

A multicentre, open study of efficacy and acceptability of isopropyl myristate 15% w/w / liquid paraffin 15% w/w shower gel (Doublebase Emollient Shower Gel) in patients with dry and pruritic skin conditions

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Introduction

All children suffering from atopic eczema require a complete emollient therapy, consisting of at least a topical emollient and an emollient wash product (NICE guideline, 2007¹). While topical emollients and bath additives are well recognised treatment modalities for these patients, emollient wash products that contain no fragrances, soaps or detergents are being sought after by healthcare professionals. A product that appears to meet these criteria, Doublebase Emollient Shower Gel, has recently become available in the UK. It contains emollients isopropyl myristate (15%) and liquid paraffin (15%), non-ionic soap substitute cetomacrogol 1000 and no fragrances or colouring agents. Patients can choose to apply it immediately before showering, during showering or immediately after showering.

Aim

The aim of this multicentre study was to evaluate the efficacy and acceptability of the shower gel in patients undergoing treatment in general practice for dry and pruritic skin conditions. This clinical study was conducted with full ethics committee approval and in accordance with GCP requirements.



Methodology

- Written informed consents were obtained prior to commencement.
- Inclusion criteria: Male or female patients, upwards of 13 years of age, who normally shower, presenting to their GP with a dry and pruritic skin condition such as eczema, psoriasis, elderly pruritus or dermatitis, and currently receiving prescribed emollient treatment, either alone or as an adjunct to other topical pharmaco-therapy.
- Exclusion criteria: breastfeeding and pregnancy (actually or potentially); patients who do not normally shower; patients older than 13 years but considered 'incompetent' to perform the assessments; patients with acute, weeping or infected dermatoses; those with a history of known or suspected intolerance or skin sensitivity to topically administered products (cosmetics, toiletries or pharmaceuticals) unless it was known that their sensitivity was to ingredients not present in the study emollient; patients who had received an unlicensed drug within the last 30 days, or those scheduled to receive an investigative drug other than the study medication during the period of the study; patients with systemic diseases which, in the opinion of the investigators, may have adversely influenced their participation in the trial; patients considered unable or unlikely to attend the necessary follow-up consultations.
- Patients were asked to use the shower gel daily over the following 14-day period. Detailed written instructions on the different ways of using the product (before, during and after showering) were provided. No instruction was given on the minimum or maximum amount of shower gel that the patients could use; this was according to personal preference. No other emollient/moisturising shower gel products were permitted to be used during patients' participation in the trial.
- The product's effectiveness was assessed by the patients in terms of its effect on four separate characteristics: skin smoothness, skin softness, lack of skin dryness and lack of skin itchiness. The cosmetic acceptability of the product was assessed in terms of texture/feel, lack of fragrance, cleaning action and lack of greasiness. Each was categorised as either 'Excellent', 'Good', 'Satisfactory', 'Poor' or 'Very Poor'. Patients were also asked to indicate the way, or ways, they liked using the product, and whether using the shower gel in addition to their other emollient was more beneficial than using their other emollient alone.
- Information on adverse events and any undesirable features was collected in CRFs, Patient Diaries and by questioning.

Conclusion

Doublebase Shower gel has been considered by patients to be effective in all four performance characteristics, with skin smoothness and softness being particularly positive. The shower gel was also, in general, deemed more beneficial than using other emollients alone. The product's very favourable cosmetic ratings with respect to its texture/feel and lack of greasiness, suggest that patients found it cosmetically appealing. The lack of fragrance was less well accepted. However, this is a necessary product feature as fragrances are notorious skin irritants and sensitisers, and so are best avoided by patients with these skin conditions. It is concluded that this emollient wash is a valuable and convenient addition to the product range, thereby facilitating implementation of complete emollient therapy.

Results & Discussion

93 patients completed the study. The most popular way of using the product was during showering, followed by after showering. Roughly a third of uses involved applying it immediately before showering. The majority of patients found the shower gel to be effective, rating it 'Excellent' or 'Good' with respect to its effects on skin smoothness (71%), skin softness (70%), lack of skin dryness (61%) and lack of skin itchiness (62%) (Table 1). The cosmetic acceptability in terms of texture and lack of greasiness was also high (68% and 59% respectively) (Table 2). The product's cleaning action was 'Good' or 'Excellent' for 57% of patients. Although only 48% of patients reported that the shower gel's lack of fragrance was 'Good' or 'Excellent', a further 37% rated this as satisfactory.

