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The Hidden Burden of Topical Corticosteroids: Integrating Literature, Prescribing Information, and Real-World Evidence

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ORIGINAL ARTICLE

Journal of Drugs in Dermatology

Cutaneous and Systemic Adverse Events Associated With Topical Corticosteroid Use: A Targeted Literature Review

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ABSTRACT

Background: Topical corticosteroids (TCS) have been used to treat chronic inflammatory skin conditions since initial approval in 1950, which was followed by reports of cutaneous and systemic adverse events (AEs) over the succeeding decades.

Methods: A targeted literature review was performed to identify case-report and observational-study publications from August 2015 to 2025 that reported TCS-associated adverse events (AEs).

Results: The 42 publications included identification of clinically meaningful cutaneous (69.0%) and systemic AEs, including hypothalamic-pituitary-adrenal axis suppression or adrenal insufficiency (40.5%) and Cushing syndrome (47.6%). AEs ranged from mild to severe and nonserious to serious, and reports implicated prolonged (≥12 months, 45.2%) or high-potency (69.0%) TCS use.

Conclusion: Overall, these results identified an opportunity to assess TCS access requirements and the need for additional clinician awareness and education to improve TCS prescribing practices, including monitoring of AEs and cumulative steroid exposure. Improving access to anti-inflammatory therapies that have demonstrated short- and long-term safety and efficacy in clinical trials and are not steroids for patients with chronic dermatoses should be prioritized. Often, gaining access to these alternative treatments requires step-through TCS therapy or other utilization management requirements, which unnecessarily puts patients at risk for steroid-associated AEs and delays positive treatment outcomes.

J Drugs Dermatol. 2026;25:11(Suppl 1):s4-10.

INTRODUCTION

Since the 1950s, topical corticosteroids (TCS) have been used to treat chronic inflammatory dermatoses such as atopic dermatitis, psoriasis, and seborrheic dermatitis.[1] Since their introduction, evidence associating TCS with cutaneous and systemic adverse events (AEs) has accumulated, particularly related to misuse, prolonged use, high-potency formulations, and application to high-risk areas.[1,2]

Concern over steroid-associated AEs may manifest as steroid phobia[1] and can cause hesitancy among patients and caregivers to maintain an appropriate treatment plan, thus exacerbating or prolonging symptoms.[3,4] TCS side effects from use in children may be impacted by higher body surface area-to-weight ratios, relatively immature cutaneous immune environment and skin barrier, and a higher likelihood of occlusive application, each of which increases systemic exposure.[2,5]

MATERIALS AND METHODS

A targeted literature review was performed to identify case-report and observational-study publications reporting AEs associated with TCS use. Titles and abstracts published from August 2015 in PubMed were searched in September 2025 with search term

categories of treatment, application, adverse effect, and type of publication (Table 1). All search terms were used in combination (eg, ["corticosteroids" OR "hydrocortisone"] AND ["topical" OR "cutaneous"] AND ["side effect" OR "toxicity"] AND ["case report" OR "case series"]). Three reviewers (SS, BS, and RH) screened and reviewed publications. Non-human and non-English reports and those without safety outcomes were excluded, as well as those in which the relationship of the reported AE to TCS was unclear or confounded by other risk factors. Cushingoid skin findings and oral mucosal events were considered cutaneous events. Serious AE classifications were clinician-derived based on details of the case(s) included in the report. Steroid potency classes VI and VII were grouped as low, classes III to V as medium, and class I to II as high. In cases where ≥1 potency group was included in a report, the highest was used; in cases where the potency group could not be determined because the concentration or formulation was missing, the lowest was used. Publication tallies were not mutually exclusive; many reported ≥1 event leading to some totals >100%.

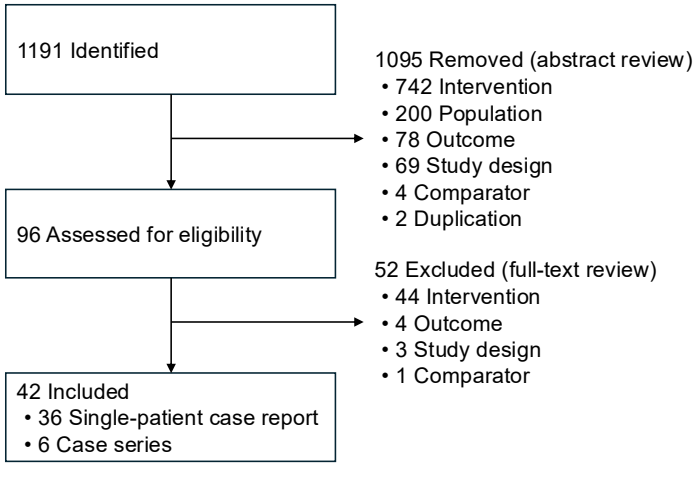
RESULTS

Overall, 1191 publications were identified, 96 were reviewed, and 42 (representing a total of 83 patients) were included in this report (Figure 1); the majority of publications (78.8%) were single-patient case reports (Table 2).

TABLE 1.

Search Strategy	
Term Category	**Specific Search Terms**
Treatment	Corticosteroids OR Glucocorticoids OR Topical Steroid OR Topical Corticosteroid OR Hydrocortisone OR Betamethasone OR Clobetasol OR Mometasone OR Fluocinolone OR Fluticasone OR Desonide OR Desoximetasone OR Triamcinolone
Application	Administration, Topical OR Administration, Cutaneous OR Topical OR Cutaneous OR Dermal
Adverse effect	Chemically Induced Disorders OR Adverse Drug Reaction Reporting Systems OR Drug-Related Side Effects and Adverse Reactions OR Safety OR Side Effect OR Adverse Effect OR Adverse Event OR Adverse Reaction OR Complication OR Toxicity OR Skin Atrophy OR Striae OR Telangiectasia OR HPA Axis Suppression OR Cushing Syndrome OR Glaucoma OR Cataract OR Topical Steroid Withdrawal OR TSW
Type of publication	Case Reports OR Case Report OR Case Series

FIGURE 1. PRISMA diagram.



Note: A full list of included references can be provided upon request.
PRISMA, Preferred Reporting Items for Systematic reviews and Meta-Analyses.

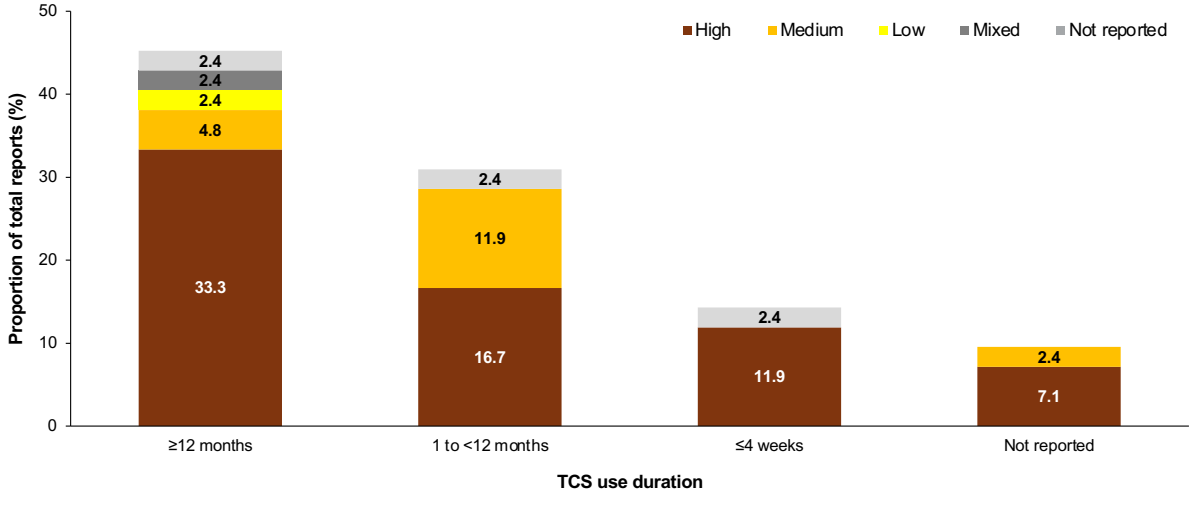
TABLE 2.

