Guidance for Graphic Design of Medication Packaging

Version 3.0

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</tbody>
</table>
Guidance for Graphic Design of Medication Packaging

Version 3.0

Drug Sector
Saudi Food & Drug Authority


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Saudi Food and Drug Authority

Vision and Mission

**Vision**
To be a leading international science-based regulator to protect and promote public health

**Mission**
Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed
### Document Control

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<tr>
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<th>Date</th>
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I. Introduction

This guidance is complementary to the GCC Guidance for Presenting the SPC (Summary of Product Characteristics), PIL (Patient Information leaflet), and Labeling Information with more illustrations and details to minimize medication errors.

It is intended for solid oral dosage forms, which are the most common type of primary packaging, and secondary packaging used on the container label. It also should be used for all injectable medicines as well. The design considerations and principles outlined also can be applied to other products dosage forms.

II. Scope

This guidance is applicable to SFDA registered or under-registration medicinal products intended for human use in Saudi Arabia.
III. Design Recommendations for Primary Packaging (Blister Packs)

1. Blister Packs for Oral Medications
   1.1 Product name and strength

The name and strength of the product should appear over each blister pocket. Batch number and expiry date should be applied on each blister pocket as well. If it is not possible, the batch number and expiry date should be added at the end of each blister strip, preferably at both ends.

Figure 1
Optional: If the medication is given every day, print the days of the week on the reverse side of the blister or capsule.

In certain cases (such as: small blister) it may not be possible to design the packaging to accommodate all critical information on each blister cell. In such circumstances, important information can appear multiple times across the back of the blister or the important information should be displayed in such a manner that it is not destroyed or eliminated when dosage units are removed.
1.2 Blister strips foil

Use non reflective, matte material. Reflective foil can cause glare by light reflecting on the foil which reduces the legibility of any information.

Figure 3
1.3 Type and background color

Type color should contrast strongly with background color. Legibility can be reduced by the combined effect of the foil material, a small font size and a background color that does not sufficiently contrast with the font color.

Figure 4
1.4 Type size and font color

Use bold or semi-bold type and avoid lightweight type. Maximize the font size to a size that is appropriate for the size of the container. Small type size and a lightweight font on a foil background impairs legibility.

**Figure 5**
1.5 Match the styles of primary and secondary packaging [optional]

A product’s primary and secondary packaging should have an identical or linked visual style.

Patients taking more than one pharmaceutical product, or the same pharmaceutical product in two or more strengths, must be able to identify which blister strip belongs to which packet because the prescription instructions are attached to the secondary packaging.

Mixing up packages and blister strips could lead to the patient taking the wrong medication or even overdosing.
IV. Design Recommendations for Secondary Packaging

Secondary packaging describes the outer package of a pharmaceutical product. It serves to hold the primary packaging and is not in contact with the product. The combined impact of all design elements, such as color and typography, should be evaluated.

Company’s pharmaceutical products should not have the same theme for outer package and should differentiate between them, to avoid similarity between products and prevent medication error.

1. Allocate white space for the dispensing label [optional]

Have a clearly designated white space for the dispensing label if possible. Label dimensions vary but a minimum of 70 x 35 mm is suggested, as this is the most common size for dispensing. The white space should not interfere or cover the legibility of the critical information on either side.

1.1 Brand name, generic name and strength position

The brand name, generic name and strength of the product should be directly above or beside the space provided for the dispensing label. Pharmacy staff can then easily check that the product description on the dispensing label correctly matches that on the secondary packaging.
Figure 8
2. **Put critical information in the same field of vision on at least three non-opposing faces (one side for Arabic & one side for English)**

A standard packaging container has six faces on which information can be displayed. Critical information should be in the same field of vision on at least 3 of the non-opposing faces of the secondary packaging. This means putting the information on the top or bottom face, one of the side faces, and one of the end faces. If it is feasible, display a product description (the brand name, generic name and dosage strength of the product) on more than three non-opposing faces.

*Figure 9*
3. **Orient text in the same direction** [optional]

The text on every face, excluding the ends, should be oriented in the same direction in a way to easily read the information when the product is placed at any side on the shelf.

![Figure 10](image-url)
4. **Use blank space to emphasize critical information**

Leave sufficient space around critical information, so that it can be easily seen. If the secondary packaging is cluttered with text and images, it can be difficult to recognize important information and identify the correct packaging.

