

Medication Guide Statements

Approved Medication Guide Statements

For unit-of-use packaging

ATTENTION DISPENSER: Dispense the enclosed [or accompanying] Medication Guide to each patient.

For bulk pharmacy packaging

ATTENTION DISPENSER: Each time [Product Name] is dispensed give the patient a Medication Guide, also provided at [www.\[ProductName\].com](http://www.[ProductName].com) or 1-888-394-7377.

Design Guidelines for Medication Guide Statements

Font family Helvetica Neue Std.

Font weight Medium Condensed.

Font size

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

Relational size

Font size must be 100–120% of font size of NDC Number.

Placement

Principal display panel in a rectangular box where the box length is approximately three times the height.

Box should consist of at least a 1/2 point border, in the strength differentiation color, with a 3 to 5 point overall margin between the box and the text.

Preferred: Statement appears above Sunovion Corporate Branding with space below the statement at least 1/8" from Corporate Branding.

Medication Guide Statements must be prominently displayed.

Spacing between lines (leading): Baseline to baseline spacing between lines will be 110–120% of font size.

Alignment: Right 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.

Reference

21 CFR Section 208.24. Distributing and dispensing a Medication Guide.