doi:10.36849/JDD.10424

 ORIGINAL ARTICLE Journal of Drugs in Dermatology

Topical Corticosteroid Approved Labeling in the US: A Modern Inter- and Intra-Product Analysis

Adam J. Friedman MD,[a] Lawrence F. Eichenfield MD,[b] Mark Boguniewicz MD,[c] Elaine C. Siegfried MD,[d] Douglas DiRuggiero DMSc,[e] Lisa Weiss MMSc,[f] Melissa S. Seal PhD,[g] Brett Stephenson PharmD,[g] Raja Mikkili MA,[g] Robert C. Higham MPAS,[g] Diane Hanna DNP DCNP FAANP,[g] Alexandra K. Golant MD[h]

[a]George Washington School of Medicine and Health Sciences, Washington, DC
[b]Departments of Dermatology and Pediatrics, University of California San Diego-School of Medicine and Rady Children's Hospital, San Diego, CA
[c]National Jewish Health, Denver and University of Colorado School of Medicine, Aurora, CO
[d]Division of Pediatric Dermatology, Saint Louis University School of Medicine, St. Louis, MO
[e]Skin Cancer and Cosmetic Dermatology Center, Rome, GA
[f]Goodman Dermatology, Canton, GA
[g]Arcutis Biotherapeutics, Inc., Westlake Village, CA
[h]Icahn School of Medicine at Mount Sinai, New York, NY

ABSTRACT

Background: A wide variety of prescription-strength topical corticosteroids (TCS) have been commercially available for many decades. Product labels often vary, reflecting inconsistent guidance for dosing, duration of use, and safety.

Objective: This study was designed to analyze and compare dosing and safety information among TCS product labels approved by the United States (US) Food and Drug Administration (FDA).

Methods: The FDA's openFDA Public Label API was used to collect US TCS labels. The content of each label was searched for safety terminology and quantitative use limits. These data were assessed for consistency across products.

Results: Warnings for a variety of adverse events (AEs) were found in TCS labels including, but not limited to, allergic contact dermatitis, skin infections, hypothalamic-pituitary-adrenal (HPA) axis suppression and Cushing syndrome, cataracts and glaucoma, and carcinogenesis. However, none of these warnings were included in all labels and were inconsistent among labels for the same active ingredient. Recommended limits on treatment duration and total weekly dose were included in some labels (35% and 22%, respectively) but many had no limits. If TCS are applied as described in the labels, patients with ~15% or greater affected body surface area will exceed weekly dose limits for HPA axis suppression.

Conclusions: FDA-approved product labels are intended to inform clinical decision support systems. TCS product labels unfortunately do not contain warnings for known AEs and have inconsistent or absent dosing recommendations. Lack of guidance and inconsistent safety information diminish awareness of the risks associated with long-term use and/or overuse of these medications and can impact access. TCS label review and revision are warranted to eliminate inconsistency, modernize language around warnings and precautions, and provide clear dosing instructions and exposure limits to better inform clinicians, patients, and caregivers about safe use of these medications.

J Drugs Dermatol. 2026;25:11(Suppl 1):s11-20.

INTRODUCTION

Topical corticosteroids (TCS) have been prescribed for over 70 years by a number of medical specialties to treat a range of inflammatory dermatoses.[1,2] These drugs have evolved to include a variety of formulations across a wide spectrum of potencies, each with exposure-related risks impacting safe treatment durations, dose limits, and application sites.[2-5]

Cutaneous (eg, barrier compromise, atrophy, striae, dyspigmentation) and systemic (eg, adrenal insufficiency, cataracts) TCS adverse events (AEs) are well documented.[2-5] The risks increase with overuse from prolonged, frequent, and/or widespread application, application under occlusion, use of higher-than-necessary potencies, and concomitant use of multiple formulations for differing indications. Use of high-potency TCS on high-risk sites (eg, face and skin folds) carries an increased risk of percutaneous absorption and associated systemic AEs. These risks are greater for children.[2]

Increasing recognition of TCS-associated AEs has prompted statements and updated regulations regarding safe use from several organizations outside of the US: the United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA), Health Canada, and the Food and Drug Administration (FDA) of the Philippines.[6-8]

The long history of TCS use, increasingly rigorous US FDA clinical trial and product labeling requirements, and a substantial increase in safety and efficacy data has yielded inconsistent TCS labeling. Drug prescribing information is designed to provide a comprehensive overview of the product to support treatment selection and enable safe and effective use. These labels are used to inform several popular clinical decision support systems (eg, Micromedex®, epocrates®, UptoDate®). Thus, inconsistent labeling within a drug class, or contradictions within a single label, may generate confusion, misuse, overuse, and AEs as well as suboptimal adherence and efficacy.

The goal of this manuscript is to provide a comprehensive analysis of dosing and safety information among all existing US FDA-approved TCS product labels. We offer suggestions to encourage updated and uniform TCS labels based on these findings.

