

Systematic evaluation of topical dosage form types and approved indications for dermatologic use

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INTRODUCTION

Suitability of the dosage form (e.g., gel, ointment, etc.) of a drug product for a given indication is important for optimal therapeutic effect and user compliance.

We reviewed the current landscape of approved dosage form types and labeled indications for dermatologic reference listed drug (RLD) products in the United States, to explore whether a trend exists between the dosage form and indication for these products.

METHODS

The FDA database *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”) was surveyed on 12/31/2024, to yield the list of approved topical products and their dosage form information.

This list was filtered to include products that have an RLD designation, e.g., innovator topical products. The list of topical RLDs was further screened based on labeled indication(s) to include only products for dermatologic uses (and exclude products for application to only mucosal membranes or eyes or for systemic use). Products without accessible labeling at this time were excluded from the subsequent analysis.

A correlation was explored between the types of dosage forms and the indications by analyzing whether there is a trend in types of dosage forms for a given indication based on properties of the disease or condition and/or the treatment needs. Similar indications or dosage forms were consolidated during the analysis.

1814 topical products approved in United States

• Source for products and dosage forms: Orange Book as of 12/31/2024

• Filter: Route of administration contains “topical”

374 topical RLDs

• Filter: RLD designation is assigned

361 products with accessible labeling

• Source for labeling:

• FDA internal databases

• External databases such as Drugs@FDA.

347 products for dermatologic use

• Screen criterion: Approved indication(s) in the labeling include(s) dermatologic diseases or conditions

360 products based on unique (consolidated) indications

• One product may be counted more than once if it has multiple indications.

Does a trend exist?

• Types of consolidated dosage forms vs. consolidated indications

Figure 1. Sources of information and flow of product screening and subsequent analysis

CONCLUSION

- The prevalence of dosage form types approved for topical dermatologic products generally aligns with their indicated treatment needs.
- This supports the importance of making rational choices related to selection of the dosage forms and excipients during development.

RESULTS

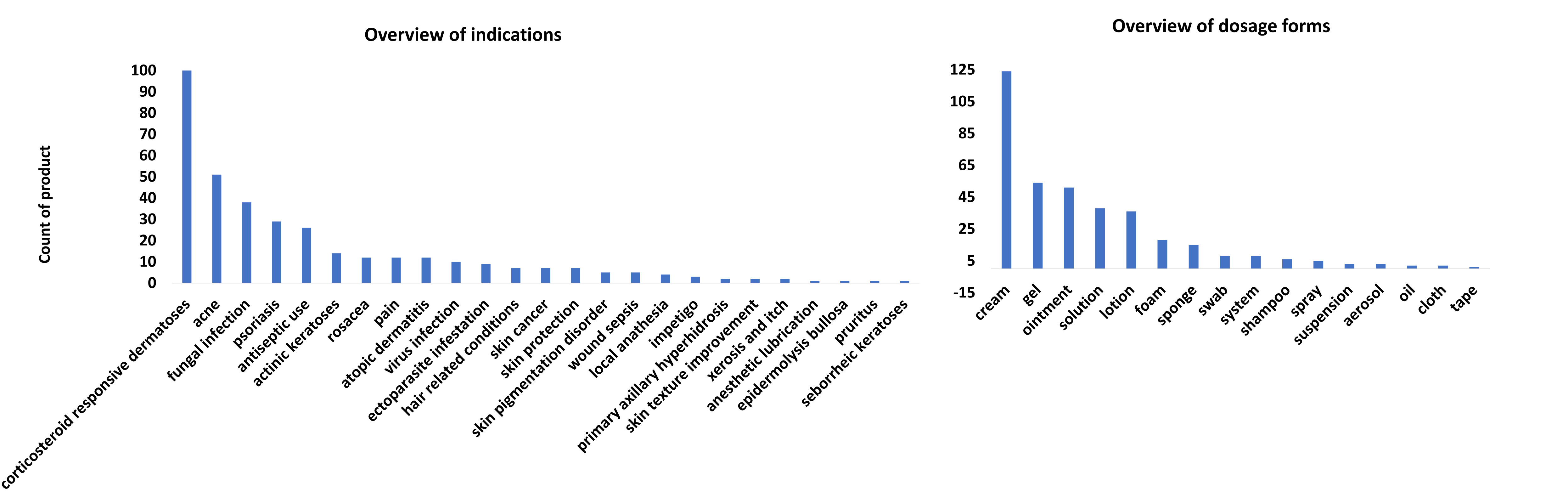


Figure 2. Overview of indications and dosage forms approved for topical RLD products (e.g., innovator topical products) for dermatologic use. Both indications and dosage forms were consolidated. 360 products were identified and comprise of 25 (consolidated) indications and 16 (consolidated) dosage forms.

