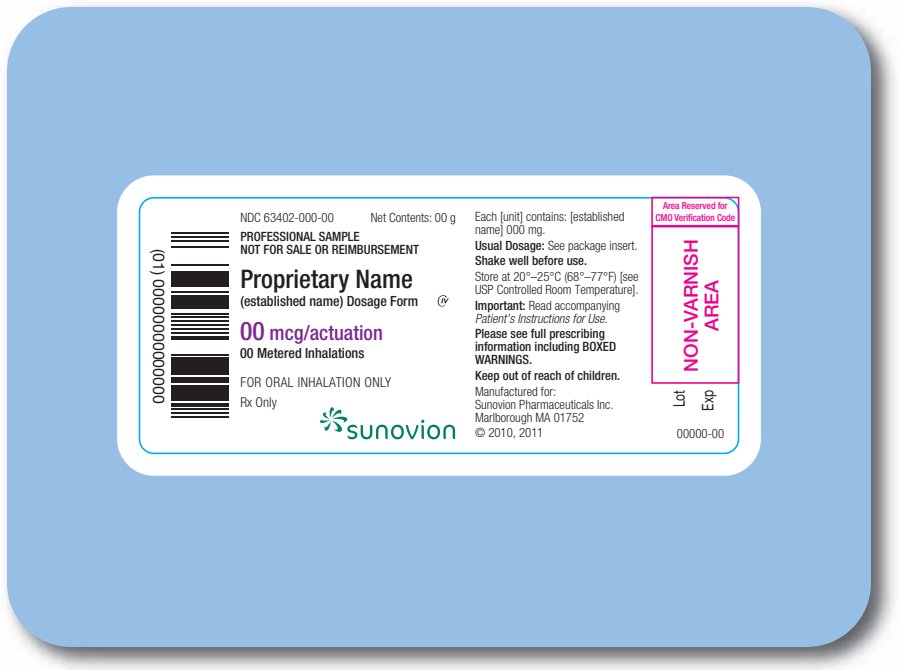


Inner Label

Complete Design and Content Guideline

Contents

Introduction

Welcome to the Inner Label
Complete Design and Content Guideline.

The purpose of this Guideline is to provide a framework for the consistent development of an inner label for Sunovion, while at the same time allowing flexibility in design and product branding.

An inner label is a label that is contained within another level of packaging when the unit is stored on a shelf at the healthcare provider or pharmacy.

The Guideline is relational in nature. It shows the relative size and positioning of mandated content for a Sunovion inner label. A package designer may choose to maintain the relational spirit of the Guideline but adjust its implementation based on label dimensions, to achieve legibility and an aesthetically pleasing presentation.

It is recommended that the placement of the Sunovion Corporate Branding element and the NDC number be used as starting points for the design of an inner label, and lay out from there.

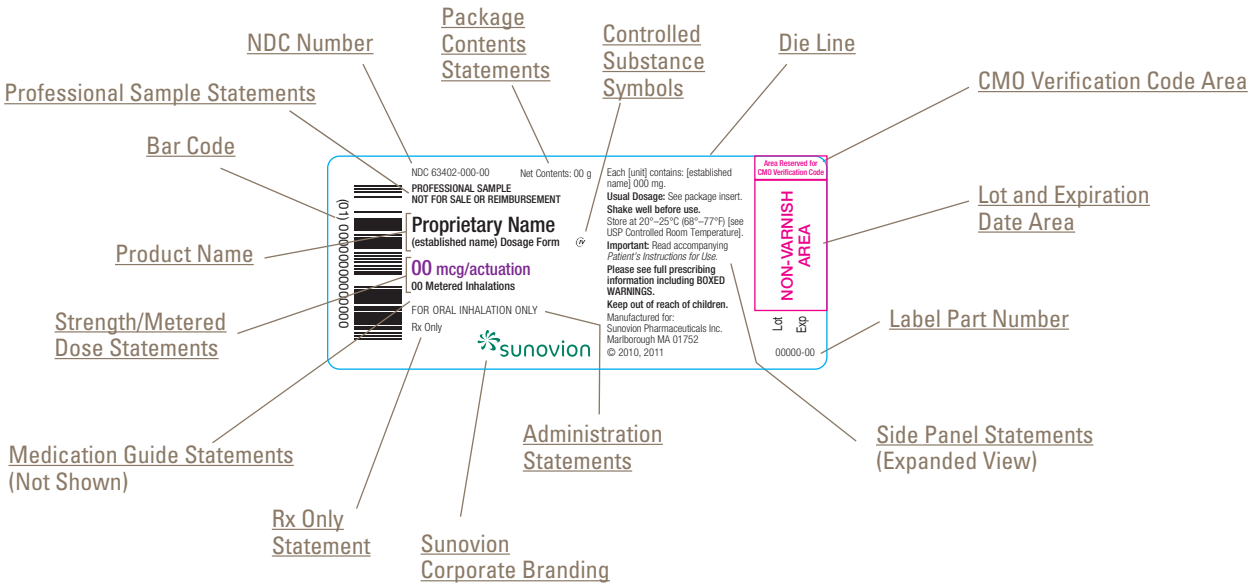
Please note that content may change from label to label at the discretion of Sunovion Regulatory Affairs.