**Critical information is**

1. Brand and generic name of the product.
2. Strength and dosage form.
3. Total volume or concentration of vial and bottle, plus the “per mL” amount (e.g., 10 mg/2 mL and 5 mg/mL).
4. Warning statements in some cases.

The net quantity number should be moved away from the strength number.
5. **Ensure the generic product name is suitably clear**

The generic name should be at least 50% the size of the brand name. Patients can be given different brands of the same medication which can lead to them confusing brand names with generic names. This can result in them taking multiple doses of the same medication.

![Figure 12](image)
6. Differentiate between strengths of the same pharmaceutical product

Make pharmaceutical product strengths stand out through typeface, type weight, color and shape. This is particularly important if all secondary packaging from a manufacturer looks similar.

Figure 13
7. **Do not add trailing zeros to numbers**

Do not add trailing zeros to numbers; always use whole numbers. If numbers have a trailing zero (a decimal point followed by a zero, for example 5.0 mg) it is easy to miss the decimal point and dispense a tenfold overdose. For example, a practitioner could administer 50 mg instead of 5 mg.

*Figure 14*
8. Use the same unit for all different strengths from the same pharmaceutical product

In addition, different strengths of the same pharmaceutical product should be expressed in the same way, such as 250 mg, 500 mg, 750 mg. (e.g., 500 mg, not 0.5 g)

---

![Figure 15](image_url)
9. Use of leading zero

For an amount less than one, always use a leading zero to avoid any confusion in the concentration (for example use 0.25 not .25).

![Figure 16](image)
10. **Critical information size**

Use the largest size font possible for that package size so that the information is readable and clear.
11. Use upper and lower case lettering

Entire sentences written in upper case letters or italic type are hard to read. Use the lower case except for the first letter of the generic names, brand names, sentences or paragraphs. Italic types should not be used where there is an alternative method of emphasis such as bold type. Mixed case lettering should always be used for sentences.
12. Use sans serif typefaces

Use a sans serif typeface, such as Arial, Helvetica or Universe. The choice of typeface influences legibility. Ornate typefaces are difficult to read. They are not suitable for medication packaging, where clarity, accuracy and legibility must be paramount.

---

Figure 19
13. **Use bold or semi-bold type**

Lightweight type reduces legibility. Patients, especially those who are partially sighted, find bolder type easier to read. Use bold or semi-bold type and avoid lightweight type for all critical information.

---

**Figure 20**

![Box with Proprietary Name and Generic Name](image1)

√

![Box with Proprietary Name only](image2)

X

![Box with Proprietary Name and Generic Name](image3)

10 mg

10 mg

10 mg

10 mg
14. Condensed typefaces

Do not use condensed typefaces when possible. Condensed typefaces reduce legibility and increase the chance of error. Condensed typefaces may be necessary on blister packs on each pocket and on small vials to fit all the required information, but should not be used when there is adequate space for normal typeface.
15. Do not compress lines of text close together or adjust the space between letters

Reducing the space between lines, known as the leading, and reducing the space between letters, known as the kerning, affects legibility. Do not compress lines of text close together. Leave enough space between lines and letters.
An irregular amount of space between words affects legibility. Align text to the left hand margin and do not center justify text. Align all English text including the critical information to left side (left justified) and for the Arabic version, it should be aligned to the right side (right justified).
17. Images and logos

Images or logos should not be near the text, as it could interfere with reading it, or it may look like it is part of the text. Text should remain unbroken. Fitting text around or over images or logos breaks the flow of information.
18. **Create a strong contrast between type and background color**

There should be a strong color contrast between the type and background colors. Dark colored type (e.g. black, dark blue) should be on a light colored background (e.g. white, pale pink, pale yellow). The reverse is true as well. Insufficient contrast between the background and the type reduces legibility.
V. Using Color

Secondary packaging describes the outer package of a pharmaceutical product. It serves to hold the primary packaging and is not in contact with the product. The combined impact of all design elements, such as color and typography, should be evaluated.