Report Characteristics		
		n (%) [N=42]
Patient age group	Adults only	21 (50.0)
	Children only	19 (45.2)
	Adults and children	2 (4.7)
Type	Single-patient case report	36 (85.7)
	Case series	6 (14.3)
Setting	Outpatient (dermatology or primary care)	17 (40.5)
	Emergency department visit (not admitted)	6 (14.3)
	Inpatient or hospitalization	3 (7.1)
	Not reported	16 (38.1)
Geographic location	Japan	4 (9.5)
	Mexico	4 (9.5)
	France	3 (7.1)
	India	3 (7.1)
	Italy	3 (7.1)
	United States	3 (7.1)
	Australia	2 (4.8)
	Morocco	2 (4.8)
	Nepal	2 (4.8)
	Pakistan	2 (4.8)
	Saudi Arabia	2 (4.8)
	Turkey	2 (4.8)
	Argentina	1 (2.4)
	Chile	1 (2.4)
	Croatia	1 (2.4)
	Denmark	1 (2.4)
	Germany	1 (2.4)
	Ireland	1 (2.4)
	Spain	1 (2.4)
	Not reported	8 (19.0)
TCS potency	High	29 (69.0)
	Medium	5 (11.9)
	Low	2 (4.8)
	Mixed	4 (9.5)
	Not reported	3 (7.1)
Frequency of TCS use	At least once daily	14 (33.3)
	Weekly/monthly	8 (19.0)
	Variable	19 (45.2)
	Not reported	1 (2.4)
Duration of TCS use	≥12 months	19 (45.2)
	1 to <12 months	13 (31.0)
	≤4 weeks	6 (14.3)
	Not reported	4 (9.5)

TCS, topical corticosteroid.

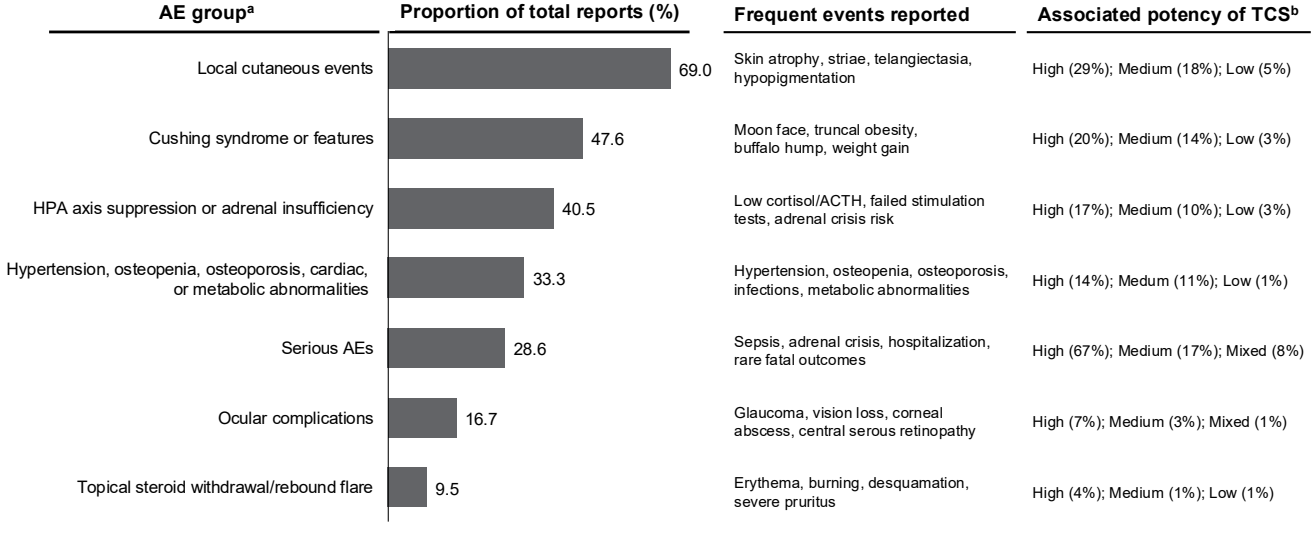
Reports included adults (50.0%) and children (45.2%) with global representation across 19 countries. TCS were the primary exposure; clobetasol, betamethasone, and hydrocortisone were the most commonly reported TCS, and high-potency formulations (class I-II[6]) were frequently (69.0%) implicated. TCS were applied at least once daily in 33.3% of the reports. Duration of TCS use was chronic (≥12 months) and intermediate (1 to <12 months) in 45.2% and 31.0% of the reports, respectively. TCS applied under occlusion were associated with AEs in 5 (11.9%) reports. One-third (13/42; 33.3%) of reports involved chronic application of high-potency TCS (Figure 2).

FIGURE 2. Duration of use by TCS potency.



Note: There was one study where duration was not reported and TCS potency was unclear.
TCS, topical corticosteroid.

FIGURE 3. AEs by potency of associated TCS.



[a]AE groups not mutually exclusive; multiple AEs may have been noted in an individual report. [b]Proportions calculated based on the number of reports identifying TCS potency/total reports (or, in the case of serious AEs, total serious AE reports); potency not reported for 1% of reports that included local cutaneous events, 8% of those including serious AEs, and 1% those reporting topical steroid withdrawal/rebound flare. High potency: class I and II; medium potency: class III–V.
ACTH, adrenocorticotropic hormone; AE, adverse event; HPA, hypothalamic-pituitary-adrenal; NA, not available; TCS, topical corticosteroid.

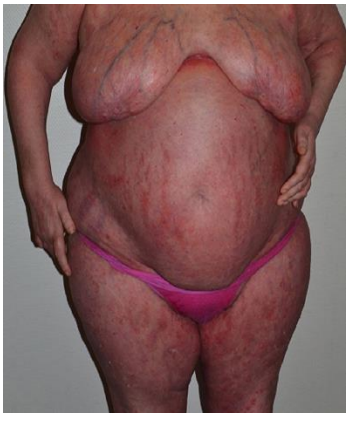
FIGURE 4. Examples of TCS-associated adverse events from included reports.



Cushing syndrome in a boy aged 14 months treated with topical hydrocortisone acetate 1% cream and clotrimazole, followed by betamethasone dipropionate cream 0.05% for 10 months for dermatitis of the scalp and perineal area. Image used with permission per CC BY-NC 4.0 from Hansen S, et al. Iatrogenic Cushing's syndrome in an infant due to prolonged use of topical corticosteroids. Case report. Article in Spanish. *Rev Chil Pediatr.* 2018;89(3):368-372.



Striae, atrophy, telangiectasia, and visible veins with crusting and ulceration in a pregnant female aged 18 years following prolonged use (≈6 months) of Zalim lotion (ie, phenol, tincture iodine, and crystalviolet) and clobetasol propionate 0.05%. Image used with permission per CC BY-NC 4.0 from Mathur M, et al. Misuse of topical over-the-counter medication: a case report. *Clin Case Rep.* 2024;0:e8949.



Severe cutaneous atrophy, diffuse telangiectasias, faciotruncal obesity, broad purple abdominal striae, and limb muscle wasting in a female aged 38 years with Netherton syndrome using topical betamethasone for ≈10 years to treat severe pruritus. Additional diagnoses upon examination included osteoporosis, Cushing syndrome, corticotropic insufficiency, and inframammary, axillary, and intergluteal superinfected intertrigo. Image from Valette C, et al. Fatal outcome of Netherton syndrome due to excessive use of topical corticosteroids in an adult patient. Article in French. *Ann Dermatol Venereol.* 2020;147(1):36-40.

TCS, topical corticosteroid.

Local, cutaneous AEs were noted in 69.0% of reports and were largely associated with prolonged (>1 month [per label]) or high-potency TCS use (Figure 3). Among published reports of cutaneous AEs, 37.9% described striae, 34.5% cushingoid cutaneous changes, 31.0% hypertrichosis/hirsutism, 24.1% purpura/ecchymosis, 20.7% skin atrophy, 20.7% secondary skin infection, 20.7% hypopigmentation, 17.2% telangiectasia, and 13.8% acne/acneiform eruptions. Resolution of cutaneous AEs varied across reports; mild atrophy and erythema were considered partially reversible with TCS discontinuation; however, other AEs (ie, striae and telangiectasia) persisted. Systemic AEs were typically associated with high-potency TCS use, occlusion, extensive body surface area exposure, or prolonged (>1 month [per label]) duration of exposure. Systemic AEs included hypothalamic-pituitary-adrenal axis suppression/adrenal insufficiency (40.5%); Cushing syndrome or features (47.6%); hypertension, osteopenia, osteoporosis, and cardiac or metabolic abnormalities (33.3%); and ocular complications (eg, glaucoma, visual impairment, and corneal infection; 16.7%; Figure 3 and Figure 4). Topical steroid withdrawal syndrome was described in 9.5% of publications.

Cases were from outpatient (40.5%), inpatient (7.1%), and emergency (16.6%) settings, indicating that AEs occurred across the spectrum of mild to severe and nonserious to serious (serious AEs were noted in 28.6% of reports). Many cases involved inappropriate use patterns (ie, self-medication [individual treatment without medical guidance], over-the-counter access [varies by country], excessive dosing [additional applications than prescribed], prolonged use without medical supervision, and application to high-risk areas [eg, face and diaper region of children, including reapplication with diaper changes]).

