

the helen hamlyn
research centre



NHS
National Patient
Safety Agency

Design for patient safety

A guide to the graphic design of medication packaging

Second edition

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About this publication

Design for patient safety: A guide to the graphic design of medication packaging is based on the results of a design research collaboration between the National Patient Safety Agency (NPSA) and the Helen Hamlyn Research Centre (HHRC) at the Royal College of Art, London. Editing, design and production of the document by the NPSA publishing department.

The purpose is to allow busy designers, purchasers and others with an interest in package legibility and comprehensibility to quickly and simply understand how and why good design can contribute to patient safety through the clear labelling of medicines.

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Research and methodology

The study was carried out over a one-year period by Thea Swayne, a postgraduate specialist in information and graphic design, working to a brief set by the NPSA and the HHRC. Existing design guidance was reviewed and consultations were undertaken with experts in graphic and information design, and in design for patient safety.

A wide range of stakeholders contributed to the research – including patients, pharmaceutical industry personnel, NHS agencies, nurses and pharmacists. Observational research was undertaken in key end-use environments, such as wards, pharmacies and patients' homes. A collection of current medicine packages was assembled as part of the study, and an analysis was carried out of common problem factors for which design solutions were proposed. The outcome was a design rationale to enhance patient safety and a fully illustrated set of design considerations with both good and bad examples.

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Foreword



*Professor Sir Liam Donaldson,
Chief Medical Officer*

In the Department of Health's 2003 report, *Design for patient safety*, I offered a new perspective on improving patient safety and set out how we should be making use of the many opportunities for effective design in healthcare to address some of the safety challenges we are facing.

Concentrating on design for safer packaging of prescription medicines, this latest publication seeks to resolve some of the risks associated with medication error and, once again, draws attention to the need for an inclusive and systems-wide approach.

Ensuring the safety of patients must become a high visibility issue for anyone involved in the delivery of healthcare. This publication is a further contribution to the important work that is taking place in this field.

Introduction

Design for patient safety: A guide to the graphic design of medication packaging shows how graphic design on medicine packaging can enhance patient safety and details best practice based on established guidelines. It is aimed at packaging designers and pharmaceutical companies. It will also be of interest to those in the NHS who regulate and purchase medication.

There are an estimated 900,000 recorded adverse events in the NHS every year.¹ Improvements to the design of medicine packaging could reduce this figure whilst also improve medication compliance. It is estimated that a third of medication errors are caused by confusion over packaging and labelling instructions.² Healthcare is delivered in many different contexts and patients' sensory, physical and mental capabilities vary greatly. Design solutions have to address these factors.

Design for patient safety: A guide to the graphic design of medication packaging focuses on:

- blister packs: the most common type of primary packaging for prescription medicines;
- secondary packaging used to contain blister packs;
- the label attached to secondary packaging in pharmacies.

The design considerations and principles outlined can be applied to other products such as patient information leaflets and tablet bottles.

There is a comprehensive checklist that details the key factors that impact on patient safety. In line with the Medicines and Healthcare products Regulatory Agency (MHRA) guidance document,³ user research and evaluation is recommended when significant changes are made to any packaging. The checklist can help ensure that any testing of individual designs is thorough and effective.

The examples of best practice have taken into account the views of patients as well as those of pharmaceutical industry personnel, NHS agencies, nurses and pharmacists. They have also been researched in key end-use environments including hospital wards, pharmacies and patients' homes.

Design for patient safety: A guide to the graphic design of medication packaging is the result of a collaboration between the National Patient Safety Agency (NPSA) and the Helen Hamlyn Research Centre (HHRC) at the Royal College of Art, London. It builds on the *Designing for patient safety* study commissioned by the Department of Health and the Design Council, and undertaken jointly by the HHRC, the University of Cambridge and the University of Surrey.⁴

Although the ideas in this publication require further research, they provide the foundations for establishing graphic design best practice guidelines that have the potential to increase patient safety.

Ideas for further research include looking at:

- how design can help patients on multiple medication schedules;
- information on the tablet itself;
- adding a picture of the tablet on secondary packaging;
- matching machine-readable codes on packaging and dispensing labels;
- putting small products in larger packaging for, in particular, ophthalmic products;
- a 'header' area away from the tablets on blister strips where all critical information would remain intact.

References

- 1 www.npsa.nhs.uk/about
- 2 'Reducing Medication Errors Through Naming, Labeling and Packaging', Berman A., *Journal of Medical Systems*, Volume 28, Issue 1, 2004
- 3 *Best practice guidance on labelling and packaging of medicines*, Medicines and Healthcare products Regulatory Agency, London, 2003
- 4 *Designing for patient safety: a scoping study to identify how the effective use of design could help to reduce medical accidents*. Robens Centre for Health Ergonomics at the University of Surrey, Engineering Design Centre at the University of Cambridge and Helen Hamlyn Research Centre, 2003

Stakeholder review panel

A stakeholder review panel was formed to ensure *Design for patient safety: A guide to the graphic design of medication packaging* addresses a wide and representative range of issues. The panel members are:

Roger Coleman,	Professor of Inclusive Design and Co-founder, Helen Hamlyn Research Centre, Royal College of Art
Steven Drewett	Outpatient, Haematology & Oncology, Hammersmith Hospital
Colum Menzies Lowe	Head of Design and Human Factors, National Patient Safety Agency
Professor David Cousins	Head of Safe Medication Practice, National Patient Safety Agency
Wendy Harris	Head of Safety Solutions, National Patient Safety Agency
Professor Peter Buckle	Director of Ergonomics, European Institute of Health and Medical Sciences, University of Surrey
Jonathan Milner	Business Development Manager, InTouch PharmaMed, a Matthews Brand Solutions company
Stein Lyftingsmo	Community and Hospital Pharmacist, Norway and Editor of website on labelling of medicines
Sue Kilby	Head of Practice, Royal Pharmaceutical Society of Great Britain
Rachel Dean	Acting Senior Graphic Designer, Royal National Institute of the Blind
Jeff Willis	Deputy Head of Communication Art & Design Department, Royal College of Art
Careen Snadden	Technical Director, Almus Pharmaceuticals
Howard Stokoe	Principal Pharmacist, NHS Purchasing and Supply Agency
Brian Parkinson	Making Sense Design and co-facilitator of Designers in Health Network
Idris Hughes	Community Pharmacist and author
Yogini Jani	Senior Pharmacist, UCLH NHS Foundation Trust
Grant Courtney	Strategic Development Manager, GlaxoSmithKline
Jan MacDonald	Medicine and Healthcare products Regulatory Agency
James Ward	Senior Research Associate, Engineering Design Centre, University of Cambridge
Matt Kennedy-Martin	Head of Government Relations, Design Council

User testing

Packaging design should take into account the needs and capabilities of the widest possible range of potential users, and in particular older and partially sighted users, and how they interact with the medicine in the home.

It should also consider the needs of pharmacists and, in particular, how they identify, classify and differentiate between medicine packages.

1

Pharmaceutical companies should develop their own methods for testing their packaging on users.

The example below is developed from *A guideline on the readability of the label and package leaflet of medicinal products for human use*.¹

Aim

There are a number of core tasks that are critical for the safe use of pharmaceutical packaging. The aim is to assess how users find the information they need and how they then interpret this information. The test should be able to highlight any undesirable outcomes and determine the best combination of design elements.

Method

Test on a minimum of 20 people and a range of users including patients, pharmacists and carers. This will vary for each product.

Manufacturers should carry out the testing. Designers should be involved.

Participants

Start by testing the products on 10 critical users who are likely to encounter problems. This should include users with lower visual abilities and reduced cognitive and dexterous functions.

If a user becomes confused, note how they deal with the difficulty.

If a user does not understand a question, avoid giving the answer. Instead, ask them what they think it means.

Testing procedure

Test one user at a time, allowing at least half an hour for each person. They can be asked about using more than one packaging, but do not ask more than 15 questions in a single session. Two questions concerning the same information should not follow one another.

Ask users to carry out their normal routine for reading information on packaging:

- 1 Observe and write down what they do.
- 2 Ask users to write down in their own words what they did.
- 3 Ask questions that might extend the information gathered.
- 4 Ask specific questions about the legibility of particular design elements on the packaging.
- 5 Determine if specific information on the packaging can be found quickly and easily.
- 6 Determine if information on the packaging is understandable and informative.
- 7 Ask users to find a particular piece of information and explain it in their own words. This will reveal how well they understand the information. If this involves a physical activity such as mixing something together, they should be asked to do this and actually go through the procedure on the package.

Results

Reviewing the data should reveal any major problems with the legibility of information on the packaging. At this stage, it is possible to redesign or rewrite the information before further testing.

Once satisfactory data has been obtained from 10 users, a further 10 should be tested. The objective is to have at least 16 users out of 20 able to answer each question correctly. It may be necessary to clarify the performance of the questionnaire, which may include rewriting and remodelling the questions to achieve a better level of performance.

Reference

- 1 *A guideline on the readability of the label and package leaflet of medicinal products for human use*, European Commission, Belgium, 1998

Tablets 500mg

... every four hours ...
... little water until dispersed and drink further ...

DO NOT EXCEED THE STATED DOSE
Do not give to children under 12 years of age without the advice of a doctor. There is a possible risk of Reye's syndrome when given to children under 12 years of age.

... if you have ever had ...
... if you are taking ...
... if you are pregnant ...
... if you are breastfeeding ...
... if you are taking ...
... if you are taking ...
... if you are taking ...