MATERIALS AND METHODS

The US FDA's openFDA Public Label API at api.fda.gov/drug/label.json, was used to collect existing US TCS labels from two sequential queries executed on April 16, 2026.

- Query 1: filtered on openfda.pharm_class_epc containing "corticosteroid" and route containing "topical"
- Query 2: a supplemental query filtered on specific substance names that were underrepresented in query 1 (eg, clobetasol, mometasone, halobetasol, betamethasone, fluticasone) due to incomplete pharmacologic class tagging on openFDA

Result sets were then merged and deduplicated.

The content of each label was searched for quantitative use limits and safety terminology based on well-known TCS-associated ocular AEs,[9,10] hypothalamic-pituitary-adrenal (HPA) axis suppression with adrenal insufficiency,[11] and a recently recognized concern of topical steroid withdrawal (TSW) that is distinct from rebound following TCS discontinuation.[12,13] Structured fields were extracted using regex patterns anchored to standard US FDA label phrasing: pediatric-specific; cataracts/glaucoma; diaper-dermatitis-prohibited; ophthalmic-warning; surgery/adrenal-concern; nursing-mothers; pregnancy-category-C; carcinogenesis-positive-finding; HPA-quantitative-threshold; maximum grams per week; maximum duration in weeks; minimum pediatric age; presence of boxed warning; and presence of HPA, Cushing, or atrophy terminology. References to TSW were extracted using the search terms "topical steroid withdrawal," and "topical corticosteroid withdrawal." Terms serving as possible proxies for TSW based on potential misclassification were "red skin syndrome," "tachyphylaxis," and "rebound", but only a few instances were found (see RESULTS).

The most-prescribed TCS and their 2023 prescription (Rx) volumes were extracted from ClinCalc DrugStats Database v2025.08 (published at https://clincalc.com/Drugstats/), mapped to the open FDA substance name field, and combined with the FDA's Structured Product Labeling standard (SPL)-level data from the TCS queries to produce a list of the top 50 TCS by volume. Volume was ranked at the molecule (salt/ester) level because ClinCalc/MEPS publishes per-molecule volume, not per stock-keeping unit (SKU).

Using the top 50 listing of TCS molecules, a full set of safety elements in labels was identified. The list included: risk of HPA axis suppression, risk of Cushing disease, risk of skin atrophy, risk of cataract/glaucoma, risk of intracranial hypertension, risk of faltering growth, pediatric-use section included, risk of carcinogenesis, quantitative HPA dose threshold, weekly dose in grams limit, duration limit, and modern pregnancy format. Each label was scored 0 to 12 based on the number of these elements that were present. Labels were then analyzed by format. The modern format uses a combined Warnings and Precautions section and the removal of Pregnancy Categories.

RESULTS

Collected Data

Query 1 returned 736 labels, while query 2 returned 316 additional labels. These result sets were merged and deduplicated to yield 1052 unique labels. The 1052 labels included 724 Rx and 328 over-the-counter (OTC) labels. The 724 Rx labels involved 21 unique corticosteroid salt/ester molecules at multiple strengths in various formulations. Combination products with antifungals, vitamin D, and other agents were not excluded.

Despite the name 'Top 50,' the top 50 TCS by 2023 US Rx volume were represented by 61 unique SKUs spanning 19 salt/ester molecules. Since all SKUs of a molecule share one volume figure, they are retained rather than split at the rank-50 cutoff. These constitute approximately 99% of US TCS prescribing volume. The distribution of potencies of these products is shown in Table 1.

TABLE 1.

Potency of Top 50 Corticosteroids Represented by 61 Unique Stock Keeping Units	
Potency Class	**Corticosteroids, n (%)**
Super (Class I)	14 (23)
High (Class II)	11 (18)
Upper mid (Class III)	4 (7)
Mid (Class IV)	7 (11)
Lower mid (Class V)	12 (20)
Mild (Class VI)	9 (15)
Least (Class VII)	3 (5)
Not specified	1 (2)

Warnings and Precautions

Of the 1052 TCS labels, none contained boxed warnings.

The Warnings and Precautions sections of the Rx TCS labels indicated that TCS are associated with HPA axis suppression and Cushing syndrome, ophthalmic AEs, and carcinogenesis. Other sections of the labels contained precautions for use by nursing mothers and a recommendation to notify clinicians that the patient is using TCS if surgery is planned.

Warnings for effects on the endocrine system such as HPA axis suppression and Cushing syndrome were found in 98% (708/724) of all TCS Rx labels and 100% (61/61) of the top 50 TCS Rx labels. The exact wording of the warnings varied widely but consistently described the effects of HPA axis suppression as "reversible upon discontinuation."

Although ocular AEs (eg, glaucoma and cataracts) are known corticosteroid AEs, only 17% (125/724) of Rx labels and 21% (13/61) of the top 50 labels identified contained a warning for them. The majority of mentions were found in labels for mometasone furoate (94% [33/35]) and betamethasone dipropionate (62% [52/84]).