We hope you find this Guideline to be a useful tool and we welcome comments or questions to SunovionStyle@sunovion.com.

Consistent, compliant, and great packaging. That's our mission.

The Editors

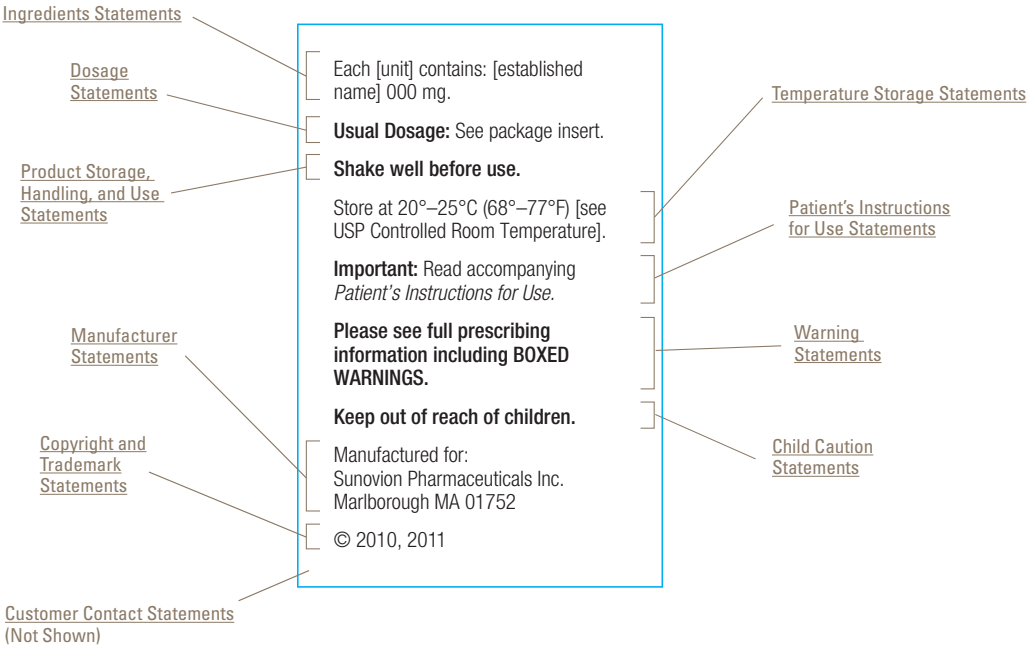
Inner Label Template



Preferred Relational Width of Principal Display and Side Panels

Bar Code: Bar height should be 1/4" (6.35 mm; 18 points), with a minimum 1/16" (1.5 mm; 4.5 points) quiet zone on all sides.
Principal display panel: Should be approximately 55% of the label width (excluding Lot/Exp Area and bar code).
Side panel: Should be approximately 45% of the label width (excluding Lot/Exp Area and bar code).

Inner Label Template–Side Panel Statements Expanded View



Administration Statements

Approved Administration Statements

For products with actuator

FOR INTRANASAL USE WITH [PROPRIETARY NAME] NASAL ACTUATOR ONLY

FOR ORAL INHALATION WITH [PROPRIETARY NAME] ACTUATOR ONLY

For inhalation or nasal spray products

FOR ORAL INHALATION ONLY

FOR INTRANASAL USE ONLY

Design Guidelines for Administration Statements

Font family Helvetica Neue Std.

