

# 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 interaction

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](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto: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 Pharmaceuticals Limited  
Avonbridge House  
Bath Road  
Chippenham  
Wiltshire  
SN15 2BB  
United Kingdom

## **8 MARKETING AUTHORISATION NUMBER**

PA0943/014/001

## **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**

January 2017