Product Storage, Handling, and Use Statements

Approved Product Storage, Handling, and Use Statements

Shake well before use.

Shake gently before use.

For foil pouches

Unit-dose vials should remain stored in the protective foil pouch at all times.

Once the foil pouch is opened, the vials should be used within two weeks.

Once removed from the foil pouch, the individual vials should be used within one week.

Open the foil pouch just prior to administration.

After opening the foil pouch, the unused vials should be returned to, and stored in, the pouch.

For products with actuator

For optimal results, canister should be at room temperature when used.

For aerosol products

CONTENTS UNDER PRESSURE. Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 49°C (120°F) may cause bursting. Never throw canister into fire or incinerator.

For concentrated products

Dilute before use.

For solutions

Discard if solution is not colorless.

For inhalation or nasal spray products

Avoid spraying in eyes.

Design Guidelines for Product Storage, Handling, and Use Statements

Font family Helvetica Neue Std.

Font weight

Medium and Light as shown in the Approved Statements above.

If space constraints: Medium and Light Condensed.

Font size

4–7 point suggested. Panel size dependent. Sunovion approval required for size below 4 point.

Relational size

All Descriptive Text must be the same size.

Placement

Preferred: Side panel within Descriptive Text block (see Preferred Order of Descriptive Text).

Spacing between lines (leading): When statements are longer than one line, baseline to baseline spacing between lines will be 110–120% of font size.

Spacing between paragraphs (paragraph leading):
Baseline to baseline spacing between paragraphs will be 150–200% of font size.

Alignment: Left aligned.

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Margins

Margins from all edges of label must be a minimum of $^{1}/_{16}$ " (1.5 mm; 4.5 points).

Color

Light background color: Black.

Dark background color: Reverse to white. Font weights should change to Bold and Medium.

Preferred Order of Descriptive Text

- 1) Ingredients Statements
- 2) Dosage Statements
- 3) Product Storage, Handling, and Use Statements
- 4) Temperature Storage Statements
- 5) Patient's Instructions for Use Statements
- 6) Warning Statements
- 7) Child Caution Statements

Paragraph treatment: Product Storage, Handling, and Use Statements, as well as each Descriptive Text category, should be a separate paragraph.

If space constraints: Product Storage, Handling, and Use Statements can be combined into one paragraph.