Font weight Light Condensed.

Font size

5–7 point suggested. Panel size dependent.

Relational size

Font size should be 120% the size of the NDC number.

Font tracking

For statements that appear in all capital letters, increase tracking as follows: QuarkXPress setting at +6; Illustrator and InDesign settings at +30.

Placement

Principal display panel, beneath Strength/Metered Dose Statement.

Spacing from baseline of Strength/Metered Dose Statement to baseline of Administration Statement should be 250% of font size, or adjusted as necessary to achieve an equal amount of white space above and below the Strength/Metered Dose Statement.

Alignment: Left aligned.

If space constraints: Administration Statement can appear on the same baseline as the Strength/Metered Dose Statement, right aligned.

Margins

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

Reference

21 CFR Section 201.5. Drugs; adequate directions for use.

Bar Code

Approved Bar Code GS1 Databar 14 (GS1 Databar Omnidirectional)

Bar code is mandatory for Retail Packaging and optional on Sample Packaging.

Design Guidelines for GS1 Databar 14 (GS1 Databar Omnidirectional)

Font family

Preferred: Helvetica Neue Std human readable font.

If space constraints: Human readable not required.

Font weight

Regular.

Specifications

Bar height: 1/4" (6.35 mm; 18 points)
NBR: 0.0100
BWA: -0.0020

Encoding

(01) signifying GS1 Databar Omnidirectional format, followed by 003 ("3" signifying a subsequent 10-digit NDC Number), followed by check digit number.

The check digit is calculated on the 13 preceding digits to obtain a GTIN-14.

Example: (01) 00363402NNNNNX

Placement

Preferred: Left of the principal display panel.

Alignment

Rotate 90° (ladder format); center vertically.

When printed on a curved surface, such as a round bottle, bars should be perpendicular to the axis of the bottle so that a scan line can pass through the bar code on as flat a plane as possible.

Quiet Zone

Quiet zone should be a minimum of 1/16" (1.5 mm; 4.5 points) on all sides of bar code.

Exception: 1/32" (.75 mm; 2.25 points) acceptable from bar code to human readable.

Color

Black.

Background: There should be no background or gradient behind the bar code. If there is a background on the label, the bar code must be set in a white box to prevent scanning interference.

Reference

21 CFR Section 201.25. Bar code label requirements.

CMO Verification Code Area

Approved handling of CMO Verification Code Area

Area Reserved for
CMO Verification Code

Design Guidelines for CMO Verification Code Area

Font family Helvetica Neue Std.

Font weight Medium.

Font size

4–8 point suggested. Panel size dependent.

Placement

Location designated by Contract Manufacturing Organization (CMO).

Quiet Zone

CMO will include the required quiet zone for the bar code in the area reserved for CMO verification.

Color

Keyline border: Magenta (does not print).

Text: Magenta (does not print).

Background: There should be no background or gradient behind the CMO Verification Code Area. If there is a background on the label, the bar code must be set in a white box to prevent scanning interference.

Verification Code Handling

CMO creates and places the verification code in the boxed area.

Exception: CMO may require Sunovion to add a Verification Code, e.g., Pharmacode.

In this case, the CMO Verification Code Area would not be called out, but would be replaced with the actual code, built according to Engineering Drawing Specifications.

Exception: CMO may use text for verification, and may provide specs for text to be placed in the reserved area.

Pharmacode

Number of bars/value: Assigned by CMO.
Thick bar: 1.5 mm.
Thin bar: 0.5 mm.
Space between bars: 1 mm.
Bar height: Assigned by CMO.
Read direction: Assigned by CMO.
Color of bars: Black preferred.

Exception: CMO may direct a pharmacode or equivalent with different specifications.

Controlled Substance Symbols

Approved Controlled Substance Symbols

Design Guidelines for Controlled Substance Symbols

Symbol size

Symbol should be 100–120% the height of the capital letters in Established Name or Dosage Form.

Symbol size must be large enough to easily identify the product's controlled substance designation.