Packaging design checklist

2

Issue	Recommendation	Page
Secondary packaging		
Medicine name and strength obscured	<i>Allocate 70 x 35mm white space for dispensing label</i>	19
Dispensing label and medicine name mismatched	<i>Position the generic name and medicine strength above or next to the space for the dispensing label</i>	21
Critical information does not appear in the same field of vision	<i>Put critical information in the same field of vision on at least three non-opposing faces</i>	23
Some text can only be read by flipping the pack or reading upside down	<i>Orientate text in the same direction</i>	25
Difficult to recognise important information	<i>Use blank space to emphasise critical information</i>	27
Brand name confused with the generic name of a medicine	<i>Ensure the generic medicine name is suitably clear</i>	29
Medicines with similar names confused for one another	<i>Use Tallman lettering to emphasise the difference between look-alike or sound-alike medicine names</i>	31
Wrong strength of a medicine selected	<i>Differentiate between strengths of the same medicine</i>	33
Easy to miss the decimal point in numbers with a trailing zero	<i>Do not add trailing zeros to numbers</i>	35
Small type size is difficult to read	<i>Body text in a minimum of 12 point</i>	37
Sentences in capital letters or italic type are hard to read	<i>Use upper and lower case</i>	39
Simulated handwriting and ornate typefaces are hard to read	<i>Use sans serif typefaces</i>	41
Lightweight typeface is hard to read	<i>Use bold or semi-bold type</i>	43

Issue	Recommendation	Page
Secondary packaging		
Condensed typeface is hard to read	<i>Do not use condensed typefaces</i>	45
Squashing lines of text closer together or reducing the distance between individual letters makes text difficult to read	<i>Do not squash lines of text closer together or adjust the spaces between letters</i>	47
Irregular amount of space between words	<i>Align text to the left</i>	49
Text illegible over an image or logo	<i>Do not place text over images or logos</i>	51
Insufficient contrast between background and type	<i>Create a strong contrast between type and background colour</i>	53
Using colour		
Colour differentiation inadvertently associated with a particular feature	<i>Use colour differentiation to highlight information</i>	57
Colour does not help distinguish between products in a manufacturer's range	<i>Use opposing, meaningless colours</i>	59
Primary packaging		
Glare caused by light reflecting on the foil	<i>Use non-reflective foil</i>	63
Text damaged when blister strip is cut	<i>Put medicine name and strength clearly on each pocket</i>	65
Reduced legibility due to combined effect of foil material, small type size and background colour	<i>Create a strong contrast between type and background colour</i>	67
Reduced legibility due to combined effect of a small type size and lightweight font on a foil background	<i>Use bold or semi-bold type</i>	69
Blister strip with the wrong secondary packaging	<i>Match the styles of primary and secondary packaging</i>	71

Design recommendations for secondary packaging

The term secondary packaging describes the outer package of a pharmaceutical product. It holds the primary packaging and does not touch the medicine.

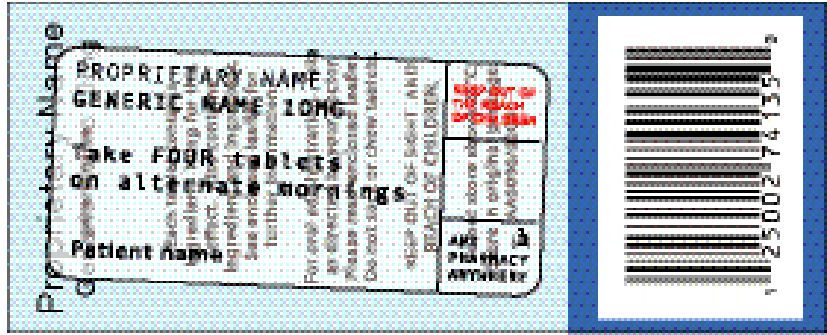
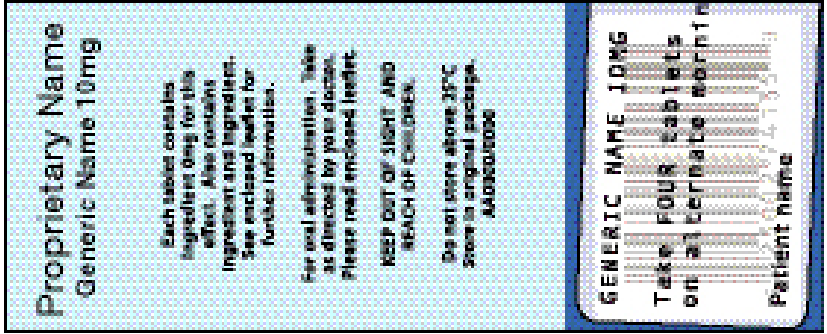
The combined impact of all design elements, such as colour and typography, should be evaluated.

Issue

Pharmacists produce a label that exactly repeats the prescriber's instructions and attach it to the secondary packaging.

If space is not allocated for the label, it is frequently placed over the manufacturer's text obscuring the medicine name and strength.

The underlying text may also show through the label making the instructions difficult to read.

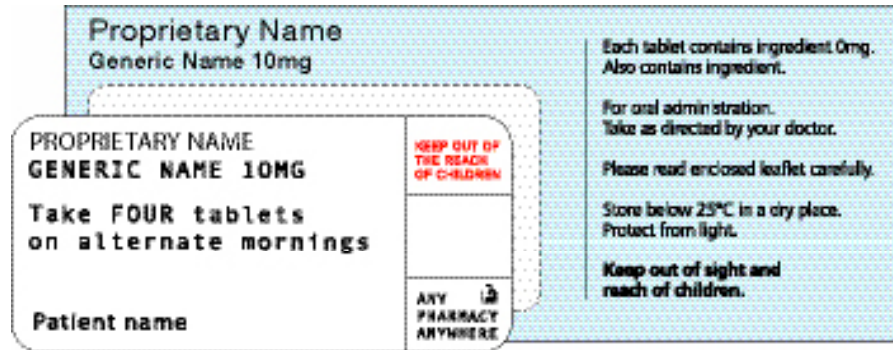


Recommendation

Allocate 70 x 35mm white space for dispensing label

Have a clearly designated space for the dispensing label. This should be a white space in which there is no text or image.