DISCUSSION

Inappropriate TCS use is at least in part related to unclear and inconsistent instructions on frequency and duration of use.[7] Most often, patients are directed to apply TCS based on "fingertip units"; however, this comes with a wide variation on number of applications per day and an inconsistent approach to reducing application frequency over time.[7] Repeated prescription renewals without reassessment may unintentionally extend exposure to TCS beyond the originally planned treatment period, particularly among patients with chronic relapsing disease. Overall, these patterns suggest that AEs are not driven by TCS potency alone but rather by management gaps and cumulative corticosteroid exposure. Collectively, corticosteroid potency, treatment duration, application frequency, body surface area treated, anatomical location, occlusion, repeated treatment courses, and lack of follow-up with patients to ensure appropriate use each contributed to development of AEs.

This review is limited in sample size compared to the expansive number of corticosteroid prescriptions filled,[8] and for which case reports can provide heterogenous information, often in unstructured and inconsistent formats. Use of case-based evidence introduces bias toward more severe or atypical AEs, and overall AE occurrence may be underrepresented from lack of reporting in published literature.

Overall, these findings support a broader framework for TCS use that emphasizes cumulative exposure rather than isolated treatment episodes. Taken together, these data underscore the need to optimize TCS prescribing practices by selecting appropriate TCS potency, limiting treatment duration, reassessing recurrent prescriptions, and minimizing unnecessary cumulative corticosteroid exposure. Findings highlight a need for ongoing monitoring of cutaneous and systemic adverse effects and standardized approaches for documenting cumulative steroid exposure. Additionally, there is an opportunity to discuss the risk-benefit balance and overall cost burden of all topical treatments, including direct and indirect costs of related AEs. Topical therapies that are not steroids are recommended in treatment guidelines and are valuable therapy options.[9,10] Policies requiring treatment with TCS prior to implementing newer and more targeted non-steroid treatments can inadvertently prolong corticosteroid exposure, increasing patient risk for steroid-associated AEs and delaying positive treatment outcomes. Modern steroid-sparing treatments have been assessed using current regulatory standards that support consistent, long-term use in chronic inflammatory dermatoses. More appropriate access to advanced targeted topical treatments with demonstrated safety and efficacy profiles, in addition to standardized drug labels in this treatment space, are warranted.

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 Zylö Therapeutics.

Peter Lio has served as an advisor, consultant, speaker for and/or owns stock in AbbVie, Alphyn Biologics, Almirall, Amyris, Apogee Therapeutics, Arcutis, Astria Therapeutics, Castle Biosciences, Codex Labs, Concerto Biosciences, Dermavant, Galderma, Incyte, Kenvue, LEO Pharma, Lilly, Lipidor, La Roche-Posay/L'Oréal, Merck, Micreos, MyOr Diagnostics, Nektar Therapeutics, Nia Health, Pelthos Therapeutics, Novartis, Pfizer, Phyla Skincare, Pierre-Fabre, Regeneron/Sanofi Genzyme, Sibel Health, Skinfix, Song Lab Skincare, Soteri Skin, Stratum Biosciences, Sun Pharma, Theraplex, Thimble Health, Topaz Biosciences, Unilever, Verdant Scientific, Verrica, and Yobee.

Lawrence F. Eichenfield has served as 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.

Lisa Weiss has served as a speaker and/or consultant for Arcutis, Galderma, Incyte, Johnson & Johnson, LEO Pharma, Organon, Sun Pharma, Sanofi/Regeneron, UCB, and Verrica.

Jaclyn Agopian has served as a speaker and/or consultant for All Better Co., Arcutis, Galderma and GatherED.

Mark G. Lebwohl has served as a consultant for and/or received research funds from AbbVie, Added Health, Aikium, Almirall, AltruBio, Alumis, Amgen, Apogee Therapeutics, Arcutis, AstraZeneca, Atomwise, Avotres, BMS, Boehringer Ingelheim, Cara Therapeutics, Castle Biosciences, Celltrion, Clexio, CorEvitas, Dermavant, Dermsquared, Evommune, Facilitation of International Dermatology Education, Forte Biosciences, Galderma, Genentech, Incyte, Inozyme, Johnson & Johnson, LEO Pharma, Lilly, Mayne Pharma, Meiji Seika Pharma, Mindera, Mirium Pharma, MoonLake Immunotherapeutics, Oruka, Pfizer, Revolo Biotherapeutics, Sanofi-Regeneron, Seanergy Dermatology, Strata Skin Sciences, Sun Pharma, Takeda, Trevi Therapeutics, UCB, and Verrica.

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

Melissa S. Seal, Scott Snyder, Brett Stephenson, and Robert Higham are employees of Arcutis Biotherapeutics, Inc.

Alexandra K. Golant has served as 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.

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ORIGINAL ARTICLE

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

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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.

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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

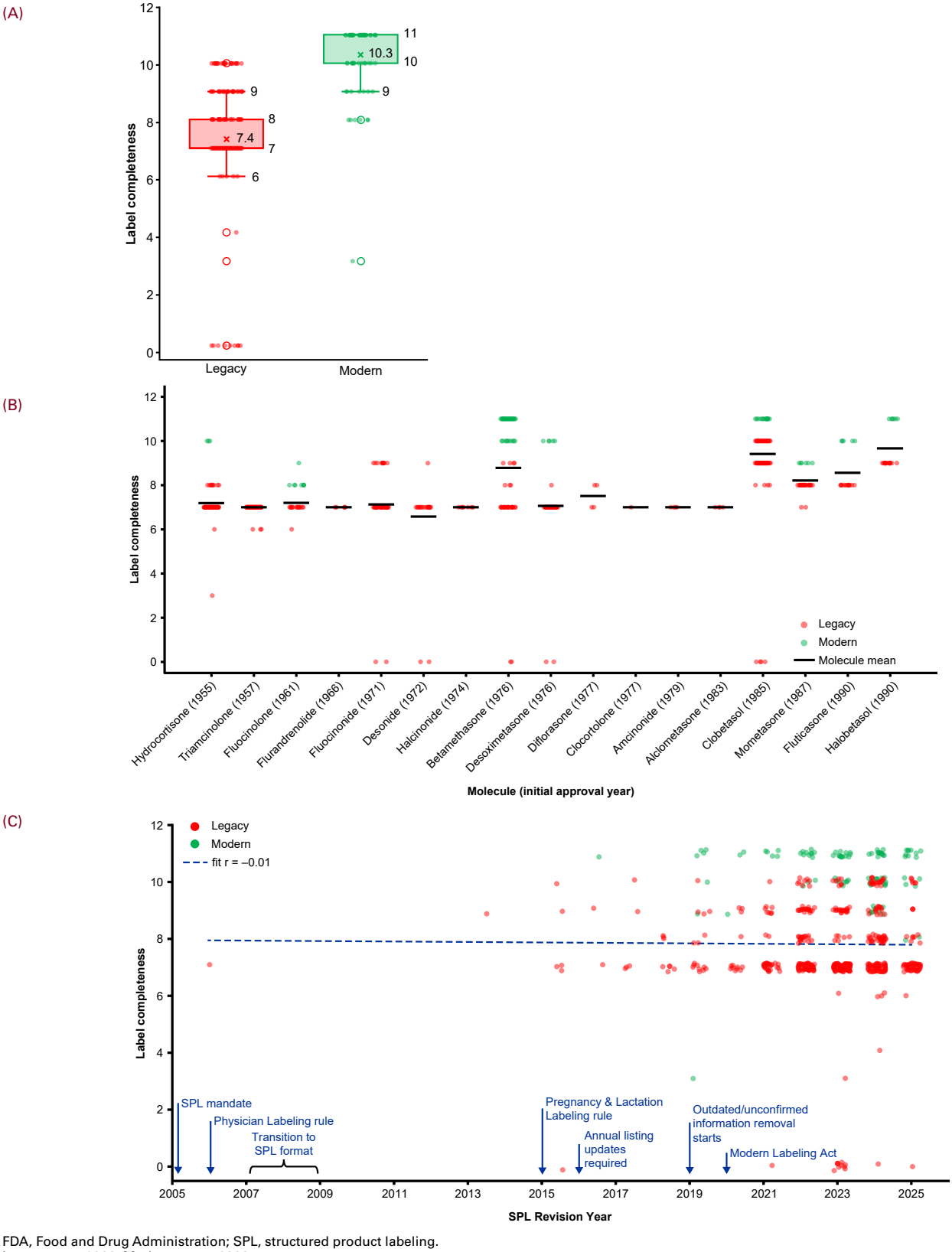
Many treatment guidelines recommend against long-term, continuous TCS use.[14,15] However, a maximum treatment duration was specified in only 35% (252/724) of Rx TCS labels and 49% (30/61) of the top 50 Rx TCS labels. Of the labels stating a maximum, 2 or 4 weeks were the most common durations for Rx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



