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

7–10 point suggested. Panel size dependent.

Relational size

All Descriptive Text must be the same size.

Placement

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

Alternate: Left side panel.

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 above and below the statement will be 150–200% of font size.

Alignment: Left aligned.

Margins

Margins from all edges of carton panels must range from $^1/8$" (3 mm; 9 points) to $^1/4$" (6 mm; 18 points).

Spacing between columns of Descriptive Text (gutter) must range from $^5/32$" (4 mm; 12 points) to $^1/4$" (6 mm; 18 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).