Placement

Principal display panel. Positioned right of, and on the same baseline as Established Name.

The horizontal space between Established Name and Symbol should be twice the width of Symbol.

If space constraints: Space between Established Name and Symbol can be reduced to the width of Symbol.

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.

Reference

21 CFR Section 1302.03. Symbol required; exceptions.

21 CFR Section 1302.04. Location and size of symbol on label and labeling.

Copyright and Trademark Statements

Approved Copyright and Trademark Statements

Copyright

Preferred:

© 2010, 2011 Sunovion Pharmaceuticals Inc.
All rights reserved.

If space constraints:

© 2010, 2011 Sunovion Pharmaceuticals Inc.

Or, placed near the Manufacturer Statement:

© 2010, 2011

Trademark

When a product name, not licensed by Sunovion, appears with register mark ®:

[Product Name] is a registered trademark of [Company Name] and is used with permission.

When a product name, not licensed by Sunovion, appears with trademark ™:

[Product Name] is a trademark of [Company Name] and is used with permission.

Design Guidelines for Copyright and Trademark Statements

Font family Helvetica Neue Std.

Font weight Light.

If space constraints: Light Condensed.

Font size

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

Relational size

Font size must be same as font size of Manufacturer and Customer Contact Statements.

Placement

Side panel, as part of the Manufacturer/Copyright/Contact Text, directly following Descriptive Text.

Spacing between lines (leading): 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 Medium.

Preferred Order of Manufacturer/ Copyright/Contact Text

1) Manufacturer Statements
2) Copyright and Trademark Statements
3) Customer Contact Statement

Paragraph treatment: Copyright and Trademark Statement, as well as each Manufacturer/Copyright/Contact Text category, should be a separate paragraph.

continues next page

Copyright and Trademark Statements

Reference

For trademark information, see 21 CFR Section 201.1 (h)(4): *Drugs; name and place of business of manufacturer, packer, or distributor.*

For copyright information, see 37 CFR Section 201.20: *Methods of affixation and positions of the copyright notice on various types of works*.

Guidance for determining or changing copyright date

Generally, copyright date is determined based on Sunovion's best estimate on piece "publication" date. This is the date the piece is distributed to the general public/consumer; typically this occurs when the piece arrives with the wholesaler or fulfillment center.

For existing packaging and labeling components:

Minor changes: No change or addition to copyright dates.

Medium changes (relevant but not significant changes): Add copyright date to those existing.

Major changes (new or significantly different label): Remove copyright date(s) and insert new date.

Customer Contact Statement

Approved Customer Contact Statement

1-888-394-7377
www.[ProductName].com

Note: Other statements may be directed by Sunovion brand team.

Design Guidelines for Customer Contact Statement

Font family Helvetica Neue Std.

Font weight Light.

If space constraints: Light Condensed.

Font size

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

Relational size

Font size must be same as font size of Manufacturer and Copyright and Trademark Statements.

Placement

Side panel, as part of the Manufacturer/Copyright/Contact Text, directly following Descriptive Text.

Spacing between lines (leading): 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 Medium.

Preferred Order of Manufacturer/ Copyright/Contact Text

1) Manufacturer Statements
2) Copyright and Trademark Statements
3) Customer Contact Statement

Paragraph treatment: Customer Contact Statement, as well as each Manufacturer/Copyright/Contact Text category, should be a separate paragraph.

Reference

21 CFR Section 201.1. Drugs; name and place of business of manufacturer, packer, or distributor.

Ingredients Statements

Approved Ingredients Statements*

Each [unit] contains: [established name] 000 mg.

Contains no preservatives.

Design Guidelines for Ingredients Statements

Font family Helvetica Neue Std.

Font weight Light.

If space constraints: 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.

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 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.

Dosage Statements

Approved Dosage Statements (depending on form of product, e.g., tablet, liquid; and dosage administration)

Usual Dosage: One tablet at bedtime.

Usual Dosage: One tablet per day with food.

Usual Dosage: See package insert.

Use only as directed by your physician. Do not exceed recommended dose.

Design Guidelines for Dosage 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.

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

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.

continues next page

Product Storage, Handling, and Use Statements

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.

