

A further call for full declaration of fragrance ingredients in medicaments

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More than 10 years ago, a case was published of an undeclared fragrance ingredient in a tar-based shampoo used for a scalp dermatosis.¹ The lack of adequate labeling resulted in an allergic contact dermatitis. It would unfortunately seem that little has changed since then. We describe a case where an inadequately labeled fragrance ingredient in a medicament caused the consumer harm.

CASE REPORT

A 79-year-old man presented with a history of recurrent staphylococcal boils and positive carrier sites on bacterial swabs. He was commenced on oral antibiotics and an eradication program with Hibiscrub 4% chlorhexidine wash (Mölnlycke, Oldham, U.K.), using the product as recommended by the manufacturer to the axillae and groin areas, with a different chlorhexidine-containing cream used to treat the nostrils. A few days after commencing the treatment, he developed an acute dermatitis only in the axillae and groin, which was initially presumed to be an irritant contact dermatitis and the Hibiscrub was discontinued. The rash persisted for 2 weeks. On review of his medical records, he was noted to have had patch test positivity to *Evernia furfuracea* 2 years previously (but was negative on testing to chlorhexidine). The ingredient label of Hibiscrub (Figure 1) revealed that the product contains perfume, listed as “Herbacol.” The Mölnlycke website gave no further details. The composition of “Herbacol” could be established only by reference to the summary of product characteristics,² which confirmed the presence of many fragrance ingredients including “tree moss” (INCI name *Evernia furfuracea*). The persistence of the clinical reaction was highly suggestive of an allergic reaction, rather than an irritant one, and the patient subsequently underwent successful and asymptomatic eradication of his *Staphylococcus aureus* infection with Octenisan (which does not contain

Evernia furfuracea). A repeated open application test with diluted Hibiscrub was positive on the left forearm after 3 days, confirming

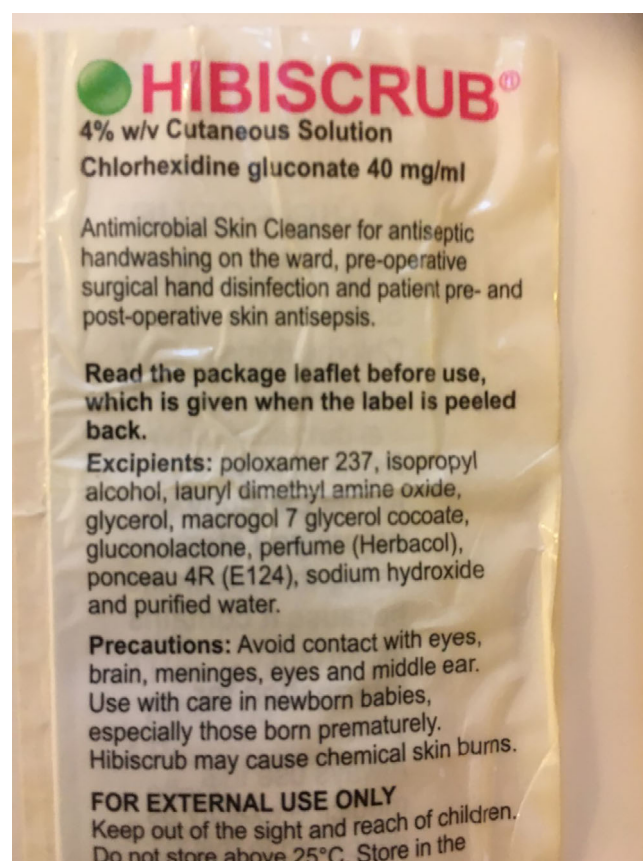


FIGURE 1 Ingredient label of the Hibiscrub product used by our patient

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the surprising diagnosis of an iatrogenic allergic contact dermatitis to *Evernia furfuracea* in Hibiscrub wash.

DISCUSSION

Consumers are clearly still at risk from inadequately (or un-) declared excipients (particularly fragrance chemicals) in medicaments. This case illustrates that not only patients, but also health care professionals may be misled. We see no reason why such fragrances should not be declared in the same manner as for cosmetic items, ideally with uniform (INCI) terminology. This would aid the prevention of allergic contact dermatitis and alleviate morbidity in our patients. The manufacturers state on the information label on Hibiscrub "Other possible side effects, for which it is not known how often they occur are: allergic skin disorders such as dermatitis...". If the product labeling is inadequate, it seems unlikely that the manufacturer will ever gather relevant information about allergic contact dermatitis from their product. It is likely that allergic contact dermatitis from medicaments is generally underreported, as many cases will be misdiagnosed as an irritant contact dermatitis. We call for adequate labeling of

medicament excipients to give the consumer at least as much information as that present in cosmetic items.

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