

MAPPING THE EMOLLIENT LANDSCAPE OF SOUTH AFRICA

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ABSTRACT

Daily leave-on emollient therapy is a foundation of long-term atopic dermatitis management. Meta-analysis suggests an equivalent efficacy of moisturisers with different base ingredients in reducing the number and prolonging the time to atopic dermatitis flares. South Africa has a large and growing number of leave-on emollients marketed for use in atopic dermatitis patients, making it challenging for healthcare providers and patients to make informed choices. The aim of this study was to map the landscape of leave-on emollients available in South Africa and to create a comprehensive, easy-to-use table to facilitate the informed prescription and use of these products. The table was created by contacting and visiting major department stores, online websites and pharmaceutical company representatives for ingredient lists, cost per gram and availability of emollients specifically marketed for leave-on care in atopic dermatitis. Fifty-eight emollients were included in the first edition of the South African emollient informed prescriber, more than two-thirds of which were occlusive moisturisers with a petrolatum or liquid paraffin base ingredient. Median (range) cost per gram and total ingredient number were R0.45 (R0.10–R4.38) and 10 (1–33), respectively. In all of the tabulated emollients at least one contact sensitiser was identified. The first edition of the 'Emollients in SA: matching cream to patient' informed prescriber was published in September 2018 and was made available at the annual national allergy and dermatology congresses. The prescriber will be updated annually to ensure that emollients new to the market are included, and that pricing and availability information remain accurate.

INTRODUCTION

Atopic dermatitis (AD) is growing in prevalence worldwide.¹ Emerging research has identified epidermal-barrier dysfunction as a critical component in AD pathophysiology. Barrier dysfunction leads to increased skin-moisture loss, a reduced ability to protect against harmful chemicals and an altered microbiome, all of which contribute to a pro-inflammatory immune response.^{2,3} The use of moisturisers counteracts this by providing the skin with exogenous lipids to improve the functioning of a damaged or dysfunctional skin barrier. They decrease trans-epidermal water loss and prevent skin dryness to inhibit the epidermis being penetrated by environmental allergens and pathogens.³ Their use is evidence-based; a recent Cochrane meta-analysis concluded that daily moisturiser use decreased the severity of eczema, the number of flares experienced and the amount of topical corticosteroids needed.⁴

Table I below shows the classification of moisturisers used by the Cochrane investigators into humectants, occlusives and emollients; it highlights their various active ingredients and

modes of action. Moisturisers can be purchased in a variety of formulations – oil-in-water creams, water-in-oil creams, ointments, lotions, oils, gels, sprays and emulsions – and can be further classified into leave-on or bath moisturisers and soap substitutes.⁴ Prescribers recommend emollient for different reasons and consumers are often overwhelmed by both the expanse and the cost of the available products.⁵ Globally, and in South Africa, a large number of moisturisers are marketed to patients with AD. Doctors and patients often have personal preferences without having a solid knowledge of the products available. Products differ widely in availability, complexity and cost. Therefore, the aim of our study was to conduct a comprehensive mapping of the products currently marketed in South Africa in order to produce an informed prescriber that could serve as a resource for our own clinical practice as well as for that of other doctors and patients alike.

METHODS

A large number of moisturisers are marketed in South Africa; therefore, a priori, we needed to develop a set of inclusion and exclusion criteria that would focus the 'mapping' to include

TABLE 1: MOISTURISER CLASSIFICATIONS USED IN THE COCHRANE META-ANALYSIS

	ACTIVE INGREDIENTS	MODE OF ACTION
Hydrophilic/humectant moisturisers	• Urea • Glycerol • Lactic acid	Increases the attraction and retention of water by the stratum corneum to maximise hydration.
Lipophilic/occlusive moisturisers	• Petrolatum • Paraffinum liquidum • Dimethicone	Creates a waterproofing barrier to prevent trans-epidermal water loss and evaporation.
Emollient moisturisers	• Lanolin • Glycerol stearate • Soy sterols	Soften and smoothen the skin.

moisturisers of most benefit to AD patients and their doctors. We compiled a comprehensive list of all the available South African emollients using both online and in-store searches. Inclusion criteria restricted products to those marketed specifically as leave-on emollients for the prevention of 'AD', 'atopic skin' or 'eczema'; and available either on-line or in-store for South African consumers. Exclusion criteria meant that products marketed for 'dry skin conditions' or specifically for acute care in AD flares were not included. The project was approved by the University of Cape Town, Faculty of Health Science Research Ethics Committee (612/2017).

Products were identified and photographed at common South African department stores. In-store employees were consulted to ensure that no 'out-of-stock' products were excluded. Sales representatives from a list of pharmaceutical companies were contacted regarding their products and an advertisement was placed on a private Facebook page that has many pharmaceutical sales representatives as members. Samples of state-supplied emollients were also collected from Groote Schuur Hospital and included in the list.

Products were then divided by their base ingredients and tabulated according to:

- their total number of ingredients;
- sizing;
- price per gram;
- in-store availability, and
- presence of AD sensitisers.

Contact sensitisers were classified according to the tables found in Osinka et al and Uter et al.^{6,7} The final tables were then sent to a random sample of local dermatologists and allergists for review in order to ensure that no accidental omissions had occurred. Certain creams have received the Allergy Foundation of South Africa's (AFSA's) seal of approval for body-care products (<http://www.allergyfoundation.co.za/about-us/seal-of-approval>). To receive this seal of approval, manufacturers must either have supplied verifiable results of independent testing or testing must have been carried out for AFSA by independent laboratories to standards created by leading allergy specialists. It must be noted that the absence of the AFSA seal does not imply non-

adherence to the recommended criteria: this is a new initiative and therefore many companies have not yet been through the application process.