1. Use color differentiation to highlight information of the same pharmaceutical product

Use color to distinguish between, for example, different strengths of the same pharmaceutical product and between similarly named pharmaceutical products.
Do not color code packaging. A color coding system allows people to memorize a color and match it to a particular product. However, creating a shortcut for identifying a pharmaceutical product without having to read the label can lead to mistakes. It is important that practitioners do not rely on color as a means to identify a specific product, as many manufacturers may use the same color for different products, or different strengths of the same product.
# Packaging Design Summary

<table>
<thead>
<tr>
<th>Issues</th>
<th>Recommendations</th>
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<tbody>
<tr>
<td><strong>Primary packaging</strong></td>
<td></td>
</tr>
<tr>
<td>Glare caused by light reflecting on the foil</td>
<td>Use non-reflective foil</td>
</tr>
<tr>
<td>Text damaged when blister strip is cut</td>
<td>Put pharmaceutical product name and strength clearly on each pocket</td>
</tr>
<tr>
<td>Reduced legibility due to combined effect of foil material, small type size and background color</td>
<td>Create a strong contrast between type and background color</td>
</tr>
<tr>
<td>Reduced legibility due to combined effect of a small type size and lightweight font on a foil background</td>
<td>Use bold or semi-bold type</td>
</tr>
<tr>
<td>Blister strip with the wrong secondary packaging</td>
<td>Match the styles of primary and secondary packaging</td>
</tr>
<tr>
<td><strong>Secondary packaging</strong></td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical product name and strength obscured</td>
<td>Allocate 70 x 35mm white space for dispensing label</td>
</tr>
<tr>
<td>Dispensing label and pharmaceutical product name mismatched</td>
<td>Position the generic name and pharmaceutical product strength above or next to the space for the dispensing label</td>
</tr>
<tr>
<td>Critical information does not appear in the same field of vision</td>
<td>Put critical information in the same field of vision on at least three non-opposing faces</td>
</tr>
<tr>
<td>Compressing lines of text close together or reducing the distance between individual letters makes text difficult to read</td>
<td>Do not squash lines of text closer together or adjust the spaces between letters</td>
</tr>
<tr>
<td>Irregular amount of space between words</td>
<td>Align text to the left for English, and right for Arabic</td>
</tr>
<tr>
<td>Text illegible over an image or logo</td>
<td>Logo should not be placed near text</td>
</tr>
<tr>
<td>Insufficient contrast between background and type</td>
<td>Create a strong contrast between type and background color</td>
</tr>
<tr>
<td><strong>Using color</strong></td>
<td></td>
</tr>
<tr>
<td>Color differentiation inadvertently associated with a particular feature</td>
<td>Use color differentiation to highlight information</td>
</tr>
<tr>
<td>Color does not help distinguish between products in a manufacturer’s range</td>
<td>Use opposing, meaningless colors</td>
</tr>
</tbody>
</table>
VI. A Guide to Labeling and Packaging of Injectable Pharmaceutical products

1. Principal Display Panel for carton (PDP): (in the red box below)

1.1. Features of front panel

Create a front panel that features only the critical information. Subsequent (noncritical) information can be shown on the back panel.

Minimum information consists of:

- Trade name
- Generic drug name
- Concentration of the pharmaceutical product:
  - Total quantity in the container (large font)
  - Concentration per unit volume (smaller font).
- Administration route(s)
- Significant Warnings
Figure 27

Key information becomes difficult to find when information is printed on packaging in a dense block using text in a small font.
1.2. Use of color

Use color to highlight key differences in information: the drug name, the quantity concentration or warning if appropriate.

Apply the color scheme consistently throughout the primary and secondary packaging.

![Figure 28](image-url)
1.3. Similar drug name

Highlight the differences between similar generic or brand names from the same company. This could be done through the use of color, or font sizes. Change the graphic component to ensure an added element of differentiation; for example this can be done by using different colors.

Use Different colors or font size to differentiate between generic names of look-alike and sound-alike products from the same company.

Figure 29
1.4. Strength

Include a representation of the full volume strength, i.e. total quantity in total volume, as well as amount per unit volume (e.g., 25 mg per 5 mL, then directly underneath and in parentheses 5 mg/mL).

Care should be taken with the spacing between mg and ml. Adjust the kerning so as to leave sufficient space around the “/” to achieve maximum legibility. It is acceptable to use the slash mark (/) if the number after the slash is a 1, as in 1 ml. If the number is something else, then use the “per” (for example, 50 mg per 2 mL, not 50 mg /2 mL). A slash can be mistaken for the number 1, so the concentration could be misread (for the above example, could be read as 50 mg in 12 mL, instead of 2 mL).
1.5. Concentration

Display concentration in total quantity /total volume, even if other units of concentration such as percentage and ratios (for example ‘1 in 1,000’) are also present.