Temperature Storage Statements

Approved Temperature Storage Statements

Storage: Store at 20°–25°C (68°–77°F); excursions permitted to 15°–30°C (59°–86°F) [see USP Controlled Room Temperature].

Store at 20°–25°C (68°–77°F) [see USP Controlled Room Temperature].

Store at 25°C (77°F) [see USP Controlled Room Temperature].

Store at 25°C (77°F) [see USP].

Do not freeze.

Protect from freezing temperatures and direct sunlight.

Protect from light and excessive heat.

Keep tightly closed.

Design Guidelines for Temperature Storage 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.

Usage of en dash and degree symbol

Temperature range uses an en dash (–) with no space around it. There is no space between the degree sign (°) and "C" or "F".

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 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: Temperature Storage Statements should be combined into one paragraph. Each Descriptive Text category should be a separate paragraph.

Reference

US Pharmacopeia. USP-29-NF24. Statements/labeling of the immediate containers or package insert.

Patient's Instructions for Use Statements

Approved Patient's Instructions for Use Statements

Attention Pharmacist (or "**Physician**" for samples)**:** Dispense with accompanying *Patient's Instructions for Use.*

Important: Read accompanying *Patient's Instructions for Use.*

Design Guidelines for Patient's Instructions for 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.

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: Patient's Instructions for Use Statements, as well as each Descriptive Text category, should be a separate paragraph.

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).

Child Caution Statements

Approved Child Caution Statements

For all packaging

Keep out of reach of children.

For non-child resistant packaging, add

Package not child resistant.

Design Guidelines for Child Caution 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.

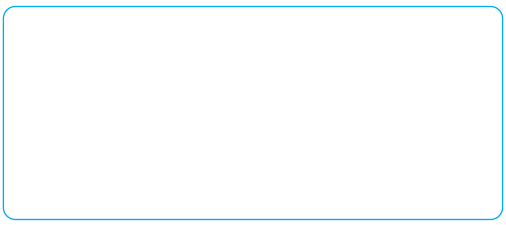
Preferred Order of Descriptive Text

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

Paragraph treatment: Child Caution Statements, as well as each Descriptive Text category, should be a separate paragraph.

Die Line

Approved Die Line



Design Guidelines for Label Die Line

Die Line Supplier

CMO will provide die line at 100% of final component size. The die will show where the label will be cut.

CMO will indicate, either on the die or on a separate engineering drawing, the position of any areas needed for their packaging equipment, such as Lot and Expiration date imprinting or verification code areas.

The die supplied by the CMO will become the foundation for the design.

Die can be edited according to Sunovion's preferences for line weight and color, but should not be edited for size or shape.

Line Weight

Stroke weight of all rules should be 1/2 point and should be set to overprint.

Stroke Color

Color type: Spot.

Color name: Die.

Color definition: 100% cyan preferred. Any alternate color except black can be used if cyan does not provide adequate contrast.

Helpful Information

Die supplied by CMO may contain useful information not needed for Sunovion's design approval process, such as label measurements or multiple placement options. This information should remain with the file, but may be moved to an invisible layer.

Exception

CMO may request their die be used in full and unedited.

Label Part Number

Approved Label Part Number

00000-00

Design Guidelines for Label Part Number Format

Font family Helvetica Neue Std.

Font weight Light.

If space constraints: Light Condensed.

Font size

4–7 point.
Sunovion approval required for size below 4 point.

Placement

Preferred: Side panel, following Manufacturer/ Copyright/Context text.

Alignment: Left aligned.

Spacing between copyright information and Label Part Number (paragraph leading): Baseline to baseline spacing between paragraphs will be 150–200% of font size.

If space constraints: Placement in any available space, with Sunovion approval.

Color

Light background color: Black.

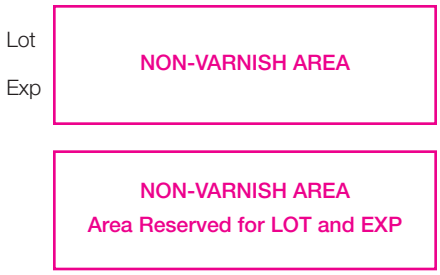
Dark background color: Reverse to white.
Font weight should change to Medium.