A consistent statement about the possibility that TCS could appear in human milk and possibly suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects in children was found in 89% (645/724) of Rx labels and 93% (57/61) of top 50 labels.[16]

Less common warnings included findings of carcinogenesis in animals in 7% (50/724) of Rx labels and 8% (5/61) of the top 50 labels, most of which were for mometasone and alclometasone. A statement that recommends alerting physicians about TCS use if surgery is planned appears in 8% (58/724) of Rx labels and 13% (8/61) of the top 50 labels, typically for high potency agents (clobetasol propionate and fluocinonide) in Section 17 Patient Counseling Information.

The search did not identify any labels using the terms "topical steroid withdrawal," "topical corticosteroid withdrawal," "red skin syndrome," or "tachyphylaxis." "Rebound" was mentioned in 0.5% (5/1052) of labels, all of them for calcipotriene+betamethasone combination products. In these 5 labels, "rebound" was listed as a post-marketing AE with no discussion of it as possibly being TSW.

When classifying each prescription label by template format—legacy (pre 2006) versus modern (post 2006)—legacy-template labels contained means of 7.4 of 12 modern safety elements, versus 10.3 for modern-template labels (Figure 1A). Within-molecule completeness also varies, with labels in the modern template generally having higher scores (Figure 1B). Original US approval year correlated with completeness across the 17 base molecules (Pearson $r \approx 0.61$).

Completeness did not correlate with the timing of the most recent label update ($r = -0.01$) (Figure 1C) but instead correlated with the original template era.

Dosing Limits

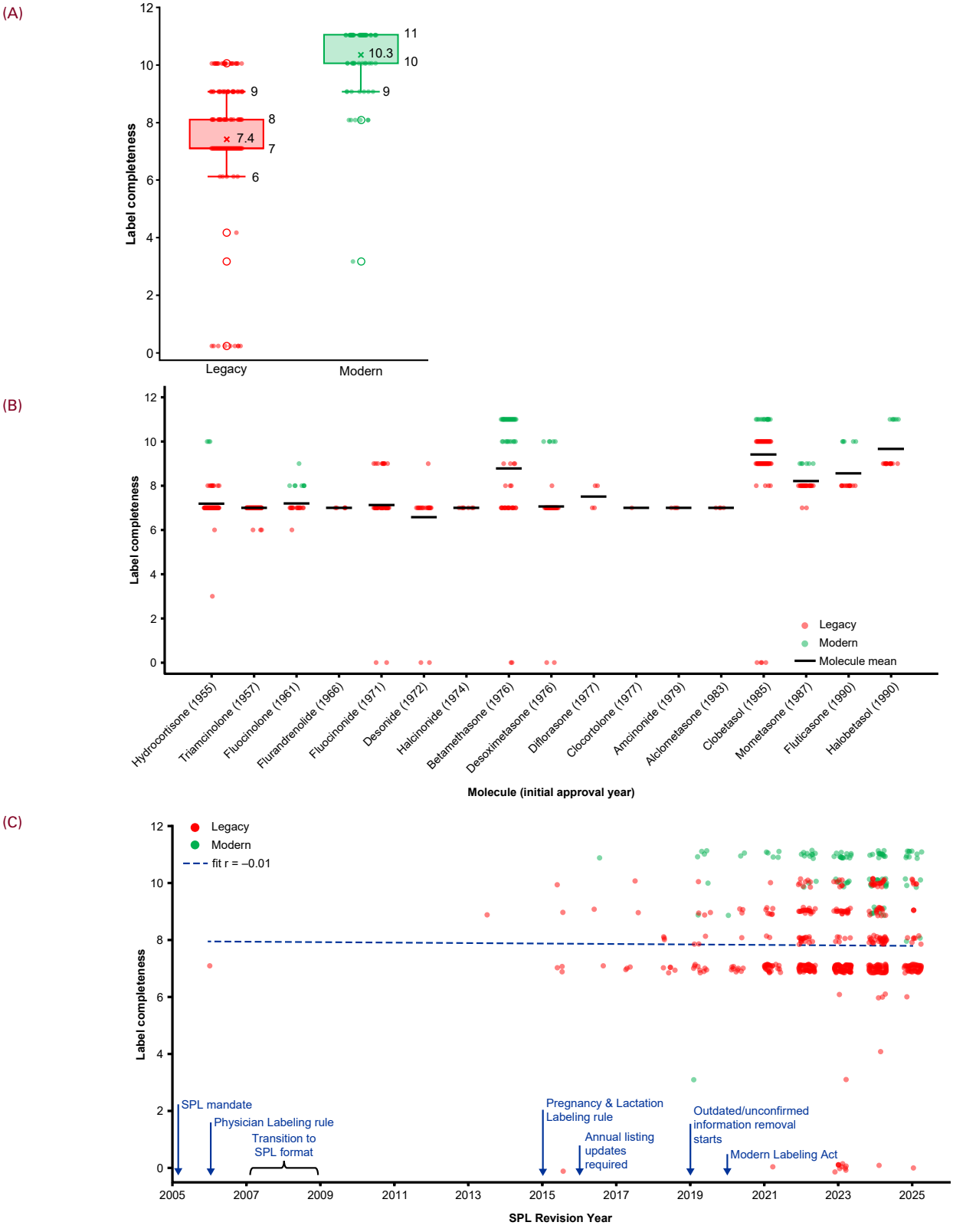
Many treatment guidelines recommend against long-term, continuous TCS use.[14,15] However, a maximum treatment duration was specified in only 35% (252/724) of Rx TCS labels and 49% (30/61) of the top 50 Rx TCS labels. Of the labels stating a maximum, 2 or 4 weeks were the most common durations for Rx TCS labels (85% [214/252]). Among the top 50 labels, maximum treatment duration was most often (80% [24/30]) included in labeling for super potent TCS (Class I) (Figure 2).

