 to 20 minutes. Pat dry with a towel. Alternatively, use a similar amount smoothed onto wet skin following a shower. Rinse off thoroughly and pat dry with a towel.

Infants and children:

Add 5 to 10 ml (½ to 1 capful) to a small bath or wash basin of water. Immerse and cover the affected areas with the bath water and soak for 10 to 20 minutes. Alternatively, repeatedly gently sponge over the affected areas. Pat dry with a towel.

There is no differentiation between the dosage quantities for the symptomatic relief of the conditions listed.

4.3 Contraindications

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. Keep out of the reach of children. For external use only.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Pregnancy and lactation

The constituents are not percutaneously absorbed or toxic if ingested. There is no evidence of safety of the drug used in pregnancy or lactation, but the active constituents have been in widespread use and in similar preparations for many years without apparent ill consequence.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Contact sensitivity reactions or mild irritant reactions may occur occasionally. In either case, treatment should be discontinued.

4.9 Overdose

Accidental ingestion may result in a purgative action due to the liquid paraffin and the oily nature of the product. Treat symptomatically. Fluid and electrolyte replacement may be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: D02AX - Other emollients

For dry skin conditions it is important to use an emollient while bathing. Doublebase Bath Additive contains 65% Liquid Paraffin and 5% Acetylated Wool Alcohols for their moisturising and skin softening properties, and is specially formulated to facilitate dispersion in bath water or for ease of application after a shower.

5.2 Pharmacokinetic properties

The active constituents are not absorbed percutaneously. Pharmacokinetic particulars are thus not relevant.

5.3 Preclinical safety data

No relevant information additional to that contained elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl Myristate
Macrogol 3 Lauryl Ether

6.2 Incompatibilities

None known

6.3 Shelf life

36 months in unopened container

6.4 Special precautions for storage

Do not store above 25^{o}C

6.5 Nature and contents of container

50, 200, 500 or 1000 ml white high density polyethylene BOTTLE fitted with a polyethylene dispensing plug and spigotted polypropylene SCREW CAP.

Supplied in original packs (OP)

Not all pack sizes may be marketed.

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
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 0173/0200

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28/03/2006

10 DATE OF REVISION OF THE TEXT

28/03/2006

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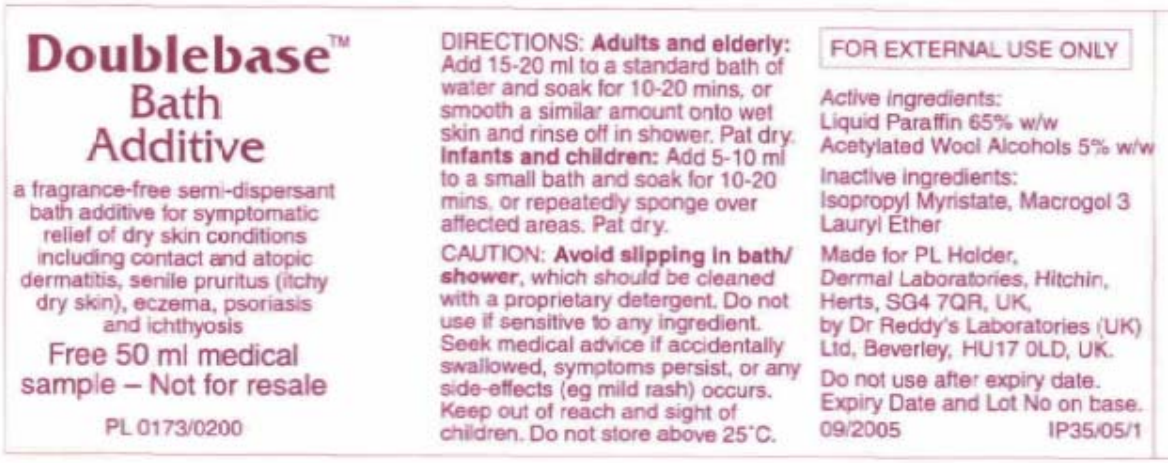
PIL/LABELLING

50ML SAMPLE CONTAINER



CONTAINER - FRONT

CONTAINER - BACK