Exception

If Label Part Number is used for online verification (i.e., Vision System), refer to Engineering Drawing Specifications for all parameters.

Lot and Expiration Date Area

Approved Style for Lot and Expiration Date Area



Design Guidelines for Lot and Expiration Date Area

Font family Helvetica Neue Std.

Font weight

Lot and Exp text: Light.

Boxed text: Medium.

Font size

4–8 point suggested. Panel size dependent.

Placement

Location designated by Contract Manufacturing Organization (CMO).

Margins

Designated by CMO.

Color

Keyline border: Magenta (does not print).

Text: Magenta (does not print).

Box color: Transparent, or color designated in engineering drawing.

References

21 CFR Section 201.18. Drugs; significance of control numbers.

21 CFR Section 201.17. Drugs; location of expiration date.

Manufacturer Statements

Approved Manufacturer Statements

Manufactured for Sunovion Pharmaceuticals Inc.
Marlborough MA 01752 USA

Manufactured for Sunovion Pharmaceuticals Inc.
Marlborough MA 01752 USA
Made in [Country]

Mfd. for Sunovion Pharmaceuticals Inc.

Sunovion Pharmaceuticals Inc.

Sunovion

Note: It is preferred to remove "ugh" from "Marlborough" on small labels over removing "Mfd. for".

Design Guidelines for Manufacturer Statements

Font family Helvetica Neue Std.

Font weight Light.

If space constraints: Light Condensed.

Font size

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

Relational size

Font size must be same as font size for Copyright and Trademark and Customer Contact Statements.

Placement

Side panel, as part of the Manufacturer/Copyright/Contact Text, directly following Descriptive Text.

Spacing between lines (leading): 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 statement to white. Font weight should change to Medium.

Line break preference

Line break after "Inc." is preferred. Additional line break after "for" is acceptable.

Preferred Order of Manufacturer/ Copyright/Contact Text

1) Manufacturer Statements
2) Copyright and Trademark Statements
3) Customer Contact Statement

Paragraph treatment: Manufacturer Statement, as well as each Manufacturer/Copyright/Contact Text category, should be a separate paragraph.

References

21 CFR Section 201.1. Drugs; name and place of business of manufacturer, packer, or distributor.

Country of origin:
19 CFR Section 134.25. Containers or holders for repacked J-list articles and articles incapable of being marked.

19 CFR Section 134.26. Imported articles repacked or manipulated.

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 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.

NDC Number

Approved NDC Number

NDC 63402-000-00

Design Guidelines for NDC Number

Font family Helvetica Neue Std.

Font weight Light Condensed.

Font size

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

Relational size

Font size must be same as font size for Professional Sample Statements.

Placement

The first line of text in the upper left corner of the principal display panel.

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 Medium.

Reference

21 CFR Section 207.35. Notification of registrant; drug establishment registration number and drug listing number.

21 CFR Section 201.2. Drugs and devices; National Drug Code numbers.

Package Contents Statements

Approved Package Contents Statements

Net Contents: 00 g

For tablets

00 Tablets

For inhalation solutions

One 00 mL Sterile Unit-Dose Vial

Design Guidelines for Package Contents Statements

Font family Helvetica Neue Std.

Font weight

Medium Condensed and Light Condensed as shown in the Approved Statements above.

Relational size

Same font size as NDC Number. Numbers (shown in Medium Condensed in the above Package Contents Statements) should be 125% of the font size of NDC Number.

Placement

First line of text in the upper right corner of the principal display panel.

Alignment: Right aligned. Base align with NDC Number.

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 and Medium.

Reference

21 CFR Section 201.51. Declaration of net quantity of contents.

Product Name

Approved Product Name Format

Proprietary Name
(established name) Dosage Form

Proprietary Name
(established name)
Dosage Form

Note: Proprietary Name, Established Name, and Dosage Form may be replaced with brand logo, pre-approved by Regulatory Affairs to ensure compliance with labeling regulations.

Design Guidelines for Proprietary and Established Name

Font family Helvetica Neue Std.

Font weight Medium Condensed.

Font size

Proprietary Name capital letter height should be a minimum 150% the height of the capital letters in Sunovion Logo and Prism.

