

# An audit of adverse drug reactions to aqueous cream in children with atopic eczema

Cork MJ, Timmins J, Holden C *et al.* Pharm J 2003; 271; 747-748

## Objective

To determine what proportion of children with atopic eczema develop cutaneous reactions to aqueous cream or other emollient creams and ointments.

## Background

A comprehensive emollient regime, comprising creams, ointments, bath oils and soap substitutes, is the first line treatment for atopic eczema. However, patient compliance is poor, most commonly because of a lack of understanding of how emollients should be used. Non-compliance is also often the result of adverse reactions to the prescribed emollient. The authors had noted that adverse reactions appeared to be more common with aqueous cream than with any other emollient. This study was undertaken to determine how many children develop reactions to emollients.

## Subjects

100 children with atopic eczema aged 1-16 years attending a paediatric dermatology clinic at Sheffield Children's Hospital.

## Methods

All reports of burning, stinging, itching or redness developing within 20 minutes of the use of emollients were noted and the relative frequencies following exposure to either aqueous cream or other emollients were compared.

A total of 14 emollients other than aqueous cream had been used, with the result that numbers using any particular one were too small to show statistically significant differences. However, the frequencies of reactions reported were similar for all of them, so the overall frequency for all other emollients was used for comparison.

## Results

A high proportion of the children reported adverse reactions following the application of aqueous cream. Similar reactions were noted after other emollients but much less often.

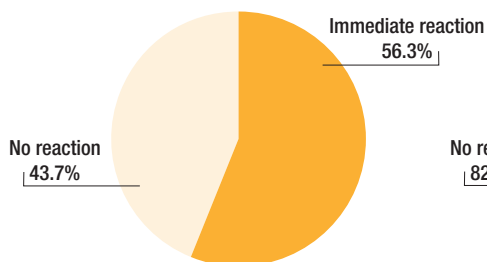
71 of the children had been exposed to aqueous cream. Of these 40 (56.3%) had developed an immediate cutaneous reaction.

There had also been a total of 622 exposures to the other 14 emollients. Only 111 (17.8%) of these resulted in an adverse reaction. The difference was highly significant ( $p < 0.001$ ).

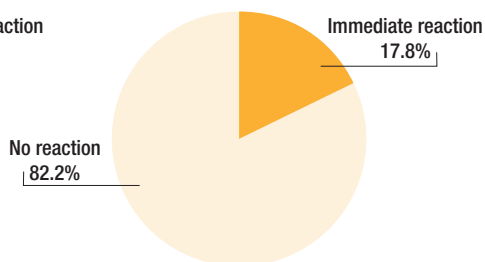
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## Results (cont.)

Frequency of immediate cutaneous reaction with aqueous cream



Frequency of immediate cutaneous reaction with other emollients



### Conclusions

The cutaneous reactions described are not allergic and may occur with any emollient. However they are so common following the use of aqueous cream that it should only be used as a soap substitute and not as a 'leave on' emollient.

If a particular emollient causes an adverse reaction, the child and parent will not use it. The best emollient is one the patient likes and will use regularly. Finding the product which best suits each individual may be a matter of trial and error.

**“The key to successful emollient therapy is education and tailoring the treatment to the individual child.”**

#### Diprobase Prescribing Information

**Uses:** Diprobase Cream and Ointment are emollients, with moisturising and protective properties, indicated for follow-up treatment with topical steroids or in spacing such treatments. They may also be used as diluents for topical steroids. Diprobase products are recommended for the symptomatic relief of red, inflamed, damaged, dry or chapped skin, the protection of raw skin areas and as a pre-bathing emollient for dry/eczematous skin to alleviate drying effects. **Dosage:** The cream or ointment should be thinly applied to cover the affected area completely, massaging gently and thoroughly into the skin. Frequency of application should be established by the physician. Generally, Diprobase Cream and Ointment can be used as often as required.

**Contra-indications:** Hypersensitivity to any of the ingredients. **Side-Effects:** Skin reactions including pruritus, rash, erythema, skin exfoliation, burning sensation, hypersensitivity, pain, dry skin and bullous dermatitis have been reported with product use. **Package Quantities:** Cream: 50g tubes, 500g pump dispensers; Ointment: 50g tubes. **Basic NHS Costs:** Cream: £1.28 (50g), £6.32 (500g); Ointment: £1.28 (50g). Legal Category: GSL. **Marketing Authorisation Numbers:** Cream: 0201/0076; Ointment: 0201/0075.

Further information available upon request from Schering-Plough Ltd, Shire Park, Welwyn Garden City, Herts, AL7 1TW.

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Please refer to the full SPC text before prescribing this product.

Adverse events should be reported. Reporting forms and information can be found at [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk). Adverse events should also be reported to Schering-Plough Drug Safety Department on +44 (0)1707 363773