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doi:10.36849/JDD.10425

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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.

J Drugs Dermatol. 2026;25:11(Suppl 1):s21-30.

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

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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.

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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.

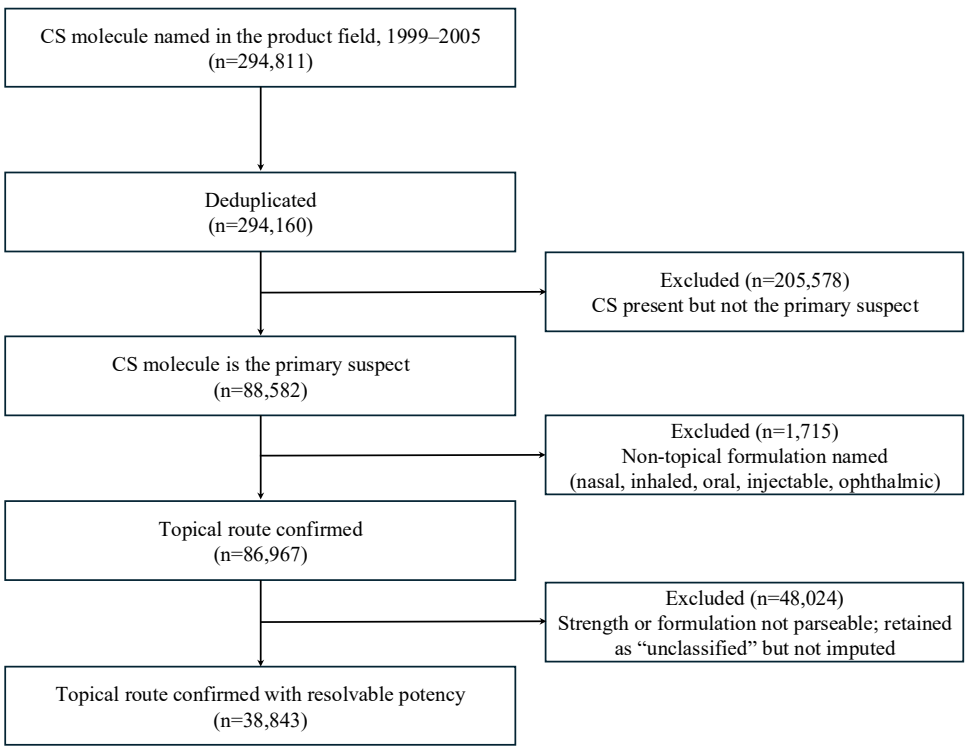
RESULTS

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.

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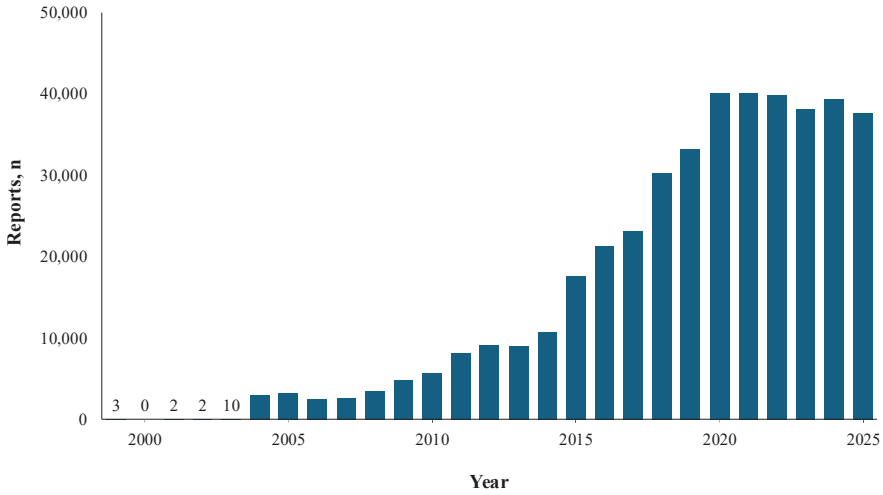
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Characterization of Reported AEs

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).