Total dose limitations to lower the risk of AEs were also included in some labels. Limits on total grams per week were found in 22% (156/724) of Rx labels and 25% (15/61) of the top 50 Rx TCS labels, with 75% (117/156) and 93% (14/15) of these specifying a 50 g/week limit. Dosage limits were mostly noted in labeling for super, high, and upper mid potency TCS (Class I-III, Figure 3), such as clobetasol, halobetasol, and betamethasone dipropionate. Quantitative dose limits specifically to reduce the risk of HPA axis suppression, most commonly 2 g/day, were found in 12% (88/724) of Rx labels and 44% (27/61) of the top 50 labels.

Directions for Use in Pediatric Patients

The minimum age for use was listed as 3 months in 4% (29/687) of Rx labels, 2 years in 5% (36/687), and 12 years in 23% (160/687), while 5% (32/687) were restricted to adults ≥18 years. The remainder (62% [428/687]) stated no explicit age minimum. The reasons for age restrictions were not stated. Note that in this analysis, 37 combination products (36 nystatin+triamcinolone and 1 acyclovir+hydrocortisone) were excluded because the non-corticosteroid agent carried a pediatric age restriction.

FIGURE 1. TCS label completeness: (A) Label completeness by template era (legacy vs modern). (B) Within-molecule completeness spread. (C) Completeness vs SPL revision date with major FDA labeling changes.



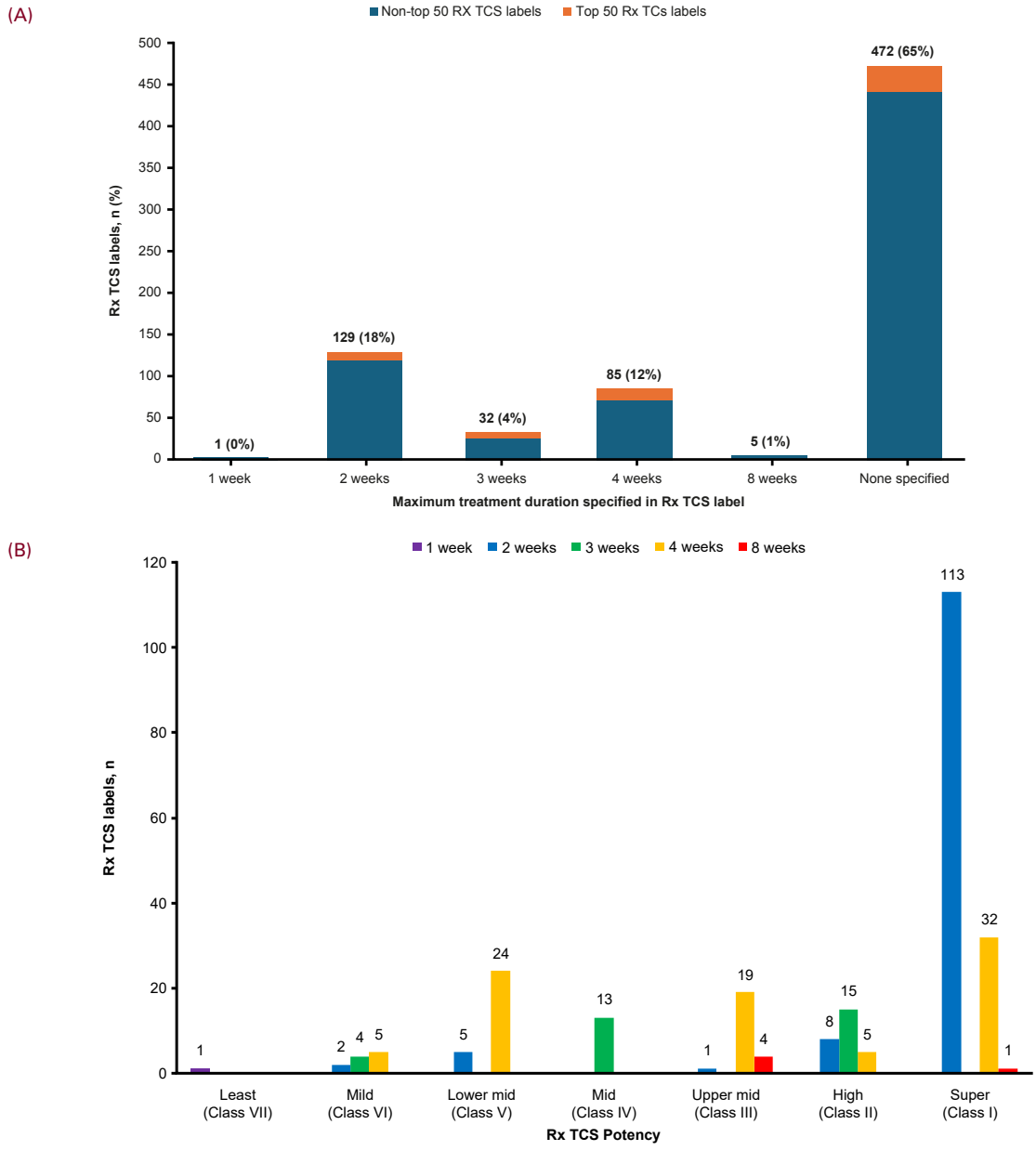
FDA, Food and Drug Administration; SPL, structured product labeling.
Legacy = pre 2006, Modern = post 2006.

