

# BATHE Study

## Bath Emollient Information

The BATHE study is testing bath emollients without the addition of antimicrobials or anti-itch agents. There are many different products but the suggested mechanism of action is similar, i.e. oily substance creates a film over the skin surface to prevent dry skin.

The British National Formulary (BNF) lists many different bath additives, but in clinical practice a few of these are commonly prescribed. For this reason we will encourage participating practices to only issue the following:

- Oilatum Fragrance Free Junior
- Balneum Bath Oil
- Aveeno Bath Oil

These account for the majority of bath emollient prescriptions in the UK and appear in local prescribing formularies for participating centres. We also would prefer that participants in the intervention group who have previous experience of bath emollient are also only prescribed one of the above, but they can choose or if they don't have a preference, then the GP can choose.

If participants wish to change bath emollient during the trial then they will be encouraged to use one of these, but may choose others if their GP is happy to prescribe them. Some emollient products contain additional ingredients such as antipruritics and antiseptics (for instance, Dermol) and we would ask participants **NOT to use** the ones highlighted over leaf.

### Pharmaceutical licensing

Oilatum Fragrance Free Junior and Balneum bath oil are licensed for pharmaceutical use in the EU and are being used within their licensed indication in this study. Aveeno Bath Oil does not have a EU pharmaceutical Marketing Authorisation but is approved by the ACBS (Advisory Committee on Borderline Substances) for the treatment of eczema. All three products have been used widely for many years with no safety concerns and are available to purchase over the counter without a prescription.

### Prescribing arrangements

When a participant is randomised to the intervention the clinical studies officer / nurse will arrange for a bath emollient to be prescribed and recorded by their own GP. It will therefore be labelled by the community pharmacist in the usual way and products will be issued with information leaflets listing indications, contra-indications, possible adverse events, etc., in the usual way.

### Adverse reactions

Known adverse reactions to bath emollients are recorded in the Summary of Product Characteristics for Oilatum Fragrance Free Junior and Balneum bath oil. These include: skin irritation, rash, erythema (redness), pruritus (itch). Accidental ingestion may cause gastrointestinal irritation with nausea, vomiting and diarrhoea. There is an increased risk of slipping due to the oil film on the skin and the oil film in the bath or shower. Aveeno Bath Oil does not have a Summary of Product Characteristics as it is not marketed as a pharmaceutical, but adverse reactions are likely to be the same.

## Prescribing instructions

The GP can choose the directions and quantity of prescribing. Please issue as repeat prescriptions.

Suggested regimens are:

Oilatum Junior Emollient bath additive

Direction: Add 1 – 3 capfuls to the bath

Quantity: 500ml

Balneum Bath Oil

Add 20 – 60ml to the bath

Quantity: 1 litre

Aveeno Bath Oil

Add 20 – 30ml to the bath

Quantity: 500ml (i.e. 2 \* 250ml)

## Emollient bath additives that CAN be prescribed to children in BATHE study

Product	Allowed in BATHE?	Comments
Aveeno Bath Oil	Yes	
Balneum Bath Oil	Yes	
Cetraben Bath Additive	Yes	
Dermalo Bath Emollient	Yes	
Diprobath Bath Additive	Yes	
Doublebase Bath Additive	Yes	
E45 Emollient Bath Oil	Yes	
Hydromol Bath and Shower Emollient	Yes	
Imuderm Bath Oil	Yes	
Oilatum Emollient Bath Additive	Yes	Oilatum 'Junior' is preferable (less fragrance)
Oilatum Junior Emollient Bath Additive	Yes	
QV Bath Oil	Yes	

## Emollient bath additives that SHOULD BE AVOIDED in BATHE study

Product	Allowed in BATHE?	Comments
Aveeno Colloidal Bath Additive	No	Sachets, not liquid
Balneum Bath Oil Plus	No	Contains antipruritic
Dermol 600 Bath Emollient	No	Contains antimicrobial
Emulsiderm Liquid Emulsion	No	Contains antimicrobial
Oilatum Plus Bath Additive	No	Contains antimicrobial