

Warning Statements

Approved Warning Statements

In case of accidental ingestion, immediately contact your physician, pharmacist, or a poison control center.

Please see full prescribing information including BOXED WARNINGS.

Design Guidelines for Warning Statements

Font family Helvetica Neue Std.

Font weight Medium.

If space constraints: Medium 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.

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 weight should change to Bold.

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: Warning Statements, as well as each Descriptive Text category, should be a separate paragraph.

Reference

21 CFR Section 201.57. Specific requirements on content and format of labeling for human prescription drug and biological products described in 201.56(b)(1).