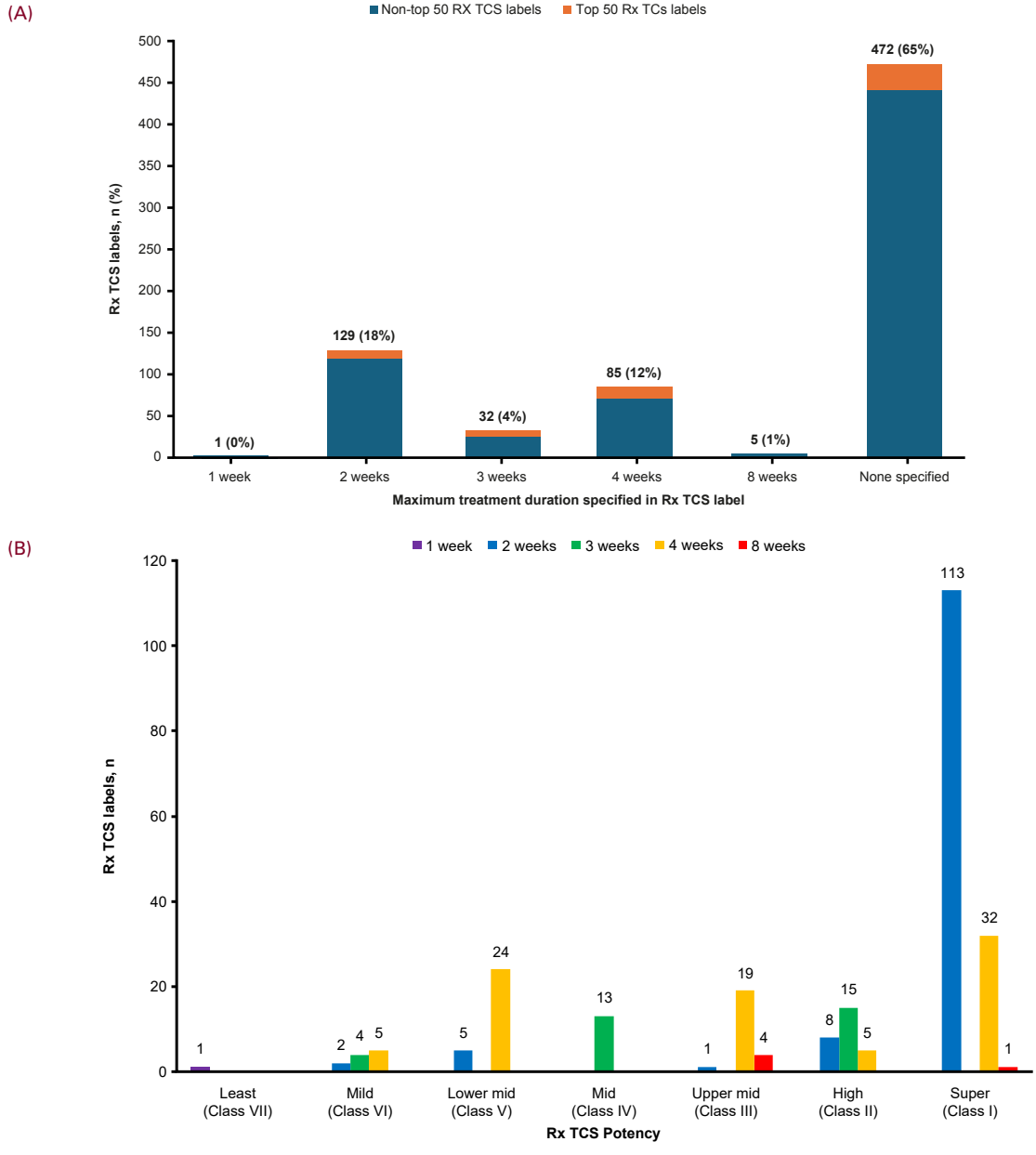
FDA, Food and Drug Administration; SPL, structured product labeling.
Legacy = pre 2006, Modern = post 2006.

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.

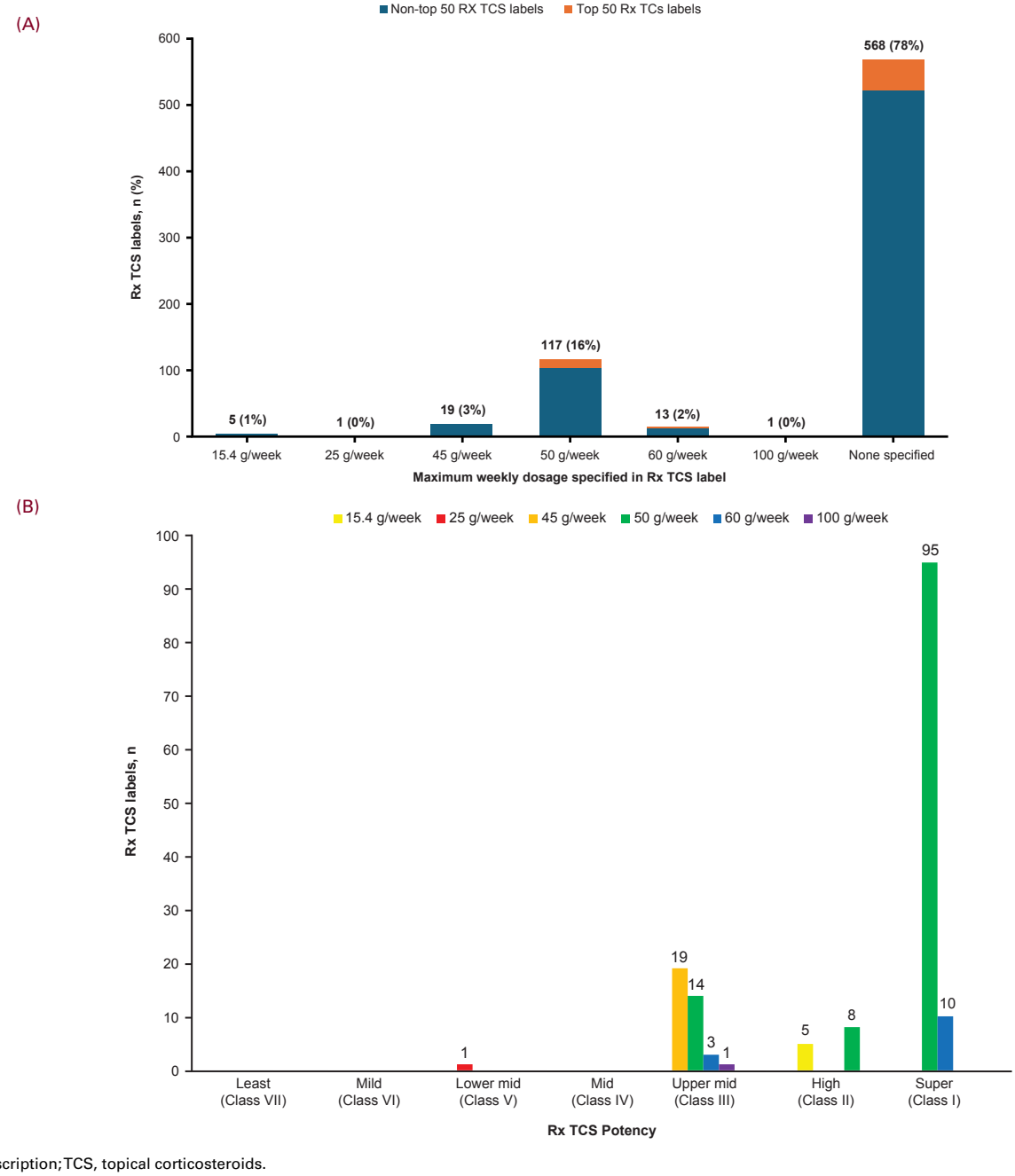
DISCUSSION

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]