Pediatric-specific content was found in 90% (651/724) of Rx labels and 93% (57/61) of the top 50 Rx TCS labels. Such content was listed in the Warnings and Precautions, Pediatric Use, and Patient Counseling Information sections.

Warnings for pediatric use were focused on HPA axis suppression and its signs and symptoms. Pediatric patients may be more susceptible to systemic toxicity due to their larger skin surface to body mass ratios.[16] HPA axis suppression is mentioned in the Pediatric Use section of 87% (633/724) Rx labels and 90% (55/61) of top 50 labels. Faltering growth and intracranial hypertension are known effects of HPA suppression in children.[4,17] Warnings for both faltering growth and intracranial hypertension were present in 88% (636/724) of Rx labels and 90% (55/61) of top 50 labels. However, the language of these warnings appeared to be class-wide and not specific to products.

The occlusive nature of diapers and the increased risk of TCS absorption when used under occlusion prompted statements against use in the diaper area in 16% (112/724) of Rx labels and 20% (12/61) of top 50 labels. Mometasone (97% [34/35]), fluticasone (67% [12 of 18]), and alclometasone (100% [4 of 4]) labels were the only labels that included this precaution; other labels do not include this specific concern.

FIGURE 2. Maximum treatment duration specified in label by (A) duration and by (B) TCS potency.



Rx, prescription; TCS, topical corticosteroids.