When using numbers of 1,000 and above, use commas to help prevent misreading.

Do not superimpose information on other information.

<table>
<thead>
<tr>
<th>Proprietary Name</th>
<th>Generic Name</th>
<th>2 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mg per 10 ml</td>
<td>(20 mg / ml)</td>
<td>for intravenous use</td>
</tr>
</tbody>
</table>

Figure 31

<table>
<thead>
<tr>
<th>PROPRIETARY NAME</th>
<th>Logo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic name 2%</td>
<td>20mg/ml 10 Ampoules x 10ml</td>
</tr>
<tr>
<td>Each 10ml contains Lidocaine Hydrochloride HCL 200mg</td>
<td></td>
</tr>
<tr>
<td>Excipients: Sodium Chloride, Sodium Nitrate, Water for injections</td>
<td></td>
</tr>
<tr>
<td>Follow directions for use carefully.</td>
<td></td>
</tr>
<tr>
<td>Keep out of the reach of children.</td>
<td></td>
</tr>
<tr>
<td>Discard any unused contents.</td>
<td></td>
</tr>
<tr>
<td>Solution only to be used if it is clear and undamaged.</td>
<td></td>
</tr>
<tr>
<td>Directions for use carefully.</td>
<td></td>
</tr>
<tr>
<td>Active ingredient: Water for injections 0.90% w/w</td>
<td></td>
</tr>
<tr>
<td>For use only by qualified medical personnel.</td>
<td></td>
</tr>
<tr>
<td>Manufacturer address: 16235, Apple Street, Bridge town, Copper city, DE 1213</td>
<td></td>
</tr>
</tbody>
</table>

Extended Logo
1.6. Administration route

Make positive statements- use ‘do’s’, rather than ‘do not’s’ as much as possible.
Use specific directions and avoid using technical terms that are not well understood. (e.g. ‘For Parenteral Use’ meaning: For intravenous, intramuscular, intradermal, subcutaneous, intrathecal).

**Figure 32**

- Routes which should not be used are stated rather than routes that should.
- Always use positive statements regarding the route of administration.
1.7. Warnings

Separate warning notices from the main part of the text and highlight the warning.

<table>
<thead>
<tr>
<th>Proprietary Name</th>
<th>Proprietary Name</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Generic Name</strong></td>
<td><strong>Generic Name</strong></td>
</tr>
<tr>
<td><em>500 mg</em></td>
<td><em>500 mg</em></td>
</tr>
</tbody>
</table>

**Must be diluted before use.**
For injection or infusion as sodium salts.
Read directions for use carefully.
Store below 25°C.

- ✓
- ✗

Warning about unusually high doses or potential allergies, for example, are often not highlighted and become lost in dense blocks of text.
1.8. Injectable pharmaceutical products intended for use by patients

For injectable pharmaceutical products that are intended for use by patients, leave a clearly designated blank space for the pharmacy label that is a minimum size of 70 x 35 mm. Position the drug name and strength near the space.

For injectable pharmaceutical products that come in a multi dose format as insulin, it is recommended that the drug concentration be represented as strength per unit volume.

Figure 34
2. Ampoules

2.1. Text orientation

Print the pharmaceutical product name longitudinally, along the length of the ampoule. A good rule of thumb is: if the visible width of the label is less than the height of the label then the name should be printed longitudinally.

- The information listed below is the minimum and must be present on containers more than 10 ml (the small container exceptions apply to containers of 10 ml or less):
  1. Pharmaceutical product name (brand name and nonproprietary name)
  2. Expression of strength
  3. Route of administration
  4. Warnings, where important
  5. Expiry date
  6. Batch number
  7. Marketing authorization holder
2.2. Labeling methods

- Use paper labeling where possible, and ensure that the label does not wrap completely around the ampoule to allow for inspection of contents.

If ceramic or clear plastic labeling must be used, highlight key information by inverting the text color.

Keep information to a minimum and reduce overlapping with text from the reverse side as much as possible.

Labels should not come off in use and should be printed with ink that does not run when sprayed with alcohol to disinfect the ampoule surface in the pharmacy or during clinical procedures.

