

Ingredients Statements

Approved Ingredients Statements*

Each [unit] contains:
[established name] 00 mg.

Contains no preservatives.

For blister wallets

Each [unit] contains 00 mg of
[established name].

Design Guidelines for Ingredients Statements

Font family Helvetica Neue Std.

Font weight Light.

If space constraints: Light Condensed.

Font size

7–10 point suggested. Panel size dependent.

Relational size

All Descriptive Text must be the same size.

Placement

Preferred: Outside Panel 3 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.

Additional placement: Ingredients Statement shown above for blister wallets should also be placed on inside panel in close proximity to the area where medication is dispensed.

Margins

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

Color

Light background color: Black.

Dark background color: Reverse to white. Font weight should change to 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: Ingredients Statements, as well as each Descriptive Text category, should be a separate paragraph.

Reference

21 CFR Section 201.10. Drugs; statement of ingredients.

*Other formulation ingredients may be needed.