Dispensing label dimensions vary, but a minimum of **70 x 35mm** is suggested as this is the most common size for dispensing labels.

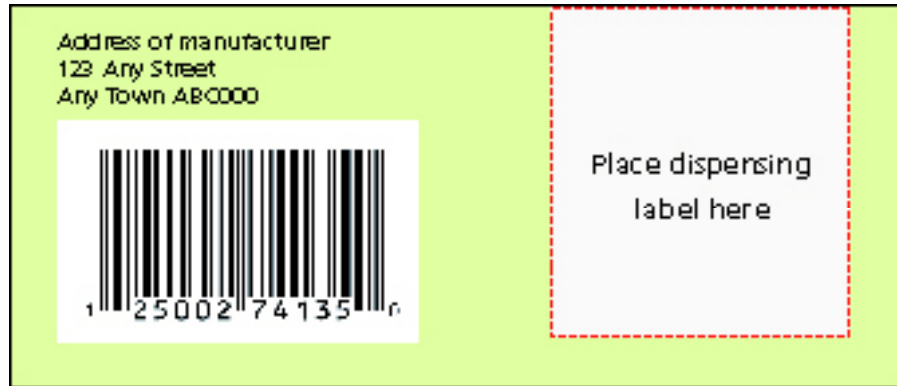




Issue

In the pharmacy, the prescription is read; the medicine is picked from the shelf; the medicine type and dosage are checked against the prescription; and a dispensing label is produced by the dispensary system and attached to the secondary packaging.

Occasionally, due to human error, the dispensing label and medicine name on the secondary packaging are mismatched.

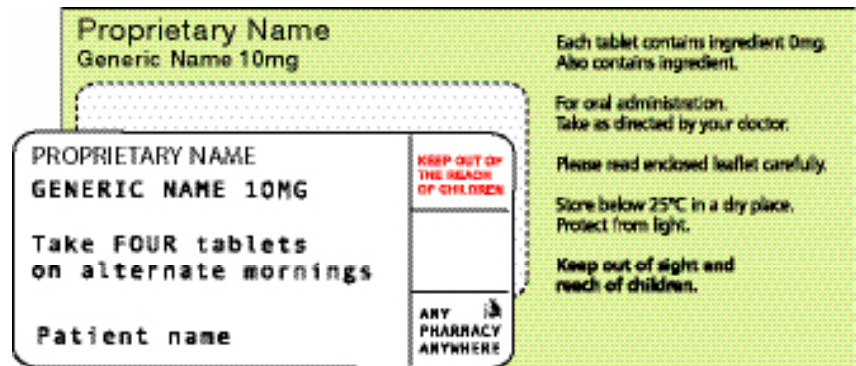


Recommendation

Position the generic name and medicine strength above or next to the space for the dispensing label

The generic name and strength of the medicine should be directly above or beside the space provided for the dispensing label.

Pharmacy staff can then easily check that the medicine description on the dispensing label correctly matches that on the secondary packaging.



Issue

The following critical information does not always appear in the same field of vision: medicine name, variant, strength, form and number of tablets or capsules.

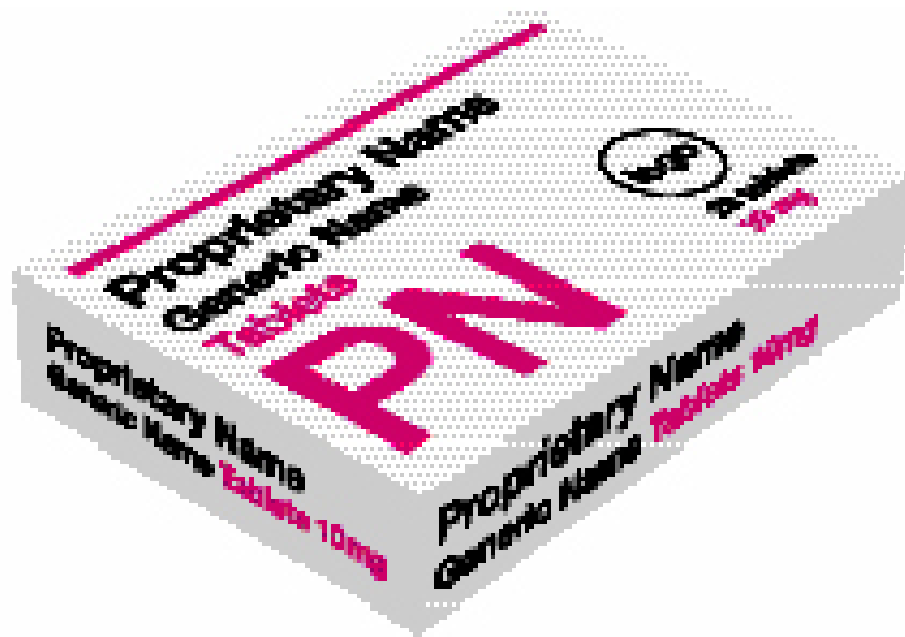


Recommendation

Put critical information in the same field of vision on at least three non-opposing faces

A standard packaging box has six faces on which information can be displayed. Critical information should be in the same field of vision on at least three non-opposing faces of the secondary packaging.