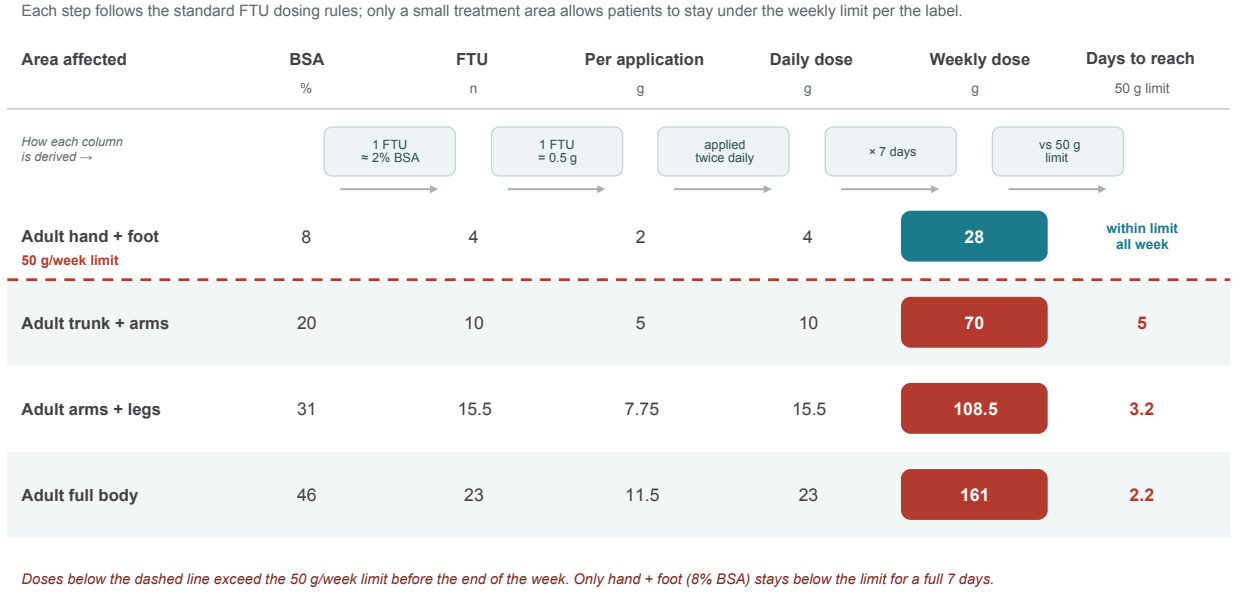
Dosing inconsistencies within labels also exist. Restrictions on duration of TCS use and maximum weekly dose are found in some labels, and support for these limits is found in treatment guidelines for dermatologic diseases such as atopic dermatitis and plaque psoriasis, particularly for higher potency 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.

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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.

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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.

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ORIGINAL ARTICLE

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Real-World Study of Topical Corticosteroid-Associated Adverse Events in the FDA Adverse Event Reporting System

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ABSTRACT

Background: Corticosteroids (CS) and topical CS (TCS) are widely used, yet the real-world burden and reporting patterns of associated adverse events (AEs) remain incompletely characterized.

Methods: Reports in the FDA Adverse Event Reporting System (FAERS) from 1999–2025 containing 18 CS terms corresponding to US FDA-approved topical active ingredients were identified using the openFDA application programming interface. AEs, temporal trends, treatment duration, age, seriousness, and potency were characterized.

Results: 422,947 AE reports identified CS as a suspected cause. Among 1,619,452 coded reaction terms in 294,811 reports with CS as a product, systemic terms (38.8%) were more frequent than cutaneous (8.4%); known CS AEs were infrequently reported. 57.1% of reports reflected ≤2 weeks of use and 12.7% >12 months. Adults aged ≥65 years were disproportionately represented. Regarding TCS, reports showed no clear pattern in relation to potency; however, serious and systemic AEs were more prominent among milder classes. Nearly two-thirds (64.5%) of reports were received after 2018, coinciding with increased regulatory and public attention to TCS-associated AEs.

Discussion: This analysis identifies real-world CS AE reporting patterns not readily apparent from established safety concerns or product labeling. The findings highlight gaps in our understanding of CS-associated AEs and the need to better characterize their spectrum, use patterns, and affected populations. However, spontaneous reporting is subject to biases and cannot estimate AE incidence or comparative risk.

Conclusion: This large-scale analysis characterizes >25 years of CS-associated AE reporting and supports further characterization of CS-associated AEs to inform clinical guidance, regulatory labeling, and patient monitoring.

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INTRODUCTION

Topical corticosteroids (TCS) have been in use since the 1950s[1] and are currently among the most widely used medications in the United States (US), with over 15 million prescriptions filled in 2023.[2] Soon after their introduction, reports emerged describing both cutaneous and systemic adverse events (AEs) with TCS use.[3-7] Risk awareness has increased over time, especially for higher-potency agents and prolonged use, and among vulnerable populations (eg, infants, young children, and older adults).

Accumulating evidence regarding TCS-associated AEs has prompted increased regulatory scrutiny in multiple countries.[8-13] In parallel, growing engagement among medical experts, professional organizations, and advocacy groups reflects a broad shift toward TCS stewardship. Statements from the Society of Dermatology Physician Assistants and the Society of Dermatology Nurse Practitioners support cumulative TCS exposure monitoring as a means to improve patient safety and outcomes.[14,15] Efforts to promote more appropriate corticosteroid (CS) use across therapeutic areas, including asthma and inflammatory bowel disease, have also emphasized reducing cumulative systemic CS

exposure and minimizing related AEs.[16-18] For example, an expert consensus panel on the management of inflammatory bowel disease concluded that long-term CS use is not ideal, citing the potential for AEs.[19] The recently established Corticosteroid Stewardship Alliance further demonstrates this cross-specialty approach to CS safety, advocating for coordinated clinical standards, improved monitoring practices, and policy approaches intended to reduce avoidable CS-related harm.[20] Collectively, these emerging recommendations are broadly aligned with regulatory guidance emphasizing awareness, monitoring, and appropriate CS use to reduce the risk of treatment-related AEs.[9-11]

Despite decades of clinical use and increasing regulatory attention, the real-world burden, spectrum, and reporting patterns of TCS-associated AEs remain incompletely characterized. The objective of this analysis was to examine and characterize postmarketing reports of cutaneous and extracutaneous TCS-associated AEs, duration of TCS use, and reporting patterns across age groups in the US; this analysis was performed using data from the US Food and Drug Administration (FDA) Adverse Event Reporting System (FAERS), now known as the FDA Adverse Event Monitoring System, database to monitor postmarketing AEs associated with regulated products.[21]

MATERIALS AND METHODS

Data Source and Collection

This study utilized data from the US FDA FAERS database and the openFDA Drug AE application programming interface (API) and included reports from January 1, 1999 to December 31, 2025.[21,22] FAERS contains AE reports submitted by healthcare professionals, manufacturers (mandatory reporting), and consumers (voluntary reporting) with each report representing ≥1 AE and naming ≥1 suspected drug.[21]

Case Identification and Cohort Derivation

CS terms for querying FAERS were compiled using the FDA Label inventory[23] to identify every CS active ingredient in an FDA-approved topically applied skin product, collapsing salt and ester variants into one molecule name (eg, 'betamethasone' covers betamethasone dipropionate and valerate; 'hydrocortisone' covers valerate and butyrate). Ingredients appearing only inside combination products that are not CS (eg, the antifungal nystatin) and CS without meaningful topical dermatologic use (eg, dexamethasone) were excluded. The 18 terms identified were hydrocortisone, triamcinolone, clobetasol, mometasone, fluocinonide, betamethasone, desonide, fluocinolone, desoximetasone, halobetasol, fluticasone, alclometasone, prednicarbate, halcinonide, diflorasone, flurandrenolide, amcinonide, clocortolone.

Two complementary query strategies were executed to identify reports including ≥1 of the 18 CS terms. A 2-field query of the "patient.drug.medicinalproduct" OR "patient.drug.openfda.generic_name" was used for overall reporting volume and temporal trend analyses. A more restrictive single-field query using the "patient.drug.medicinalproduct" field served as the basis for record-level attribution analyses, including primary-suspect status, seriousness, potency, age, and duration analyses. Because FAERS lacks a reliable route-of-administration field, molecule-level analyses inevitably include systemic (ie, oral, injectable, nasal, inhaled) formulations; therefore, 'CS' is used for these route-confounded analyses and 'TCS' only where a topical formulation was confirmed.

Reports naming CS using the single-field query went through a stepwise cohort derivation process beginning with all reports mentioning a CS in any role, followed by restriction to reports naming a CS in the free-text product field, primary suspect reports, and topical products only (cream, ointment, gel, foam; non-topical products excluded); reports with a resolvable potency classification were used for potency-specific analyses. Primary-suspect attribution was determined at the individual drug-record level by requiring the same drug entry to both match a CS and have FAERS drug characterization = 1. Reports were deduplicated using the "safetyreportid" field prior to analysis.

Analyses of AE Reports

The 800 most frequently reported Medical Dictionary for Regulatory Activities (MedDRA) preferred terms (PT) were identified from single-field query results. A cutoff of 800 PTs was selected to cover less frequently occurring terms in the long-frequency distribution tail; these were then categorized into the following clinical groups: cutaneous, systemic, non-specific, administrative (non-AE), death/serious outcome, and uncategorized. Categorization was performed using a rule-based heuristic approach. Clinical categories were not mutually exclusive; individual reaction terms could be assigned to multiple categories where appropriate. Cutaneous and systemic classifications were based on predefined term sets (28 cutaneous, 202 systemic), while terms outside these criteria were assigned to the remaining categories according to prespecified rule-based definitions.

A report-level clinical classification of AEs was conducted to remove reaction-code multiplicity using a stratified random sample of reports selected proportionally across calendar years according to report receipt date. Duration of CS use was evaluated using a stratified random sample of reports selected proportionally across calendar years according to report receipt date and categorized based on available drug start and end dates.

Patient age was summarized using the following categories for reports containing age group information (query: count=patient.patientonsetage): <1 year, 1 year, 2-11 years, 12-17 years, 18-64 years, and 65-110 years. Records with ages >110 years were excluded.