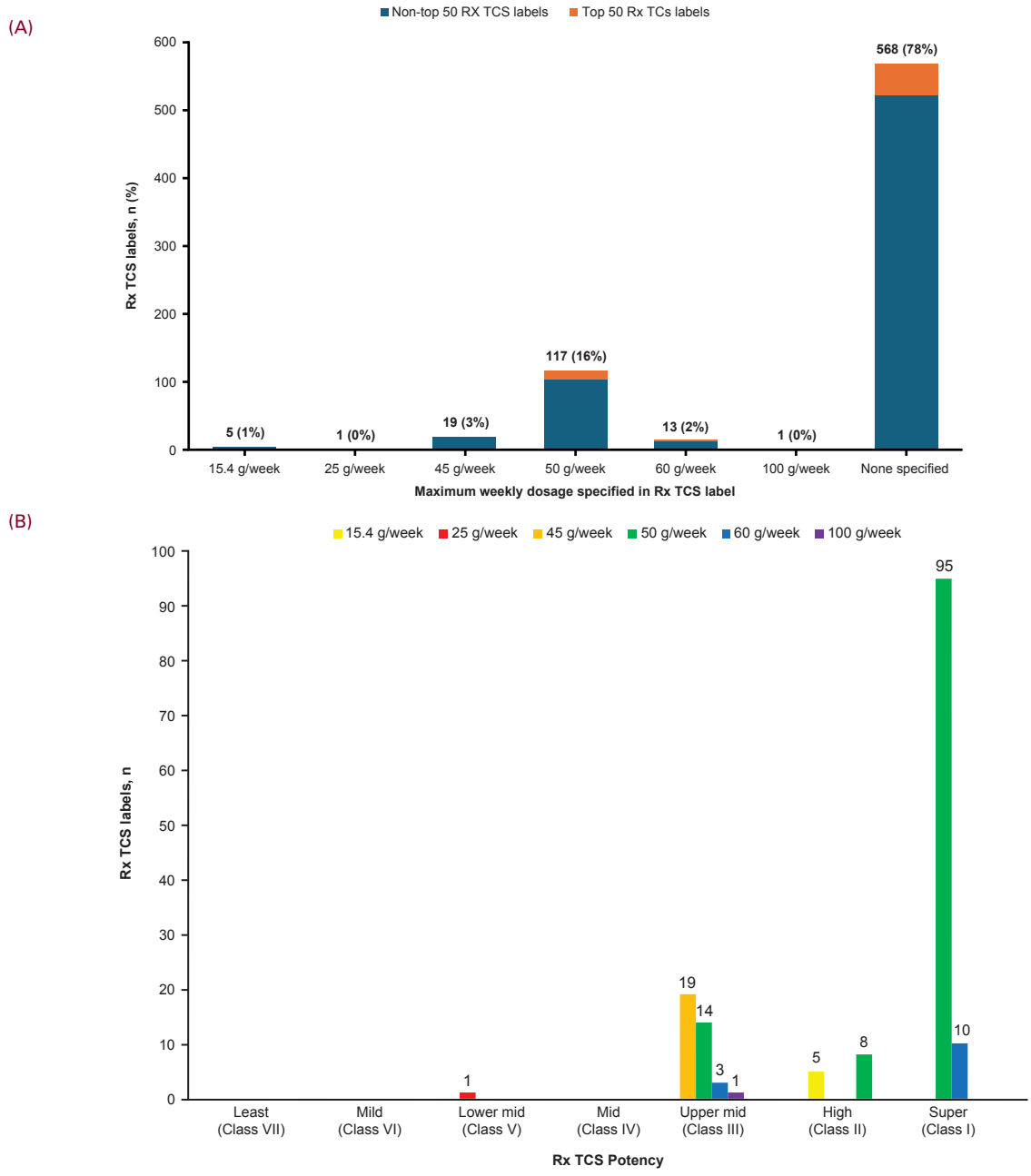
DISCUSSION

TCS have long been used as standard-of-care, first-line treatment for inflammatory dermatoses including atopic dermatitis, psoriasis, and seborrheic dermatitis, but safety concerns have always impacted their use.[18-20] Increasing TCS safety data has accumulated from clinical trials and reported clinical experience, prompting revised safety communications from professional societies and ex-US regulators regarding TCS use to support more informed choices about their use.

In 2024, the FDA of the Philippines took the important step of reclassifying all TCS as prescription only.[8] This was done to reduce the misuse and abuse of TCS and encourage corticosteroid stewardship by limiting unrecorded and unmonitored TCS use.

Improved corticosteroid stewardship has been the subject of professional society communications in the US. The Society of Dermatology Physician Assistants and the Society of Dermatology Nurse Practitioners issued statements in 2025 supporting the

FIGURE 3. Maximum treatment duration by (A) weekly dose and by (B) TCS potency.



Rx, prescription; TCS, topical corticosteroids.

assessment of cumulative steroid exposure in order to improve patient safety and outcomes related to TCS use.[21,22]

In 2022, Health Canada published a safety brief regarding TCS and the risk of TSW in their monthly Health Product InfoWatch.[7] It included instructions on how to prevent, identify, and treat TSW and reiterated that more potent TCS were more likely to be associated with it.

Similarly, in 2024 the MHRA in the United Kingdom published an update to a previous statement outlining the risks of TSW and providing advice for clinicians regarding how to identify and report it.[6] Their statement included information for clinicians to provide to patients or caregivers on proper use of TCS to help minimize the risk of AEs. It also committed to adding the potency level to product labels to relieve clinicians of the need to look elsewhere for this crucial information.

Some changes have been made in the US in response to accumulating safety data. A new ICD-10 code for TSW (L30.81) was adopted in 2026 by the WHO internationally and by the CDC in the US (with implementation expected in 2027) indicating the growing knowledge and emerging importance of this AE.[23] However, this recent development has not yet led to the acknowledgement of TSW in TCS labels in the US.

The design of prescription labels has changed since the turn of the century in many ways, as listed in Figure 1B.[24-26] Inclusion of more detailed safety statements and warnings in new and updated labels demonstrates US FDA acknowledgement of emerging and long-term safety signals; however, such statements have not been added to older TCS labels. Even when they are reissued, labels are not required to use the modern template. All corticosteroid molecules in the top 50 TCS products were approved between 1955 and 1992, so the labels that dominate US prescribing volume are disproportionately built on pre-reform templates that predate current safety-communication conventions. The top 50 molecules have all been updated recently but completeness still correlates with the original template content, not the reprint date, even though the Modern Labeling Act of 2020 put the structure in place to update labels. Overall, the precaution content of a TCS label tracks the era of its labeling template more than the drug's intrinsic risk.

Advances in the understanding of the safety profile of TCS over time are reflected in the labeling of the more recently approved molecules, and those that use the modern label format. In general, labels for molecules that were approved prior to 1985 do not contain this up-to-date information. Overall, molecules with earlier label approval dates contain fewer precautions than more modern labels for newer molecules, despite much more widespread use. For example, of 35 mometasone furoate labels, 33 (94%) included a caution for cataracts/glaucoma and 34 (97%) included a recommendation against use in the diaper region, while none of the triamcinolone acetonide or hydrocortisone labels had any such warnings across all 207 Rx labels.