This means putting the information on the top or bottom face, one of the side faces, and on one of the end faces. If it is feasible, display a product description on more than three non-opposing faces.



Issue

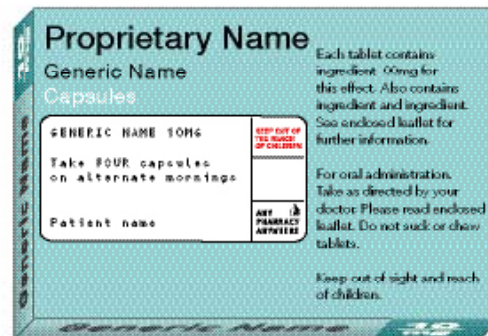
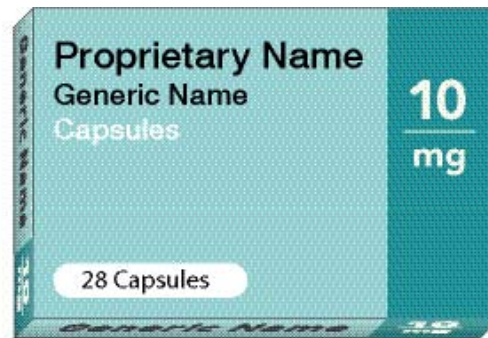
If text is not orientated in the same direction, the pharmacist and patient have to either read upside down or flip the pack to read the information.



Recommendation

Orientate text in the same direction

The text on every face, excluding the ends, should be orientated in the same direction.



Issue

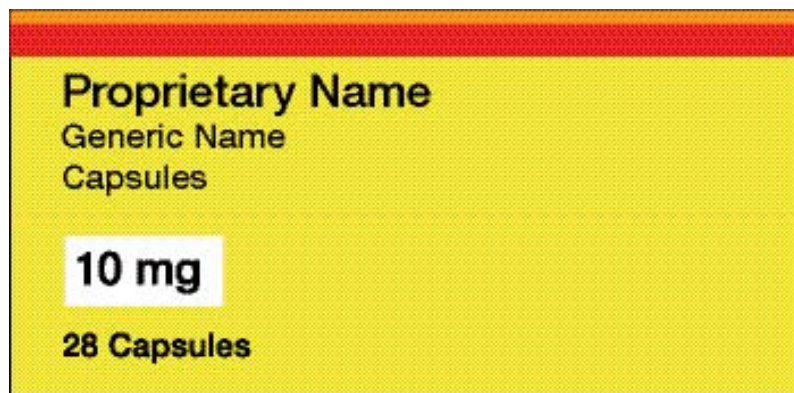
If secondary packaging is cluttered with text and images, it can be difficult to recognise important information and identify the correct packaging.



Recommendation

Use blank space to emphasise critical information

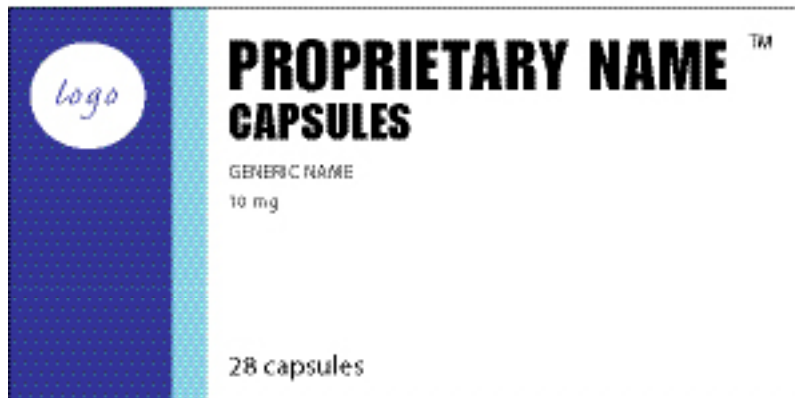
Use blank space to emphasise critical information such as the medicine name and strength.



Issue

Patients can be given different brands of the same medication which can lead to them confusing brand names with generic names.