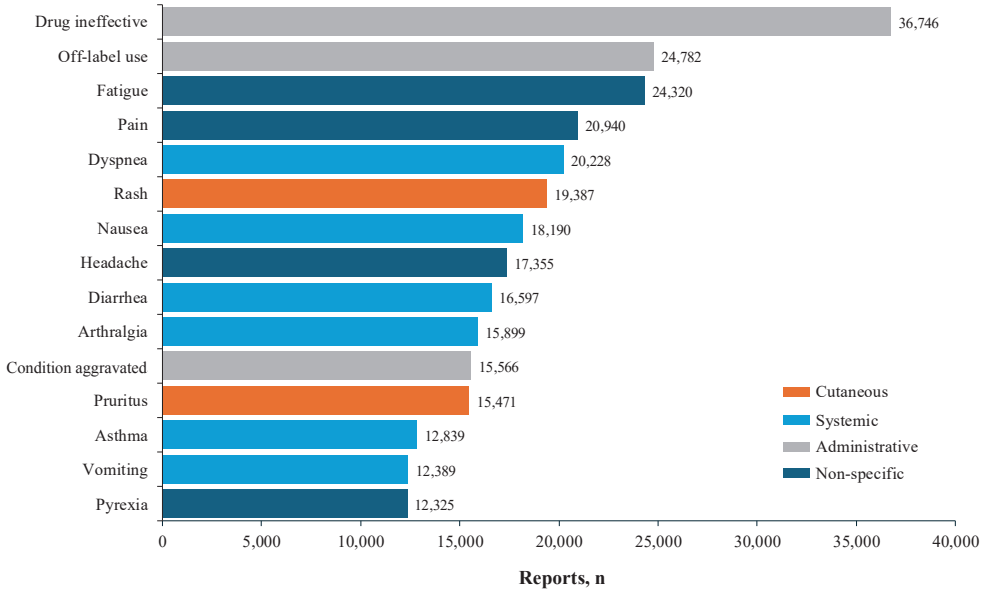
Because the highest-frequency MedDRA PTs were non-specific, we examined a pre-specified set of AEs that reflect the known pharmacology of TCS. Among local cutaneous AEs, skin atrophy was most commonly reported (n=653), followed by skin striae (n=148), telangiectasia (n=92), perioral dermatitis (n=69), 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.

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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).

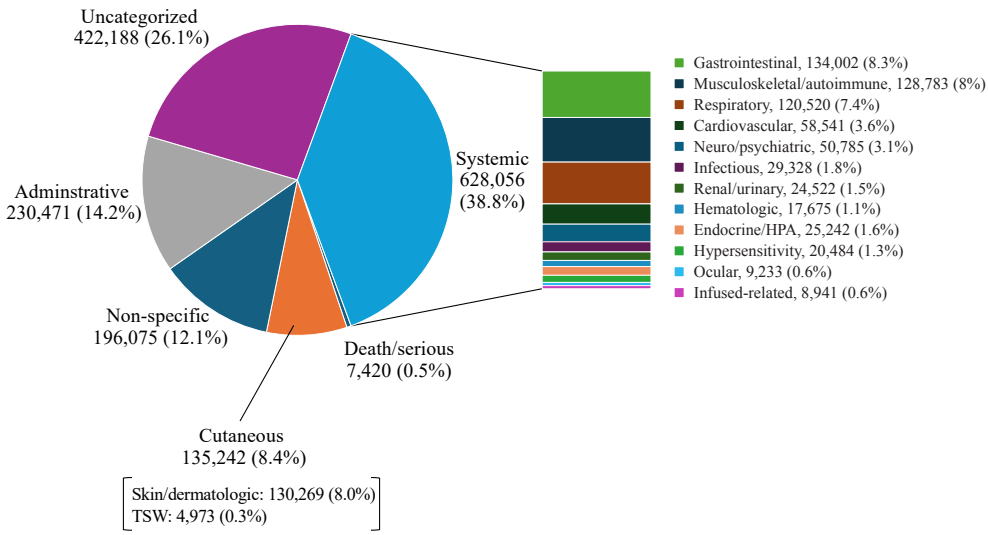
AEs by Age Group

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.

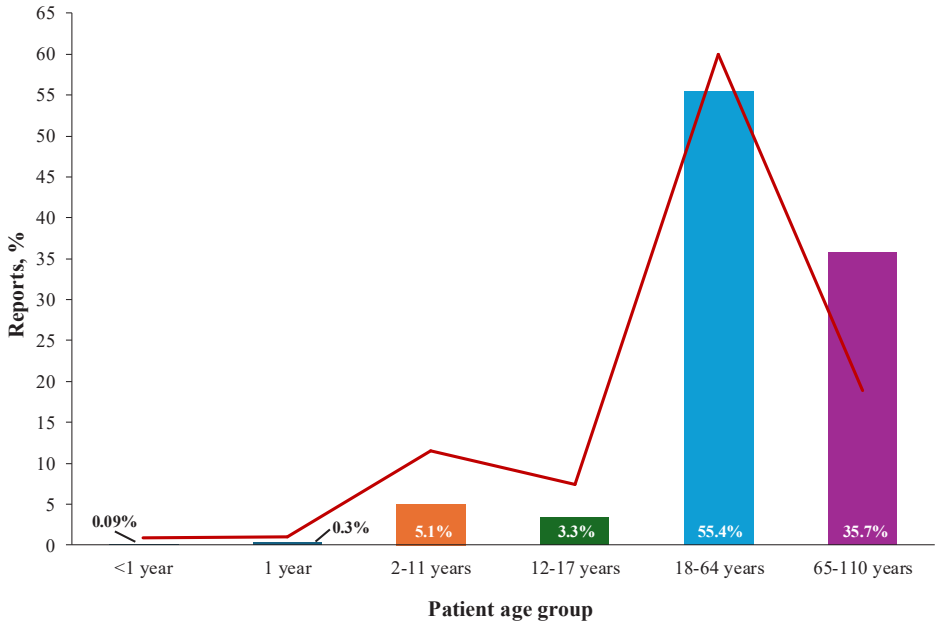


Proportions calculated from 1,619,452 coded reaction term occurrences.

