

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Q.V. Bath Oil Bath Additive

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains Light Liquid Paraffin 85% w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Bath Additive

Clear to slightly cloudy, slightly viscous, oily bath additive.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of dermatological conditions associated with dry skin including;

- atopic eczema,
- ichthyosis,
- chronic dry dermatitis,
- xerosis,
- psoriasis,
- winter itch (pruritus hiemalis),
- skin therapy in geriatric patients.

4.2 Posology and method of administration

It is intended for addition to water or for use on skin as follows;

Use in the bath :

Adults and children : Add 10ml to a warm bath, bathe for 5 to 10 minutes. Gently pat skin dry.

Baby's bath : Add 5ml to a baby's bath, bathe for 5 to 10 minutes.

Use in a shower :

Adults and children : Apply undiluted to wet skin and leave for a few minutes, then rinse and pat the skin dry.

Massage :

Adults and children : Massage onto dry area, no need to wash off.

Use in patients in bed :

Adults and children : Add 5ml to 2 litres of warm water. Sponge the affected area, pat the skin dry.

Note:

For 500ml bottles, 10ml is approximately equivalent to ONE capful.

For 200ml bottles, 10ml is approximately equivalent to TWO capfuls.

4.3 Contraindications

Q.V. Bath Oil is contra-indicated in seborrhoeic dermatitis, acute dermatoses and in patients sensitive to any of the ingredients of the product.

4.4 Special warnings and precautions for use

Avoid contact with the eyes. The solution is for external use only.

QV bath Oil contains propyl parahydroxybenzoate (E216), which may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

No known interactions.

4.6 Pregnancy and lactation

Q.V. Bath Oil may be used in pregnant or lactating women.

4.7 Effects on ability to drive and use machines

Not applicable (topical preparation).

4.8 Undesirable effects

None reported.

4.9 Overdose

Not applicable (topical preparation).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: D02AX

Q.V. Bath Oil contains light liquid paraffin which is absorbed onto the skin surface. It forms a protective layer over the surface reducing dryness of the skin and it has an emollient action improving the condition of the skin.

5.2 Pharmacokinetic properties

When applied to the skin after bathing the Bath Oil forms a layer over the surface of the skin, it resists washing and is gradually removed by the natural transpiration of skin.

5.3 Preclinical safety data

Light Liquid Paraffin has been used in human beings for a long period of time both externally and by mouth. Light Liquid Paraffin can be taken by mouth in human beings and is well tolerated although long term administration can lead to impairment of fat soluble vitamin absorption. It is also used for rectal administration as well as being applied externally to the skin. Use over a number of years shows that there is a very low incidence of reactions when it is applied topically.

In Great Britain the occupational exposure standards of mineral oil mist are $5\text{mg}/\text{m}^3$ (long-term) and $10\text{mg}/\text{m}^3$ (short-term).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol Lauryl Ether
Isopropyl myristate
Propyl parahydroxybenzoate (E216)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25° C.

6.5 Nature and contents of container

10ml (sample pack) 200 ml and 500 ml PVC bottles fitted with wadded polypropylene screw caps.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

QV Bath Oil is comparatively non-slippery, but care should be taken when getting out of the bath or shower, or handling infants.

7 MARKETING AUTHORISATION HOLDER

Ego Pharmaceuticals (UK) Limited
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Merton
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8 MARKETING AUTHORISATION NUMBER

PA 863/5/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 05 February 2004

10 DATE OF REVISION OF THE TEXT

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