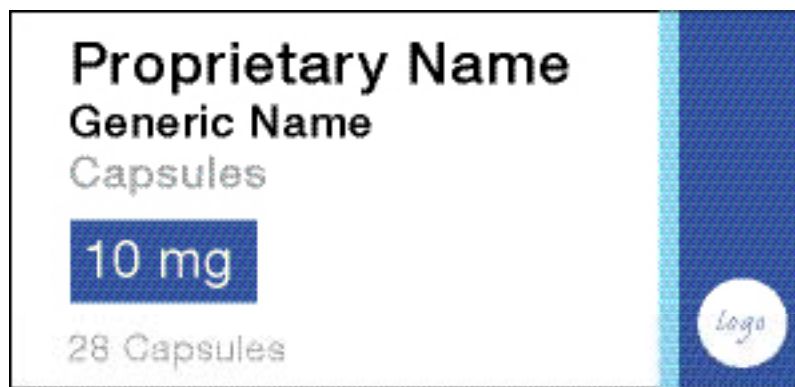
This can result in them taking multiple doses of the same medication. This risk is increased if the brand name has more emphasis than the generic name.



Recommendation

Ensure the generic medicine name is suitably clear

The generic name should be in 16 point size or greater.



Issue

Medicine names that are spelt in a similar way, with the same number of letters and word shape, can be easily mistaken for one another.

The possibility of error is increased if medicines are stored alphabetically and these medicines are next to one another.

Chlorpropamide
10 mg

28 Capsules

Chlorpromazine
10 mg

28 Capsules

Recommendation

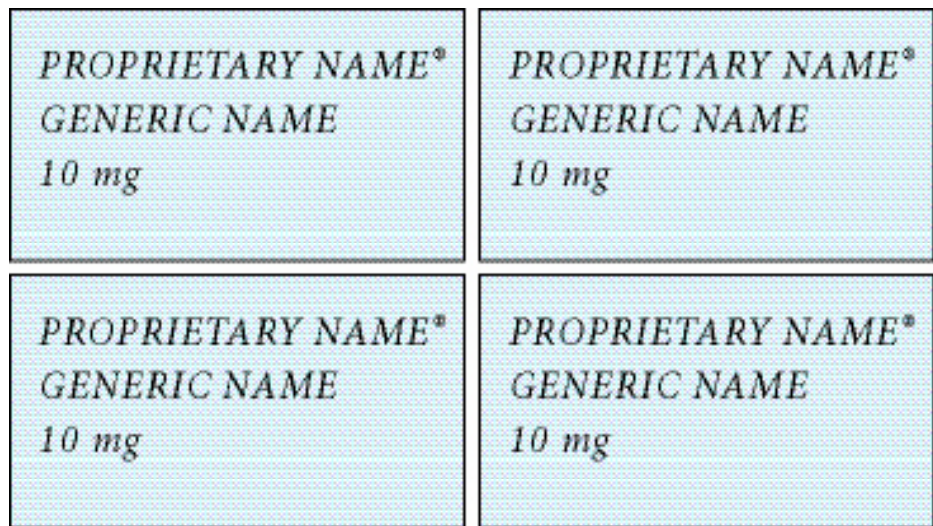
Use Tallman lettering to emphasise the difference between look-alike or sound-alike medicine names

Use Tallman (capital) letters to highlight those sections of similar medicine names that contain the characteristic of the medicine.



Issue

If the strength of a medicine is not clearly displayed, the wrong strength can be selected.



Recommendation

Differentiate between strengths of the same medicine

Make medicine strengths stand out through typeface, type weight, colour and shape.

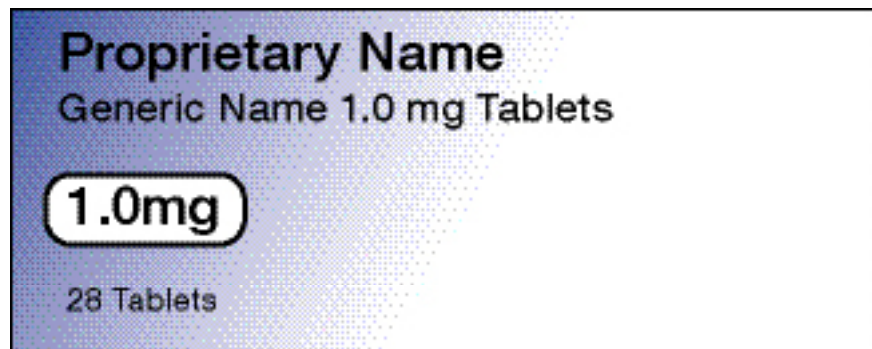
This is particularly important if all secondary packaging from a manufacturer looks similar.



Issue

If numbers have a trailing zero (a decimal point followed by a zero) it is easy to miss the decimal point and dispense a tenfold overdose.

For example, administering 50mg instead of 5mg.



Recommendation

Do not add trailing zeros to numbers

Where possible, always use whole numbers.

Different strengths of the same medicine should be expressed in the same way, such as 250mg, 500mg, 750mg.



Issue

Small type size is difficult to read.