Classification of reports with CS identified as the primary suspect as serious versus non-serious was performed according to ICH E2A seriousness criteria.[24] These criteria included hospitalization, death, life-threatening events, disability, congenital anomalies, and other medically important events. Multiple seriousness criteria could be recorded in individual reports.

Route-confirmed TCS primary-suspect reports with sufficient product information were assigned to a single US TCS potency class (I–VII)[25-27] based on reported strength and formulation corresponding to the highest-potency TCS reported. Non-topical products were excluded and reports without sufficient product information to determine potency were retained as unclassified rather than imputed.

Analyses were descriptive. Counts and percentages were calculated using the appropriate denominator for each analysis cohort as specified in individual figures and tables.

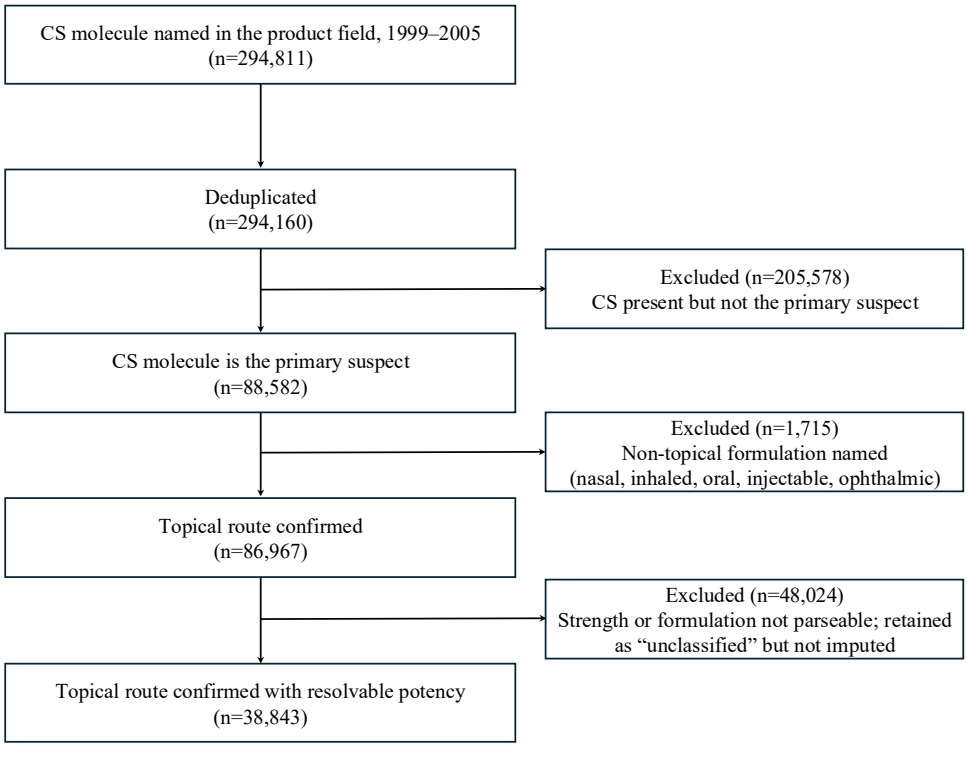
RESULTS

Cohorts

Our search identified 422,947 cumulative AE reports and 7,169 daily time points naming a CS as a suspect drug (any reported role and route of administration). Sequential cohort derivation yielded 294,811 reports naming a CS in the free-text product field (Figure 1). After deduplication, 294,160 unique reports remained, including 88,582 (30.1%) that listed CS as the primary suspect, 86,867 (29.5%) TCS primary-suspect reports, and 38,843 (13.2%) reports with sufficient information to assign TCS potency class.

The annual number of AE reports naming CS in the product field grew steadily over time (Figure 2); 190,056 of 294,811 (64.5%) were received from January 2019 onward.

FIGURE 1. Case identification and cohort derivation.



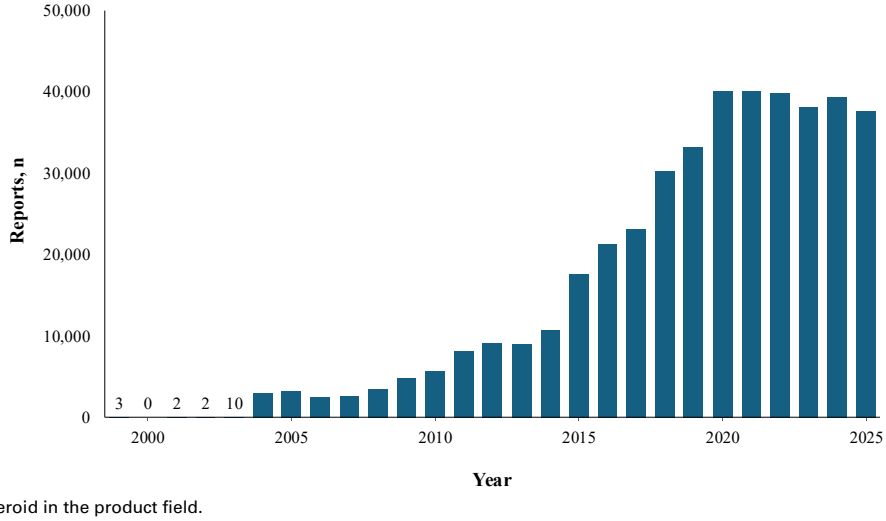
CS, corticosteroid.

Characterization of Reported AEs

Across reports with CS in the product field, 1,619,452 coded reaction term occurrences were identified using the top 800 MedDRA PTs, reflecting that individual reports contained multiple reaction terms. The 15 most frequently reported MedDRA PTs among reports with CS in the product field are shown in Figure 3. The most commonly reported AE PTs (≥20,000) were fatigue (n=24,320), pain (n=20,940), and dyspnea (n=20,228). PTs related to TCS use and efficacy also identified in ≥20,000 reports were "drug ineffective" (n=36,746) and "off-label use" (n=24,782).

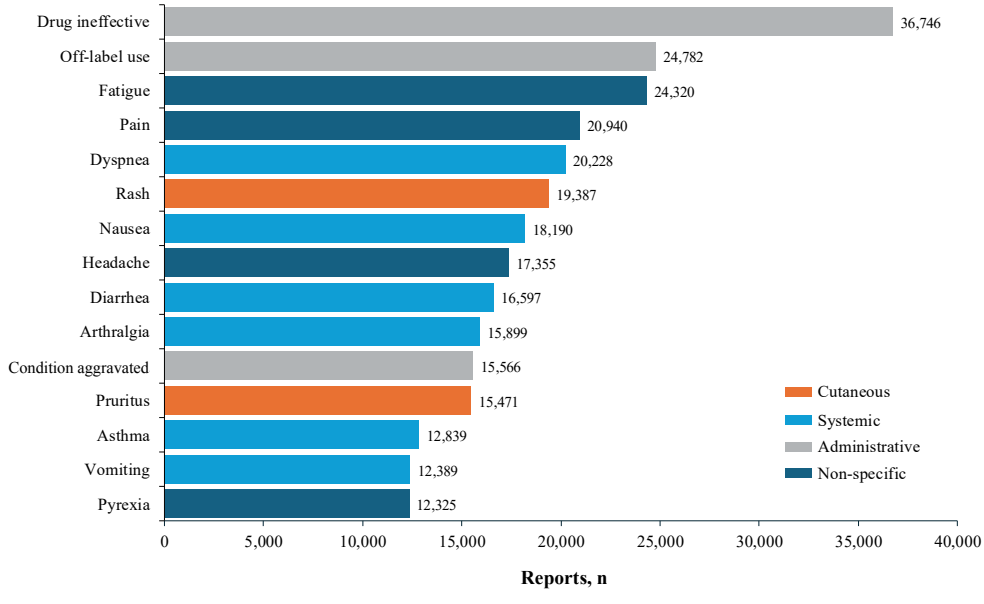
Because the highest-frequency MedDRA PTs were non-specific, we examined a pre-specified set of AEs that reflect the known pharmacology of TCS. Among local cutaneous AEs, skin atrophy was most commonly reported (n=653), followed by skin striae (n=148), telangiectasia (n=92), perioral dermatitis (n=69), and hypertrichosis (n=52). Skin hypopigmentation and depigmentation were included in 112 and 62 reports, respectively. Endocrine AEs included adrenal insufficiency (n=2,367), Cushing syndrome (n=1,383), adrenal suppression (n=433), cushingoid (n=431), and growth suppression (n=154). Ocular AEs comprised

FIGURE 2. Annual adverse event reports from 1999-2025.



From reports with corticosteroid in the product field.

FIGURE 3. Top 15 reported MedDRA preferred terms.



From reports with corticosteroid in the product field. MedDRA, Medical Dictionary for Regulatory Activities.

TABLE 1.