Table 1: Effectiveness of the shower gel

Doublebase Shower Gel Effectiveness	n=93	
	no. of subjects	% of subjects
Skin smoothness		
excellent	14	15%
good	52	56%
satisfactory	20	22%
poor	1	1%
very poor	2	2%
not applicable	1	1%
question not answered	3	3%
Skin softness		
excellent	12	13%
good	53	57%
satisfactory	21	23%
poor	0	0%
very poor	2	2%
not applicable	1	1%
question not answered	4	4%
Lack of skin dryness		
excellent	13	14%
good	44	47%
satisfactory	27	29%
poor	1	1%
very poor	3	3%
not applicable	1	1%
question not answered	4	4%
Lack of skin itchiness		
excellent	17	18%
good	41	44%
satisfactory	23	25%
poor	4	4%
very poor	3	3%
not applicable	3	3%
question not answered	2	2%

Table 2: Cosmetic acceptability of the shower gel

Doublebase Shower Gel Cosmetic acceptability	n=93	
	no. of subjects	% of subjects
Texture/feel		
excellent	10	11%
good	53	57%
satisfactory	27	29%
poor	1	1%
very poor	0	0%
question not answered	2	2%
Lack of fragrance		
excellent	14	15%
good	31	33%
satisfactory	34	37%
poor	7	8%
very poor	3	3%
question not answered	4	4%
Cleaning action		
excellent	12	13%
good	41	44%
satisfactory	26	28%
poor	10	11%
very poor	0	0%
question not answered	4	4%
Lack of greasiness		
excellent	18	19%
good	37	40%
satisfactory	30	32%
poor	5	5%
very poor	1	1%
question not answered	2	2%

The majority of patients (59%) reported that using the shower gel in addition to their other emollient(s) was more beneficial than using the other emollient(s) alone. There were no notable adverse effects

Doublebase Shower - an effective and acceptable alternative to soaps and detergent-based foaming wash products

“Healthcare professionals should inform children with atopic eczema and their parents or carers that they should use emollients and/or emollient wash products instead of soaps and detergent-based wash products.” (NICE guideline, 2007¹). The same guideline also stipulates that these emollients should be *“unperfumed”*.

Patients should be reminded that, *“It is not essential to have bubbles to clean the skin and emollient washing creams are very effective at cleaning the skin.”*

The trial summarised overleaf, shows that Doublebase Shower has been found to be an effective and cosmetically acceptable shower emollient.

Summary of Poster Overleaf:

- The aim of this multicentre study was to evaluate the efficacy and acceptability of Doublebase Shower in patients undergoing treatment in general practice for dry and pruritic skin conditions.
- Patients (aged upwards of 13 years) were asked to use Doublebase Shower daily over 14 days, according to their personal preference. Instructions were provided on the different ways of using the product (before, during and after showering).
- 93 patients completed the study. The most popular way of using the product was during showering, followed by after showering.
- The majority of patients found the shower gel to be effective, rating it ‘Excellent’ or ‘Good’ with respect to its effects on skin smoothness (71%), skin softness (70%), lack of skin dryness (61%) and lack of skin itchiness (62%) (Table 1).
- The cosmetic acceptability in terms of texture and lack of greasiness was also high (68% and 59% respectively) (Table 2). The product’s cleaning action was ‘Good’ or ‘Excellent’ for 57% of patients. Although only 48% of patients reported the lack of fragrance was ‘Good’ or ‘Excellent’, a further 37% rated this as satisfactory.
- The majority of patients (59%) reported that using Doublebase Shower in addition to their other emollient(s) was more beneficial than using other emollient(s) alone. There were no notable adverse effects.

Conclusion:

“Doublebase Shower gel has been considered by patients to be effective in all four performance characteristics, with skin smoothness and softness being particularly positive. The shower gel was also, in general, deemed more beneficial than using other emollients alone. The product’s very favourable cosmetic ratings with respect to its texture/feel and lack of greasiness, suggest that patients found it cosmetically appealing. The lack of fragrance was less well accepted. However, this is a necessary product feature as fragrances are notorious skin irritants and sensitisers, and so are best avoided by patients with these skin conditions. It is concluded that this emollient wash is a valuable and convenient addition to the product range, thereby facilitating implementation of complete emollient therapy.”