

INDIAN ASSOCIATION OF DERMATOLOGISTS, VENEREOLOGISTS & LEPROLOGISTS (IADVL) 2016



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12 August, 2016

To

Dr. G. N. Singh,

The Drugs Controller General of India,

New Delhi

Dear Dr. Singh,

Topical steroids are a boon of patients who suffer from inflammatory skin diseases. Sadly, topical steroid abuse has become an epidemic in India due to numerous medical, social and legislative factors. India has numerous potent topical steroid preparations in combination with antifungals and antibiotics. These triple and quadruple combinations are rampantly abused, leading to serious, sometimes permanent side effects.

Recalcitrance of common superficial fungal infections of the skin to routine treatment is also attributable to misuse of topical steroid-containing creams. Mometasone, hydroquinone and tretinoin containing creams have contributed to the abundance of “topical steroid damaged facies” in this skin-fairness obsessed nation.

IADVL strongly feels that all irrational topical steroid combinations that exist today should be banned, to safeguard the skin health of Indian populace. Existing guidelines from other countries or international agencies only apply to situations where patients cannot get indefinite prescription refills without regular visits to the prescribing physician. We need more stringent regulation at the level of production as there are huge challenges in implementing schedule H across this huge country.

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As per our discussion on 1st April, 2016, we are happy to send a **list of irrational and/or dangerous FDCs which should not be in the market.**

1. Any antibiotic/antimicrobial and antifungal with any steroid molecule. All triple and quadruple combinations should be banned. This should apply to those with local anesthetics or with other drugs added to antibiotic/antimicrobial/antifungal combinations.

2. Any antibiotic/antimicrobial OR antifungal with the following steroid molecules, in ointment, cream, foam or lotion form:

Alclometasone
Beclomethasone
Betamethasone dipropionate
Clobetasol propionate 0.05%
Clobetasone
Desonide
Desoximetasone
Diflorasone diacetate
Fluocinonide
Fluocinolone acetonide
Halobetasol propionate
Halometasone
Methylprednisolone aceponate
Mometasone furoate
Prednicarbate
Triamcinolone acetonide

3. Any antifungal with the following steroids in cream, lotion or ointment form:

Dexamethasone
Fluticasone propionate 0.05%/0.005%
Hydrocortisone

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4. Modified Kligman's formula with **tretinoin and hydroquinone or any other combination of lightening agents with the following steroids**

Mometasone furoate 0.1%

Fluticasone propionate 0.005%

Any steroids other than the one mentioned in point 3 above

Proposed acceptable formulations:

1. Any steroid with salicylic acid/urea/lactic acid and similar penetration enhancers and keratolytics/humectants.

2. Antibiotic combinations

Mupirocin with hydrocortisone butyrate/acetate or fluticasone propionate

Fusidic acid with betamethasone valerate 0.1%/0.12% / hydrocortisone 1%

Dexamethasone with framycetin

3. Modified Kilgman's formula containing

Fluocinolone acetonide 0.01%

Hydrocortisone 1% / hydrocortisone acetate 1%

Classification of topical steroid containing FDCs, in the order in which we would like the DCGI appointed committee to scrutinize the preparations:

Category A (High priority, to be examined by the FDC scrutiny committee at the earliest)

1. All triple and quadruple combos containing antimicrobials/antibiotics
2. Mometasone-hydroquinone-tretinoin combos

Category B (second priority)

1. Halobetasol, clobetasol, betamethasone dipropionate, beclomethasone dipropionate and mometasone furoate in combination with antifungals or antimicrobials

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Category C (third priority)

1. Antifungals in combination with Fluticasone propionate 0.05%/0.005%, Triamcinolone 0.1%, Hydrocortisone butyrate 0.1%, Hydrocortisone valerate 0.2%, Fluocinolone acetonide 0.025%/0.01% and Desonide 0.05%
2. All other topical steroid containing FDCs other than the ones approved.

We appreciate your support and endeavors towards stopping topical steroid misuse in India and hope that this class of steroid containing FDC creams which are irrational and fraught with potential of abuse will soon be a thing of the past.

Yours sincerely

Dr. Devesh Mishra
President, IADVL

Dr. Shyamanta Barua
Hon. Secretary General, IADVL

Dr. Rajeev Sharma
Chairperson, ITATSA

Dr. Rajetha Damisetty
Convener, ITATSA

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