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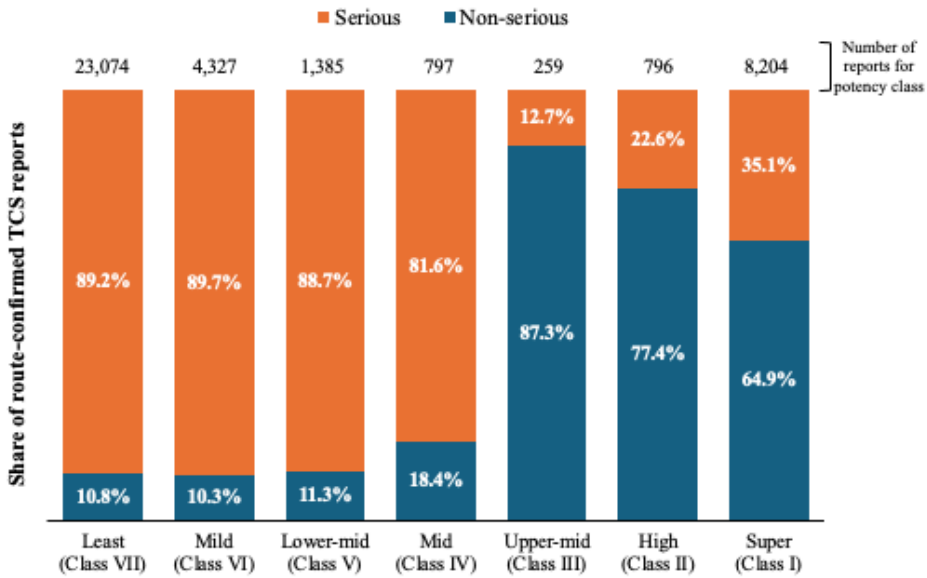
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FIGURE 5. Age distribution of adverse events.



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.

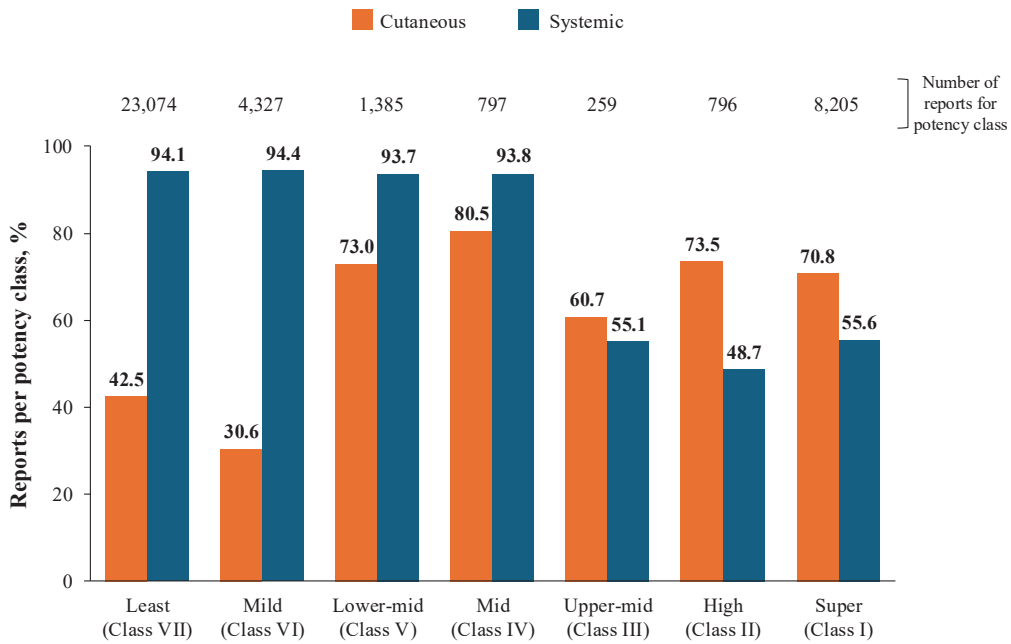


From reports with TCS as the primary suspect and assigned TCS potency class. Each report was assigned to the highest potency of the TCS. One Class I report with a blank 'serious' field was not included. Proportions were calculated using the total number of reports for each potency class.
TCS, topical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

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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

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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.

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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.

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

ACKNOWLEDGMENT

Medical writing support was provided by Jennifer Steeber, PhD, Samantha L. Dwyer, PhD, and Andrea M. Michels, of Ashfield MedComms, an Inizio company, and was funded by Arcutis Biotherapeutics, Inc.

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