Substantial differences in label details for the same corticosteroid across formulations were seen. For example, the clobetasol propionate spray label was updated in 2018 to include frequency data from a clinical study in warnings and precautions for HPA axis suppression, ophthalmic effects (eg, glaucoma), and infections.[27] In contrast, a clobetasol propionate topical solution label, last updated in 1998, does have a warning for HPA axis suppression but no data regarding its likelihood; ophthalmic effects and infections are not described.[28]

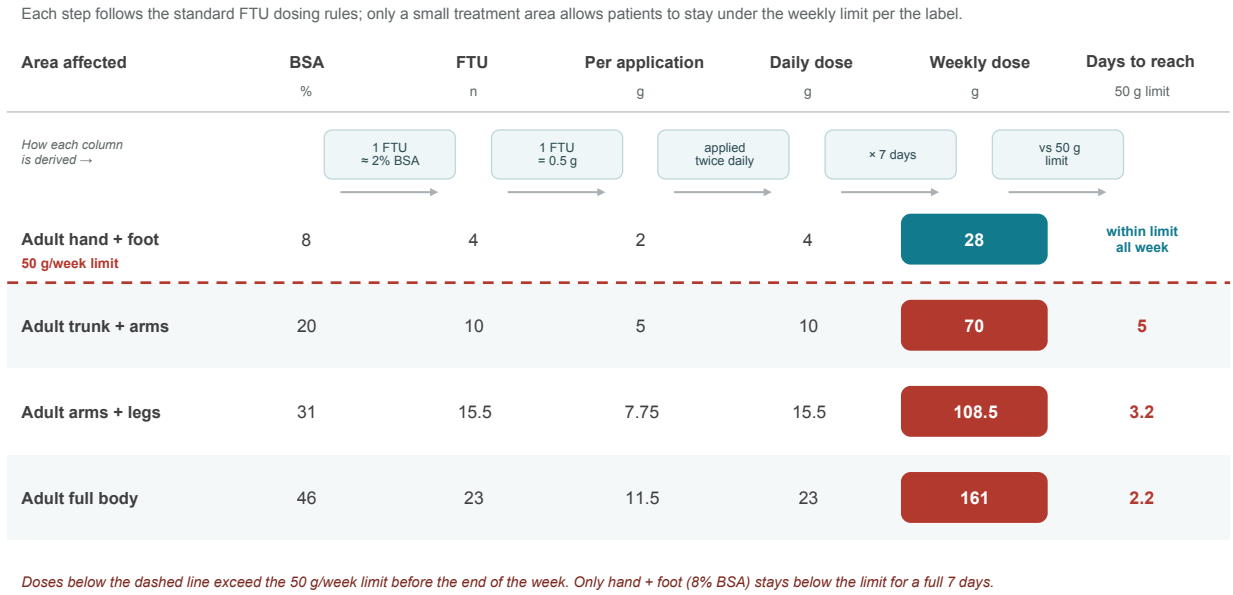
Dosing inconsistencies within labels also exist. Restrictions on duration of TCS use and maximum weekly dose are found in some labels, and support for these limits is found in treatment guidelines for dermatologic diseases such as atopic dermatitis and plaque psoriasis, particularly for higher potency molecules.[18,19] Unfortunately, the suggested maximum weekly dose and the daily dosing recommendations within the same label frequently do not match. This may cause patients to unknowingly exceed the weekly maximum dose (Figure 4).

Using these calculations, adults using TCS based on fingertip unit (FTU) quantity recommendations will reach the recommended limit when treating more than 15% BSA twice daily (application to intertriginous areas, corticosteroid potency, use under occlusion, concomitant use of corticosteroids administered by other routes, and presence of other risk factors will push this threshold lower). When patients meet or exceed the weekly dose limit, they must either choose to undertreat, potentially leading to poor disease control, or treat according to the label and exceed the limit, increasing the risk of AEs.

Some AEs are reported to occur at doses within the recommended dosing limits. HPA axis suppression and potential for iatrogenic Cushing syndrome are most likely to occur with long-term use of supraphysiologic doses of corticosteroids but may also occur at lower doses.[5] An older label (1998) for clobetasol propionate topical solution 0.05% states that doses as low as 2 g/day have been associated with HPA axis suppression, which would be reached by an adult applying the medication as directed to just 4% BSA.[28] Newer labels such as clobetasol propionate spray (2018) simply state that HPA axis suppression has been observed at the lowest doses tested.[27]

Although warnings for HPA axis suppression are found in most (98% [708/724]) labels, the wording varies widely. One consistent statement found in the warning language of most labels is that the effects of HPA axis suppression are "reversible upon discontinuation." However, data are inconsistent regarding

FIGURE 4. Time needed to breach weekly dosing limit when following dosing directions.