Height of capital letters in Established Name must be 55% the height of capital letters in Proprietary Name.

Relational size

The design objective is for the Product Name to have visual prominence over the Sunovion Logo and Prism. The package designer should exercise judgment, adjusting the size of the Product Name or the Sunovion Logo and Prism for a panel where the Proprietary Name guideline of 150% does not achieve the desired result.

Placement

Principal display panel.

Established Name and Dosage Form may appear on the same line or break into two lines as shown above, directly below Proprietary Name. When two lines, spacing from baseline of Established Name to baseline of Dosage Form must be 110% the font size.

Spacing from baseline of Proprietary Name to baseline of Established Name and Dosage Form must be at least 120% the font size of Established Name. Address any descenders in Proprietary Name either by adding extra line spacing or careful kerning.

Spacing from baseline of Professional Sample Statement (or NDC Number if no Professional Sample Statement) to baseline of Proprietary Name should be a minimum of 150% of the font size of Proprietary Name.

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 Section201.10(g)(2)–(h)(2). Drugs; statement of ingredients.

Professional Sample Statements

Approved Professional Sample Statements

PROFESSIONAL SAMPLE – NOT FOR SALE OR REIMBURSEMENT

PROFESSIONAL SAMPLE
NOT FOR SALE OR REIMBURSEMENT

Design Guidelines for Professional Sample 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 the same as font size of NDC Number.

Font tracking

For statements that appear in all capital letters, increase tracking as follows: QuarkXPress setting at +6; Illustrator and InDesign settings at +30.

Placement

The second line of text in the upper left corner of the principal display panel, directly below NDC Number.

Spacing between lines (leading): If Professional Sample Statement is two lines, baseline to baseline spacing between lines should be 105% of font size.

Spacing between paragraphs (paragraph leading): Baseline to baseline spacing between NDC and first line of Professional Sample Statement should be 150% 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.

Reference

21 CFR Section 203.38. Sample lot or control numbers; labeling of sample units.

Rx Only Statement

Approved Rx Only Statement

Rx Only

Design Guidelines for Rx Only Statement

Font family Helvetica Neue Std.

Font weight Light Condensed.

Font size

5–8 point suggested. Panel size dependent.

Relational size

Font size should be 120% the font size of NDC number.

Placement

Principal display panel.

If label includes an Administration Statement: Spacing from baseline of Administration Statement to baseline of Rx Only Statement should be 150–200% of font size.

If label does not include an Administration Statement: Spacing from baseline of Strength/Metered Dose Statement to baseline of Rx Only Statement should be 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 Medium.

Reference

Guidance for Industry. Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997 — Elimination of Certain Labeling Requirements.

Strength/Metered Dose Statements

Approved Strength/Metered Dose Statements

00 mg

00 mcg/actuation
00 Metered Inhalations

00 mcg/actuation
00 Metered Actuations

00 mcg/00 mL

Design Guidelines for Strength/Metered Dose Statements

Font family Helvetica Neue Std.

Font weight Medium Condensed.

Font size

Number(s) in Strength Statement should be the same size as capital letters in the Proprietary Name. All other text should be 80% the size of the numbers.

Metered Dose Statements should be the same size as Established Name.

Placement

Principal display panel, beneath Product Name.

Spacing from baseline of Established Name to baseline of Strength Statement should be 125% of the font size of the number(s) in Strength Statement.

Spacing from baseline of Strength Statement to baseline of Metered Dose Statement should be 125–150% of the font size of Metered Dose Statement.

Alignment: Left aligned.

Margins

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

Color

Strength Statement: Strength or product differentiation color as specified by Sunovion Regulatory Affairs and Brand Team.

Metered Dose Statement: Black.

Reference

21 CFR Section 201.51. Declaration of net quantity of contents.

Sunovion Corporate Branding

Approved Sunovion Logo and Prism

Design Guidelines for Sunovion Corporate Branding

Graphic size

Minimum width of the Sunovion Logo and Prism is 15 mm.

Placement

Lower right corner of the principal display panel.

Minimum quiet zone around Sunovion Logo and Prism is 1/8" (3 mm; 9 points).

Sunovion Logo and Prism cannot be modified in any way.

Color PMS 341 or black.