Figure 36
We recommend the addition of a peel-off label on ampoules or vials, which can be transferred to a syringe in practice, will help practitioners avoid selection errors. All syringes containing pharmaceutical products should be labeled if they leave the operator’s hands.

Figure 37
2.3. Plastic ampoules

- Use a clear font size.
- Information should be printed on paper label, if possible or direct on the ampoule with good contrast color.
- Use color to help to differentiate between products of the same company.
- Eliminate or reduce emphasis on the name of the container type such as ‘Plas-Amp’.
- Expiry dates and batch numbers should be easy-to-read and printed on the main body of the container, not on rip-off tabs.
- Where concentrations are shown, they should be expressed as total quantity in total volume (e.g., 20 mg per 10 ml) as well as the per unit volume (e.g., 2 mg/mL).

![Correct Example](image1)

![Incorrect Example](image2)

*Figure 38*
3. Vials

3.1. Critical information panel

Create an area, which highlights the critical information. This area should not be wider than the width of the bottle in order to allow seeing the critical information without the need to turn the vial (i.e., along a single line of vision).

Use appropriate font size and formatting to enable the generic drug name to be read in one glance. The generic name should be at least 50% the size of the brand name.

![Figure 39](image)

*Figure 39*
3.2. Text orientation

The drug name should be able to be seen in a single line of vision. If the full drug name cannot be seen when the vial is upright, then the label should be oriented in a longitudinal fashion, in order to have the drug name in a single line of vision.
3.3. Color schemes

Match the design of the vial label to that of the carton.

Where the flip cap is colored, use the predominant differentiating color that has been used on the label and carton if possible.
4. Pre-filled syringes

4.1. Secondary packaging

Vary the design of the secondary packaging of similar products to enable easy identification. Pre-filled syringes that may be required during a medical emergency can be easily confused, especially when there is minimal differentiation on the outer packaging. Consider the use of different colored components, for example, plungers or caps, to emphasize differences. Pharmaceutical products that come in a wide range of concentrations and doses can also be mistaken for each other.

Outer packaging, once opened, should not be easily re-sealable and should clearly indicate that the pre-filled syringe has been removed to prevent a delay in treatment if the empty pack is placed back into stock.
4.2. Text orientation on syringe

Orient text along the length of the syringe so critical information can be read holding it in the right hand, without rotating the syringe. When text is oriented around the syringe it necessitates a small font size which can be difficult to read.

Invert text color or use a background color to prevent text showing through.

Volume markings should always be visible and not covered by labels.

Figure 43
5. Infusion bags

5.1. Text positioning

The critical information should be placed at the top of the bag; this information (especially the drug name and strength/concentration) should be repeated at the bottom of the bag so that as the bag empties it can still be visualized.

Position the batch number and expiry date close together.

Invert the key information text to draw the eye to it. Key information is lost in dense blocks of text.

*Figure 44*
5.2. Font

The choice of font should be carefully considered to ensure adequate spacing between letters also the ink should not bleed. Use a san serif font as with other labels.

For multi-ingredients products, list the ingredients in table format if possible.

Figure 45
5.3. Bag volume

For fluids that come in different volume sizes, give emphasis to the volume of infusion. Vary other elements of the design to increase differentiation between labels.

When listing ingredients on the infusion bags, the strength should be represented as quantity per container.

Figure 46
5.4. Use of color

It is important to differentiate between identified high-alert infusions.

Use bold blocks of color that stand out and draw the eye to the critical information and warnings.
5.5. Bag Unit

Where the strength of pharmaceutical product is expressed in mmol, it should be represented as mmol/container volume.

5.6. Route of administration

Highlight the route of administration, particularly if it is different from the norm.
5.7. Product differentiation

Ensure there is an additional differentiator in addition to the text. For example, use color or, if this is not possible, vary the graphic components.

Figure 49
5.8. Surface finish

Use matte materials where possible to improve legibility. If materials used for the fluid bags and overwraps are reflective, the combination of the two materials can lead to impaired visibility of key information.

Figure 50
References:

- A guide to labeling and packaging injectable medicine, edition 1, 2008 National Patient Safety Agency (NHS)
- This guidance was reviewed by the Institute for Safe Medication Practices (ISMP) subsidiary, Med-ERRS (www.med-errs.com) www.ismp.org