Adverse Events by Treatment Duration	
Treatment duration range	**Reports, n (%)**
≤ 2 weeks	392 (57.1)
> 2 weeks – 1 month	90 (13.1)
> 1 – 3 months	75 (10.9)
> 3 – 12 months	43 (6.3)
> 12 months	87 (12.7)

Percentages were calculated using a stratified random sample of 687 reports with corticosteroid in the product field and known duration data.

cataract (n=1,752), glaucoma (n=697), and raised intraocular pressure (n=411). Withdrawal-specific terms included skin burning sensation (n=1,195), withdrawal syndrome (n=450), and drug withdrawal syndrome (n=362).

Of 1,619,452 coded reaction terms, 628,056 (38.8%) were systemic reaction terms and 135,242 (8.4%) were cutaneous (Figure 4). Gastrointestinal, musculoskeletal/autoimmune, respiratory, and cardiovascular AEs accounted for the largest number of systemic coded reaction term occurrences.

In a stratified random sample of 29,905 reports with CS in the product field, 16,838 (56.3%) contained ≥1 systemic event, 6,132 (20.5%) contained ≥1 cutaneous event, 12,968 (43.4%) contained 1 systemic event only, 2,262 (7.6%) contained 1 cutaneous event only, 3,870 (12.9%) contained both a systemic and cutaneous event, and 10,805 (36.1%) contained neither.

AEs by Duration of TCS Treatment

CS use duration was evaluated in a stratified random sample of 10,000 reports with a CS in the product field. Only 687 reports (6.9%) contained both drug start and end dates, permitting calculation of treatment duration. Among these, 392 (57.1%) had a treatment duration of ≤2 weeks, whereas 87 (12.7%) had a duration of >12 months (Table 1).

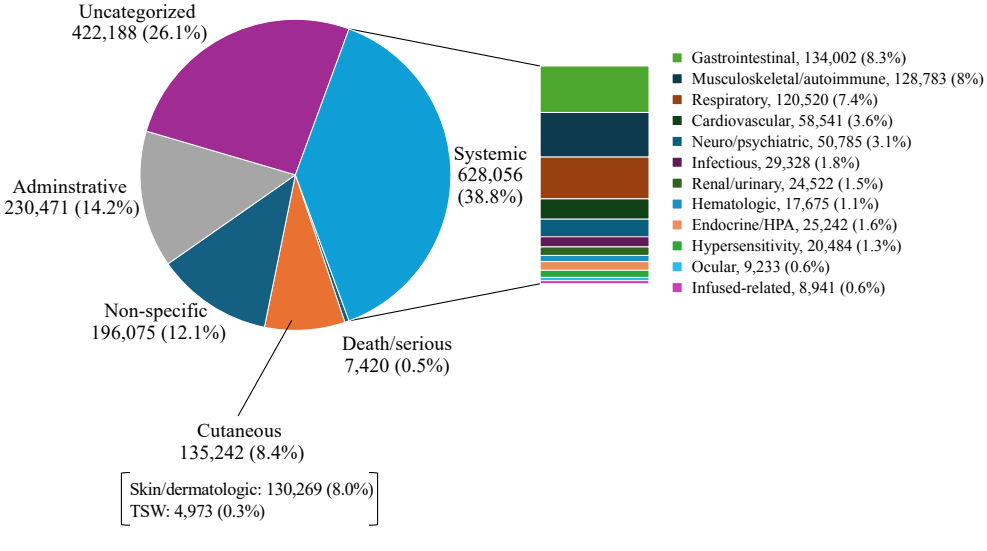
AEs by Age Group

A valid recorded age was available in 192,008/294,811 (65.1%) reports with CS in the product field; 106,456 adults (aged 18–64) accounted for the largest proportion (55.4%) of reports, followed by 68,627 patients aged 65–110 (35.7%) (Figure 5). Individuals aged 45–64 years represented the largest subpopulation of adults (n=64,070; 33.4%). Individuals aged ≤17 years accounted for 16,925 (8.8%) of reports, with children aged 2–11 years comprising the largest subgroup (n=9,767; 5.1%). Median age of onset of the reported AEs was 58 years (IQR, 41-70).

Seriousness of AEs

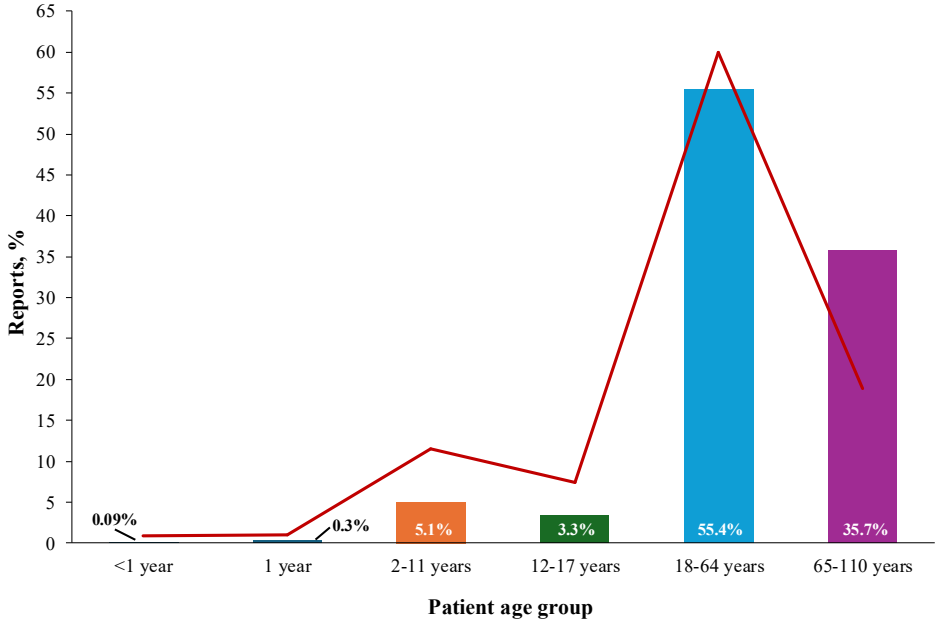
Among 88,558 reports with a CS term as the primary suspect and seriousness data, 64,665 (73.0%) were classified as serious. The majority of these (n=64,145; 99.2%) were with TCS as the primary suspect. The most frequently reported ICH E2A seriousness criterion was "other/required intervention," (n=50,959; 78.8%) followed by hospitalization (n=27,170; 42.0%), death (n=9,901; 15.3%), life-threatening events (n=9,535; 14.7%), disability (n=9,305; 14.4%), and congenital anomalies (n=3,152; 4.9%).

FIGURE 4. Clinical category of coded reaction term occurrences.



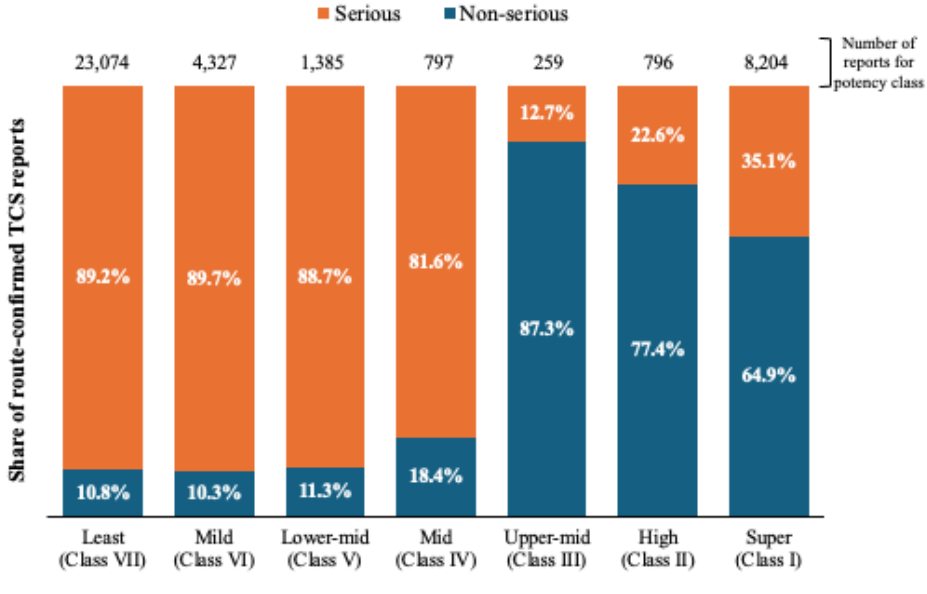
Proportions calculated from 1,619,452 coded reaction term occurrences.

FIGURE 5. Age distribution of adverse events.