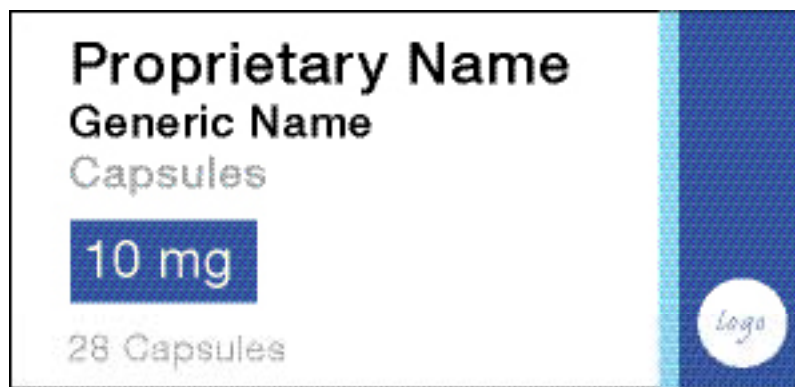


Recommendation

Body text in a minimum of 12 point

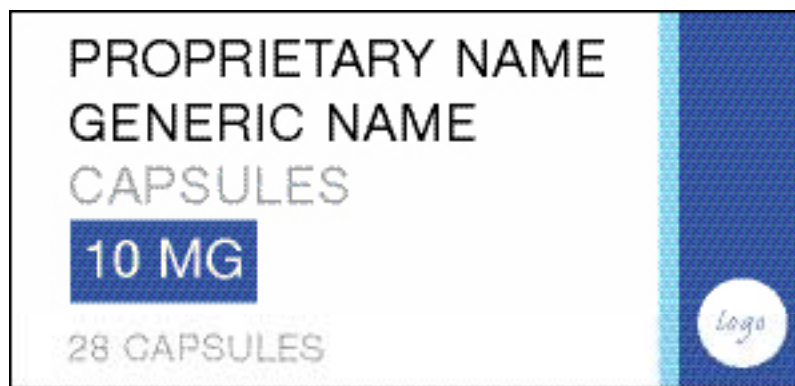
Minimum recommended type size is 12 point.

However, 14 point is more accessible for patients with sight difficulties.



Issue

Entire sentences in capital letters or italic type are hard to read.

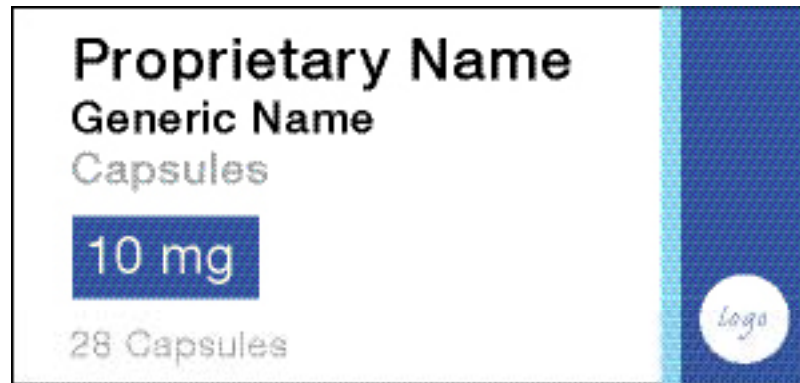


Recommendation

Use upper and lower case

Do not use capitals for generic medicine names (other than selective Tallman lettering, see page 31), brand names, sentences or paragraphs.

Italic type should not be used where there is an alternative method of emphasis such as bold type. Upper and lower case should always be used for sentences.



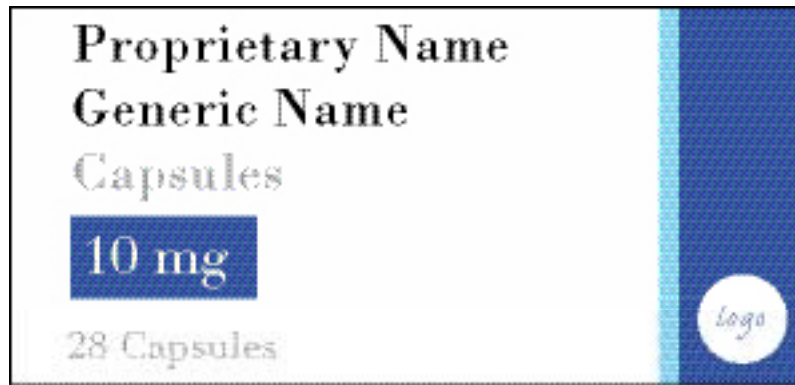
Issue

The choice of typeface influences legibility. Simulated handwriting and ornate typefaces are difficult to read.

Serif typefaces, that is typefaces with small terminal strokes added to the end of the main stroke or line of a character, are harder to read on medication packaging than sans serif typefaces, that is typefaces without serifs.

Serif typefaces are ideal for large bodies of text such as books and newspapers, where the serifs aid the reader in following and recognising lines of text at speed.

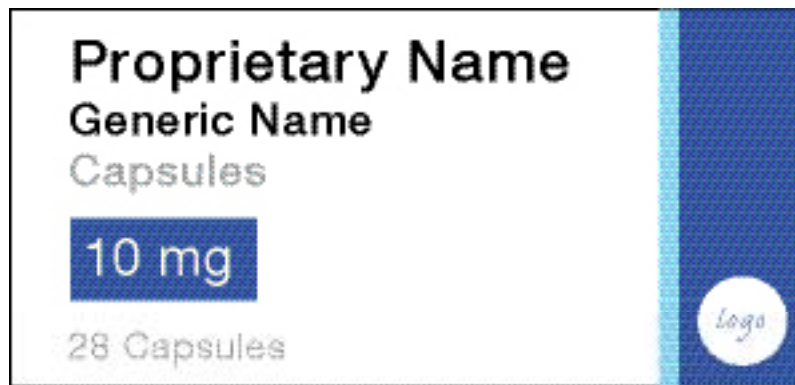
They are not suitable for medication packaging, where clarity, accuracy and legibility must be paramount.