BSA, body surface area; FTU, fingertip unit.

reversibility after continuation and duration of suppression. One review stated that the mean recovery time of the HPA axis was 3.49 months in pediatric patients and 3.84 months in adults,[4] while other studies have shown that recovery may take 2–4 years.[29]

Labels do not discuss cumulative corticosteroid dose limitations over extended time periods. However, the risk of TCS AEs is linked to cumulative dose over time, including dosing by other routes of administration. The higher a patient's cumulative dose, the more likely they are to experience events such as HPA axis suppression, cataracts, and other AEs.[30,31]

Optimal guidance for use in the vulnerable pediatric population is lacking. High potency TCS do not consistently carry stronger pediatric warnings than lower potency TCS despite the greater risk. Similarly, the minimum ages for use listed in labels do not reflect TCS potency class. Acknowledgement of increased risk with increasing TCS potency in pediatric patients would help clinicians and patients to select the correct product.

The lack of consistent dosing guidance promotes clinical confusion. It can be difficult to determine a safe dose when 18% (131/724) of TCS labels state that dosing should not exceed 50 g/week (approximately 7 g/day) but also warn that doses as low as 2 g/day can produce measurable HPA axis suppression, marking a 3.5-fold variation. Efforts to reconcile the labeled application directions, dosing limits, and thresholds to minimize AE risks can improve patient safety while maintaining effective therapy.

Limitations of this paper include that potency classification (I–VII) is not an FDA-regulated field; values were assigned using published clinical references (eg, StatPearls, American Academy of Family Physicians). Also, this analysis did not include OTC labels. This may be an area for future analysis. Other areas of future work could include analyses of the inclusion of statements regarding the risks of other AEs associated with TCS including osteoporosis, osteoporotic fracture, avascular necrosis, onset of type 2 diabetes, and menstrual abnormalities.

CONCLUSION

In this study, multiple inconsistencies in dosing recommendations and missing warnings for known AEs were identified within US FDA-approved TCS product labels. Labeling inconsistencies create medical decision-making challenges for clinicians and patients or caregivers with regards to optimal dosing and risk–benefit considerations. Decisions about potency, dosing amount, and treatment duration significantly affect risks, but drug labels often do not provide helpful guidance.

While some labels provide comprehensive guidance, consistent information is lacking for all available TCS products. It is especially important to synchronize dosing information to optimize safe and effective use of TCS across age groups. This is a call for comprehensive re-evaluation of TCS labeling, to eliminate inconsistency and modernize language around warnings and precautions to better inform risk–benefit decisions.

DISCLOSURES

Adam J. Friedman has served as a consultant, advisor, speaker for and/or received grants from AbbVie, Arcutis, Galderma, Hoth Therapeutics, Incyte, Johnson & Johnson, Kenvue, L'Oréal, La Roche Posay, LEO Pharma, Lilly, MicroCures, Mino Labs, Novartis, Pfizer, Sanofi-Regeneron, Takeda, UCB, and Zylo Therapeutics.

Lawrence F. Eichenfield is a consultant, investigator, and/or member of board of directors for AbbVie, Acrotech Biopharma, Almirall, Amgen, Apogee Therapeutics, Arcutis, Attovia, Castle Biosciences, CorEvitas, Dermavant, Dermira, Forte Biosciences, Galderma, Incyte, Janssen, Johnson & Johnson, LEO Pharma, Lilly, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi-Genzyme, Target RWE, TRex Bio, and UCB.

Mark Boguniewicz has served as an advisor and/or investigator for AbbVie, Amgen, Arcutis, Astria Therapeutics, Dermavant/Organon, Galderma, Incyte, LEO Pharma, Lilly, Pfizer, Regeneron, and Sanofi.

Elaine C. Siegfried has served as an advisory board member, data/safety monitoring board member, consultant, investigator, and/or speaker for Amgen, Arcutis, Edelife, Galderma, Genzyme, Incyte, Janssen, LEO Pharma, National Foundation for Ectodermal Dysplasias, NobelPharma, Novan, Pfizer, Pierre Fabre, Regeneron, Sanofi, and UCB.

Douglas DiRuggiero has served as an advisory board member and/or speaker for AbbVie, Amgen, Arcutis, Galderma, Incyte, JNJ, LEO Pharma, Lilly, Novartis, Sanofi-Regeneron, Sun Pharma, Takeda, and UCB.

Lisa Weiss has served as an advisory board member and/or speaker for Arcutis, Galderma, Incyte, Johnson and Johnson, Leo Pharma, Organon, Sanofi/Regeneron, Sun Pharma, UCB, and Verrica.

Melissa S. Seal, Brett Stephenson, Raja Mikkili, Robert C Higham, Diane Hanna are employees of Arcutis Biotherapeutics, Inc.

Alexandra K. Golant is a consultant, investigator, and/or speaker for AbbVie, Amgen, Apogee Therapeutics, Arcutis, BMS, Boehringer Ingelheim, Dermavant, Galderma, Incyte, Janssen, LEO Pharma, Lilly, Pfizer, Regeneron, Sanofi, and Takeda.

Funding statement: This work was supported by Arcutis Biotherapeutics, Inc.

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AUTHOR CORRESPONDENCE

Alexandra K. Golant MD

E-mail:..... alexandra.golant@mountsinai.org