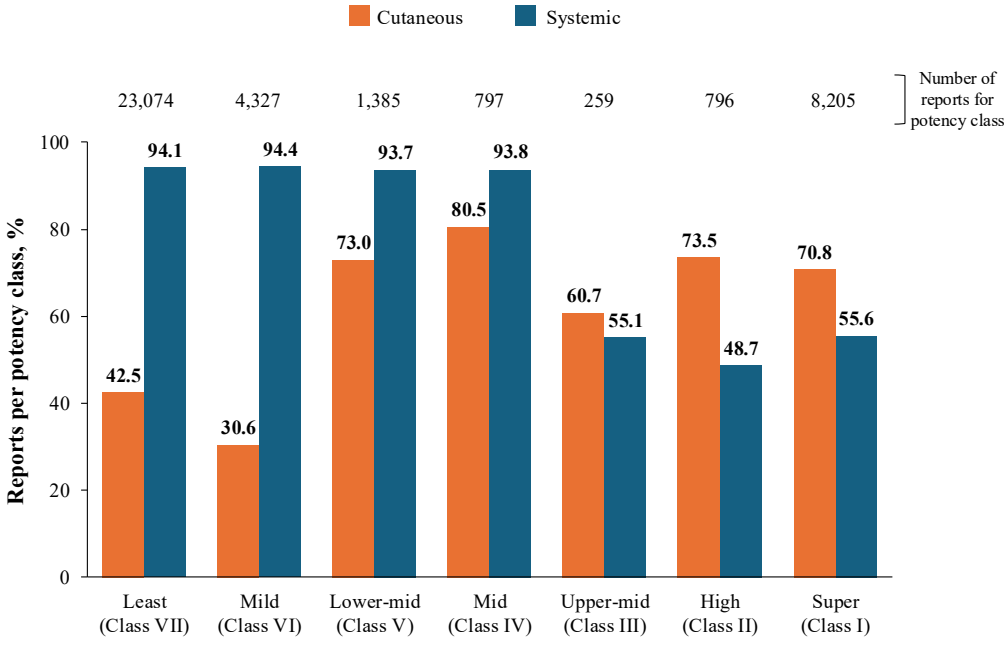
From reports with corticosteroid in the product field and known age data (192,008). The red line indicates United States Census Data from 2025.[30]

FIGURE 6. Seriousness of adverse events by potency class.



From reports with TCS as the primary suspect and assigned TCS potency class. Each report was assigned to the highest potency of the TCS. One Class I report with a blank 'serious' field was not included. Proportions were calculated using the total number of reports for each potency class.
TCS, topical corticosteroid.

FIGURE 7. Clinical category of AEs by potency of TCS.



From reports with TCS as the primary suspect and assigned TCS potency class (38,842). Each report was assigned to the highest potency of the TCS. One Class I report with a blank 'serious' field was not included. Percentages were calculated using the total number of reports for each potency class; sums will be >100% because some reports include both cutaneous and systemic AEs.
AE, adverse event; TCS, topical corticosteroids.

Potency-Class Distribution of AEs

There were 38,843 CS primary suspect reports that were route-confirmed topical and could be potency-resolved (44.7% of 86,867 primary suspect TCS reports). Among these, Class VII (least potent) TCS accounted for the largest proportion (n=23,074; 59.4%), followed by Class I (super-potent; n=8,205; 21.1%), Class VI (mild; n=4,327; 11.1%), Class V (lower mid; n=1,385; 3.6%), Class IV (mid; n=797; 2.1%), Class II (high; n=796; 2.0%), and Class III (upper mid; n=259; 0.7%).

The proportion of reports with serious AEs was lower in the most potent TCS classes (I–III: 13–35%) and higher in the milder classes (IV–VII: 82–90%) (Figure 6). Cutaneous and systemic AEs were reported across TCS potency classes (Figure 7). Reports from the most potent TCS classes (I–III) were most likely to include only cutaneous AEs (18.5–22.6%), whereas reports from the mildest classes (VI–VII) were most likely to include only systemic AEs (35.0–48.1%). Reports from classes IV and V most often included both cutaneous and systemic AEs (51.2–51.3%).

DISCUSSION

This large-scale, longitudinal analysis provides a comprehensive characterization of TCS-associated AE reporting patterns not readily apparent from established safety concerns or product labeling, spanning >25 years of real-world US pharmacovigilance data. From 1999-2025, 422,947 reports with a CS as a suspected drug (any role and any route) were submitted to FAERS, representing approximately 1% of the 33,481,755 reports in the FAERS database.[22]

Some results presented here contrasted with the known safety concerns associated with TCS[4,5] and likely reflect the heterogeneous nature of spontaneous AE reports, which capture reported events regardless of causality and may be influenced by underlying disease, comorbidities, and concomitant therapies.[28] The predominance of non-specific MedDRA PTs, the 4.6-fold higher frequency of systemic versus cutaneous reaction terms, and the high proportion of serious reports may reflect reporting bias, whereby unexpected events are more likely to be reported than expected reactions or symptoms

attributed to the underlying disease. Similarly, TCS on-target AEs were uniformly infrequent despite hypothalamic-pituitary-adrenal axis, Cushing, and skin-atrophy warnings appearing in 93–98% of prescription labels. Asymmetry between the near-universal labeling of these effects and their low frequency in spontaneous reports likely reflects reporting behavior and the limitations of FAERS rather than the incidence of these events.

Most records with known duration reflected short-course CS use (57% ≤2 weeks), consistent with recommendations.[29] A smaller but notable proportion (13%) reflected use for >12 months, which may increase the risk of cumulative CS AEs.[4]

Compared with the age distribution in the US,[30] FAERS CS AE reports were disproportionately concentrated among adults aged ≥65 years, whereas populations aged ≤17 years and younger adults were underrepresented. This likely reflects patterns of CS utilization and AE reporting rather than age-specific risk, as spontaneous reporting systems lack exposure denominators.[31]

The predominance of Class VII and substantial representation of Class I TCS among potency-resolved reports is broadly consistent with their widespread use and clinical relevance. AE patterns did not suggest a clear potency-dependent relationship, with serious and systemic AEs more prominent among milder classes. This counterintuitive pattern may reflect differences in utilization, indication, exposure, and reporting behavior rather than differences in safety. Without exposure denominators, AE risk cannot be compared across potency classes.

Nearly two-thirds (64.5%) of the cumulative volume of identified AEs were reported from 2019 onward, temporally coinciding with increased regulatory and public awareness of TCS-associated AEs, including publication of the United Kingdom Medicines and Healthcare products Regulatory Agency Drug Safety Update.[11] Rather than being an indicator of an increasing incidence of AEs, this increase in reporting volume may reflect increased public and regulatory awareness of TCS AEs.

Despite clinical recommendations and regulatory actions outside the US, FDA-approved labeling for TCS is inconsistent across products, and contradictions exist even within individual product labels. Also, many labels have not been updated to reflect contemporary understanding of TCS-associated AEs, including TSW and associated terms such as red skin syndrome, rebound flares, and tachyphylaxis.

FAERS data are based on spontaneous reports and are subject to the inherent limitations of passive pharmacovigilance systems, including underreporting, duplicate reports, and uncertainty regarding causality. Additionally, details about concentration and formulation are not reported consistently in the FAERS database; therefore, only reports with sufficient details had potency classified, which limits interpretation of potency-related analyses. Key variables, including age, treatment duration, and potency, were frequently missing or unavailable, limiting interpretation of subgroup analyses. Reporting may also vary over time according to drug utilization, manufacturer reporting practices, regulatory activity, and public awareness, complicating interpretation of temporal trends. Our analysis included reports dating back to 1999, preceding the transition to modern electronic AE reporting around 2004, which may have influenced reporting patterns over time. Accordingly, these data cannot be used to estimate AE incidence, establish causality, or directly compare risk between patient or treatment groups.

This analysis provides a large-scale overview of AEs reported in association with TCS in the FAERS database and identifies reporting patterns that may not be apparent from product labeling or individual clinical studies. Together with growing recognition of TCS-associated AEs, these findings underscore the need to better characterize the safety profile of TCS in contemporary practice and evaluate whether current clinical guidance, regulatory labeling, and patient monitoring practices adequately address the risks and consequences of treatment.

DISCLOSURES

Adam J. Friedman is 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, Zylo Therapeutics.

Kristina M. Derrick is a consultant, speaker, and/or investigator for Arcutis, Castle Biosciences, Chiesi, Colgate, Eton Pharmaceuticals, Johnson & Johnson, Kenvue, Pelthos Therapeutics, Priovant, VeraDermics, Verrica.

George Martin is a consultant and/or investigator for AbbVie, Almirail, BMS, Celgene, Dermavant, DUSA/SUN, Evelo, Galderma, Horizon, Janssen, InCyte, LEO Pharma, Lilly, Minderna, Novartis, Organogenesis, Ortho/Bausch Health, Pfizer, Trevi, UCB.

Elaine C. Siegfried is 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, UCB.

Melissa S. Seal, Jennifer C. Jaworski, Brett Stephenson, Raja Mikkili, Robert C. Higham, and Diane Hanna are employees of Arcutis.

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, Takeda.

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