

Surrogate advertisement of a super-potent corticosteroid-containing cream: An alarming development and a cautionary tale of its consequences

Sir,

Topical corticosteroid misuse and the effects thereof have been a major challenge to Indian dermatologists in recent years. It has led to a deluge of patients with red face syndrome, steroid acne, skin atrophy and myriad other adverse effects.¹⁻³ The current outbreak of poorly responsive and widespread tinea has also been blamed on the misuse of fixed drug combination creams containing potent or super-potent corticosteroids.⁴ Apart from this, two factors contributing to this misuse are: (a) the poor regulation of direct-to-consumer advertisements of drugs in India, and (b) the unrestricted availability of almost all topical and systemic drugs without a prescription. We report a recent case that exemplified these problems and starkly outlined how they can play havoc with the health of our patients.

A 5-year-old boy presented with a 10 cm annular, inflamed, itchy lesion surrounded by a hypopigmented halo on the left ankle of 2 months' duration. It started as an itchy papule that gradually enlarged over a week. At this time, the boy's father, a software engineer, went online and searched for possible remedies. After a brief internet search, he concluded that the boy had tinea and then came across the advertisement of a brand of antifungal cream. He studied the brand's ingredients on some other websites, concluded that it would be safe and effective and bought it from a local pharmacy. On applying this cream, the lesion initially improved slightly but started increasing in size later on. After 1 month of continuous use, it had enlarged considerably and the parents visited us.

On probing further, the following story emerged: The father had seen the advertisement of a popular cream called Ring Guard™ containing 2% miconazole nitrate. Because this brand was not available at a local pharmacy, another brand called Ring Out™ with exactly the same ingredient was offered to him. He immediately confirmed the active ingredient on his mobile phone, found it to be miconazole 2% and agreed to buy the offered alternative brand. He was then sold a cream called Ring Out+™, but he failed to notice the minor difference in brand name given the almost identical packaging. This particular brand contained clobetasol, neomycin and clotrimazole instead of miconazole, the use of which likely led to the exacerbation of tinea and surrounding hypopigmentation. On confronting the pharmacy salesperson, he claimed that Ring Out™ cream had been out of stock for a few months while Ring Out+™ had been introduced recently, and he had assumed that the latter was a newer version of the former with similar

ingredients.

Self-medication by laypersons is a well-known phenomenon. Some self-medication is actually desirable, so that health care facilities are not overrun by patients with trivial complaints. However, safe self-medication is predicated on clear-cut guidelines for over-the-counter drug sale and strict oversight on advertisements. In a study on Indian housewives, it was found that topical agents were the third most commonly used drugs for self-medication after analgesics and antacids.⁵

We tend to associate topical steroid misuse with poorly educated patients who take wrong advice from friends, pharmacists, quacks or even qualified practitioners. In this case however, a highly educated man who was well aware of the problems associated with topical corticosteroids, who spent considerable time collecting medical and product information from the internet, and who cross-checked information given by the pharmacy salesperson still ended up applying a super-potent steroid on the skin of his 5-year-old son for more than a month. Some factors that led to this unfortunate outcome are discussed in brief below.

There is no clear-cut definition of over-the-counter medicines in Indian drug law. This term is not even mentioned in the Drugs and Cosmetics Act, 1940, or the Drugs and Cosmetics Rules, 1945.⁶ There are lists such as schedule H, schedule H1 and schedule X which enumerate drugs that cannot be sold without a prescription, but adherence to these guidelines at pharmacies is extremely poor and many commonly used drugs are missing from schedule H. Corticosteroids are mentioned there, but can easily be bought without any prescription, as happened in this case. There are clear-cut rules that prohibit the direct-to-public advertising of schedule H drugs without the government's prior permission, but these are openly flouted⁷. Print and electronic media are flooded with completely unregulated advertisements of fixed drug combination creams containing potent and super-potent corticosteroids.

Although these issues are well known in Indian medical circles, there are more disturbing facts that came to our notice in this case. When searching online, it became clear that Ring Out™ cream was being advertised heavily on social media, TV channels and in print. However, exactly the same brand name was apparently available with two completely different sets of ingredients in the market. Ring Out™ cream was shown to contain miconazole 2% at the manufacturer's



Figure 1a: Advertised cream that is unavailable; contains miconazole 2%. (Image source: <https://www.ring-out.in>)

website,⁸ whereas at several online pharmacies, the same cream was shown to contain beclomethasone, neomycin and clotrimazole.^{9,10} When we attempted to buy either version of the brand, we failed to find a single tube at any online pharmacy. Similarly, we drew a blank when we tried to buy it at physical pharmacies in five different cities all over India. The only way we could get a tube of this cream was by asking the manufacturer, who sent it by courier. We were informed by them that the triple-combination version had never existed, the brand had always contained miconazole 2%. The mention of the sold-out triple-agent Ring Out™ cream at several online pharmacies was allegedly due to human error.

Ring Out+™ cream, however, was easily available over the internet, even at general e-commerce websites without any prescription.¹¹ It was freely available in physical pharmacies as well, in an absolutely identical packaging to that of Ring Out™ [Figure 1], albeit with the small “+” symbol. The unavailability of a heavily advertised brand and the easy availability of a very similar-looking and sounding one manufactured by the same company clearly marked this as a case of surrogate advertising. It also seemed that the same brand name Ring Out™ was somehow approved for marketing a corticosteroid–antifungal–antibacterial cream, as well as a miconazole cream.

Two profoundly worrying conclusions can be drawn from the above. One, the Indian pharma industry is going the way of the alcohol and tobacco industries by using surrogate advertising to fraudulently sell harmful products to a gullible public.¹² Two, there is something amiss in the drug regulatory setup in our country. Not only are irrational drug combinations approved for marketing, but similar-sounding brand names are approved for widely differing drugs/combinations. Most worryingly, pharmaceutical products bearing the same brand name seem to be in the market with two different sets of active ingredients. For the consumer, it means that buying the same brand name drug is no guarantee that the same active ingredient is being dispensed.



Figure 1b: Unadvertised cream that is freely available; contains clobetasol 0.05%, clotrimazole 1% and neomycin 0.5%. (Image source: <https://www.ring-out.in>)

It is high time that a clear cut official over-the-counter drug category is created in our country, and direct-to-consumer advertisements of these drugs are strictly regulated. Drug regulatory authorities should also ensure that companies cannot alter the ingredients of their brands without having to substantially change the brand name; that very similar-sounding brand names are not approved at all, and that laws restricting advertisements of prescription-only drugs are properly enforced. If this is not done, it will become virtually impossible for patients to avoid therapeutic misadventures and accidents, as happened in the index case.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the legal guardian has given his consent for images and other clinical information to be reported in the journal. The guardian understands that names and initials will not be published and due efforts will be made to conceal patient identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

Abir Saraswat, Rajetha Damisetty¹

Indushree Skin Clinic, Lucknow, Uttar Pradesh, ¹Mohana Skin and Hair Clinic, Hyderabad, Telangana, India

Correspondence: Dr. Abir Saraswat,
Indushree Skin Clinic, B-7, Indira Nagar, Lucknow - 226 016,
Uttar Pradesh, India.
E-mail: abirsaraswat@yahoo.com

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