We are conducting ongoing research in both healthy volunteers and AD patients to determine users' perceptions of emollients' qualities of 'thickness', 'greasiness', 'stickiness' and 'discomfort under clothing'. Seven emollients – each representing a different active ingredient (cetamacrogol, 5% and 10% urea, liquid paraffin, oat, shea butter, and ceramides and omegas) – were chosen. The rating of their properties was done semi-quantitatively using a scale of 1–4 ('does not possess property', 'uncertain', 'possesses the property' and 'very much possesses the property', respectively). In this first edition of the prescriber we show preliminary data from this work.

RESULTS

In September 2018, the first edition of the 'Emollient in SA: matching cream to patient' prescriber was published with the assistance of AFSA. It was distributed at both the allergy and the dermatology annual national congresses. The prescriber contains brand names and therefore cannot be published with this journal article. However, it is available in print form from AFSA or as a downloadable pdf at <http://lunginstitute.co.za/aiu/>.

A total of 58 emollients were included, 13 of them already bearing the AFSA seal of approval. The products were tabulated according to base ingredient: 13 with a cetomacrogol base, 19 with a petrolatum or paraffin base, seven with a urea base and 19 with a variety of other base ingredients. According to the Cochrane meta-analysis classification, 78% (45/58) of the available South African moisturisers are occlusive moisturisers.

The median number of ingredients for included products is ten, with the number of ingredients ranging from a single ingredient in the state-supplied liquid paraffin to up to 33 ingredients in three other moisturisers. The median price per gram was R0.45, the price per gram ranging from R0.10 to R4.38. All the aforementioned prices were accurate as at August 2018. It was found that all the included products contained at least one contact sensitiser according to the Osinka and Uter et al tables.^{6,7}

Preliminary results from the semi-quantitative trial of emollient properties displayed on the prescriber showed little variation between perceptions of the properties of the emollients.

DISCUSSION

This study has produced the first comprehensive prescriber of leave-on 'Emollients in SA: matching cream to patient', organised into a visually attractive, two-page card for ease of use. It aims to be a go-to clinical resource for clinicians and patients that will serve to simplify an otherwise complex area, similar to the posters of asthma-inhaler devices and products collated by the National Asthma Education Programme (NAEP). We hope that it will aid clinicians and AD patients to make informed decisions regarding their daily emollient use by helping

them to choose products that suit their financial constraints and personal preferences. The prescriber will be updated annually in order to incorporate new emollients and to adjust prices.

Emollient use is poised to have a place not only in the daily management of AD, but also potentially in efforts to prevent the development of AD as well as associated atopic conditions, including asthma and food allergy. Details of preliminary proof-of-principles studies and ongoing randomised controlled studies, such as Barrier Enhancement for Eczema Prevention (BEEP), PEBBLES and PREVENTADELL, have been reviewed in the previous issue of *Current Allergy and Clinical Immunology*.⁸ Should the results of these trials be favourable and indicate the need for large-scale emollient use from early infancy, there will no doubt be a surge in the development and marketing of new emollients. This will mean further growth to an already-full market; and it underscores the need for ongoing efforts to synthesise and present available products in an easily accessible and up-to-date format.

The large number of marketed moisturisers, as well as their unregulated nature, stresses the need for both independent evaluation and comprehensive mapping to ensure consumer safety and allow an easy comparison of characteristics. The South African Health Products Regulatory Authority (SAHPRA, formerly the Medicines Control Council) does not include emollients under the same regulatory framework as other pharmaceuticals. This means that it is very easy for potentially ineffective or even harmful products to be marketed to AD patients. For instance, every product we considered had at least one known contact sensitiser, and some contained multiple sensitisers. We also noted from our own clinical experience (JP) that we were unaware of some of the moisturisers in our comprehensive table, having recommended to AD patients either those we had used for many years or those introduced by a recent marketing person. These observations and concerns were key drivers of this study, and of the need for information to be made available to both prescribers and the public.

The Cochrane meta-analysis found that there is relatively little difference in efficiency and safety between different moisturiser groups. However, a qualitative review by Santer et al suggested that patient perceptions have a significant impact on the type

of emollient used and on compliance with them.⁹ Certain participants complained of reactions to particular creams and ointments; many participants described certain creams as 'extremely thick', greasy and difficult to apply.⁹ Allergologists often note that 'the best emollient is the one the patient will use'. Therefore, as a continuation of our mapping project, our research aimed at attempting to study perceptions of 'thickness', 'greasiness', 'stickiness' and 'discomfort under clothing' among both healthy volunteers and atopic dermatitis patients is ongoing.

The only limitation of this work may be the omission of certain emollients, given our inclusion or exclusion criteria. We have been encouraged, though, by the fact that more than three months since publication, we have not been contacted by dermatologists, allergologists or companies to complain about omissions. We hope that this is an indication that the table is comprehensive. An annual update of the prescriber will also allow us to consider omitted products, update pricing and, hopefully, add improved patient-perception data.

CONCLUSION

Daily leave-on emollient use for AD is guideline-driven and poised to increase if use in the prevention of other atopic disease is confirmed. Easy-to-use tools synthesising the available products and allowing patients and doctors to compare characteristics will become increasingly important with this growing market. We hope that this 'Emollients in SA: matching cream to patient' informed prescriber will become an increasingly valuable resource for South African doctors and patients alike and help to ensure the growth and continued use of emollients throughout South African communities.

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DECLARATION OF CONFLICT OF INTEREST

The authors declare no conflict of interest.

This article has been peer reviewed.

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