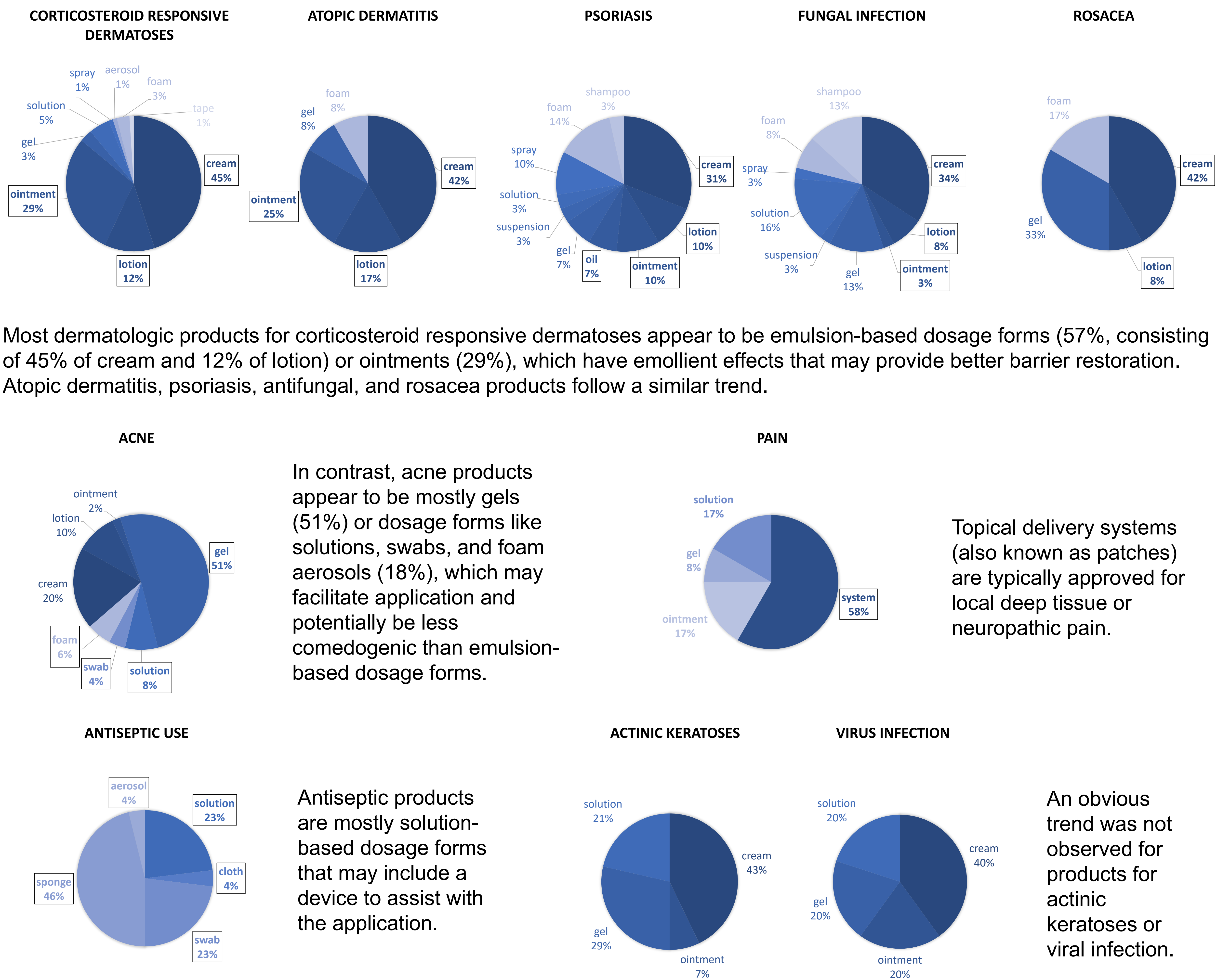


Figure 3. Dosage forms approved for the top ten indications. Figures were grouped by findings. Data labels for within-trend dosage forms were shown with frames. In addition, we noted that solutions, lotions, oils, foam aerosols, and shampoos are approved for products indicated for scalp use only, as they may offer a more homogenous distribution on the scalp.