

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Hydrobath Emollient

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Light Liquid Paraffin	37.80	% w/w
Isopropyl Myristate	13.00	% w/w
Iso-octyl Stearate	15.95	% w/w
Laureth 3	11.25	% w/w
Macrogol 7 Glycerol Cocoate	22.00	% w/w

There is no pharmacologically active ingredient.

3 PHARMACEUTICAL FORM

Bath additive

Clear, colourless, water-dispersible bath oil resulting in an emulsion of dispersed oils together with a homogenised film on the water surface.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an aid in the management of dry skin conditions such as eczema, ichthyosis and senile pruritus.

4.2 Posology and method of administration

Route of administration

Hydrobath Emollient should be used topically and is either added to water or applied to wet skin.

1. For use in the bath

a) Adults/ Children:

Add 1-3 inner capfuls to an 8 inch bath of water. Soak for 10-15 minutes.

b) Infants:

Add ½ to 2 inner capfuls to a small bath of water.

2. For application to the skin as a sponge bath or in the shower.

Adults and Children:

Pour a small quantity on to a wet sponge or flannel and rub onto wet skin. Rinse and pat dry.

4.3 Contraindications

Known sensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Keep away from eyes. Take care to avoid slipping in the bath/shower. If there is aggravation of the condition consult the doctor.

4.5 Interaction with other medicinal products and other forms of interactions

None known.

4.6 Fertility, pregnancy and lactation

Hydrobath Emollient is not contra-indicated in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Patients should be advised to take care to avoid slipping in the bath.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Not applicable. Hydrobath Emollient is for topical use only .

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The combination of oils used in Hydrobath Emollient are deposited on the skin surface during bathing and thus reduce moisture loss, provide anti-pruritic action, lubricate and soften the skin.

Hydrobath Emollient is particularly suitable for infant bathing. The preparation can also be used as a cleanser where soaps are best avoided.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Light Liquid Paraffin
Isopropyl Myristate
Iso-octyl Stearate
Laureth 3
Macrogol 7 Glycerol Cocoate

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

Hydrobath Emollient is packed in polyethylene bottles of 150ml, 350ml, 500ml and 1 litre capacity.
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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Alliance Pharma (Ireland) Limited
United Drug Distributors, United Drug House
Magna Business Park, Magna Drive
Citywest
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA2325/006/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17 June 1991

Date of last renewal: 17 June 2006

10 DATE OF REVISION OF THE TEXT

March 2019
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