Recommendation

Use sans serif typefaces

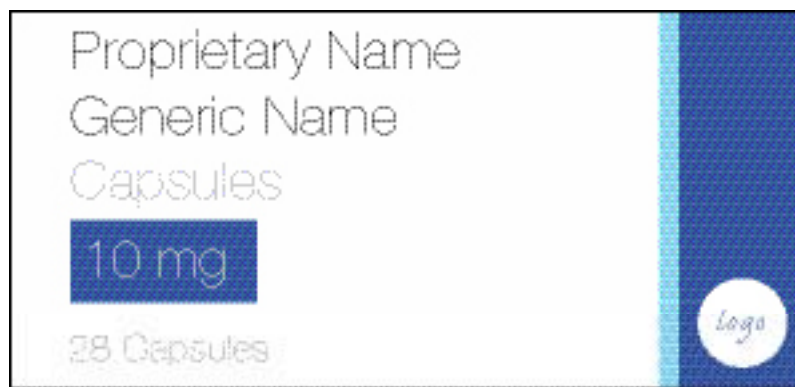
Use a sans serif typeface, such as Arial, Helvetica or Univers.



Issue

Lightweight type reduces legibility.

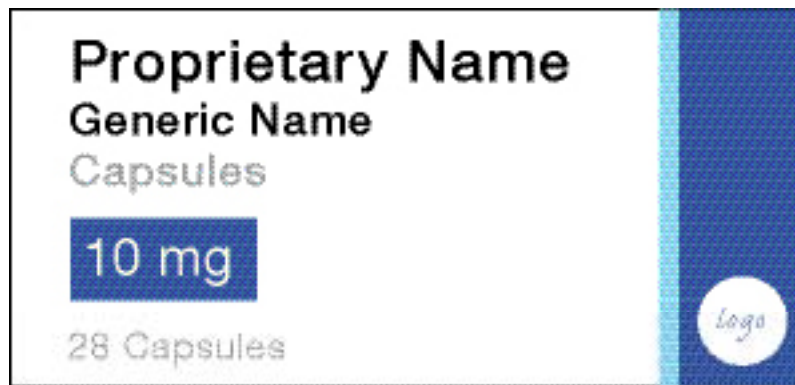
Patients, especially those who are partially sighted, find bolder type easier to read.



Recommendation

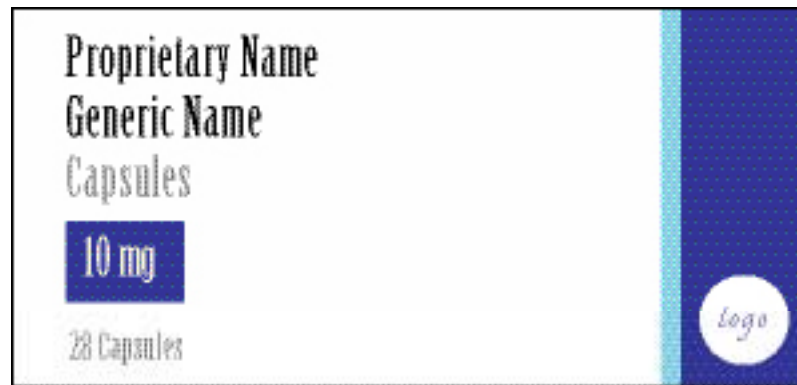
Use bold or semi-bold type

Use bold or semi-bold type and avoid lightweight type.



Issue

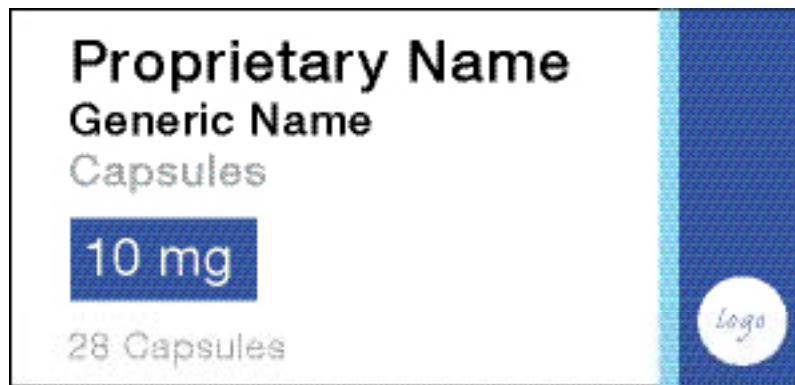
Condensed typefaces reduce legibility.



Recommendation

Do not use condensed typefaces

Do not use condensed typefaces.



Issue

Reducing the space between lines, known as the leading, and reducing the space between letters, known as the kerning, affects legibility.

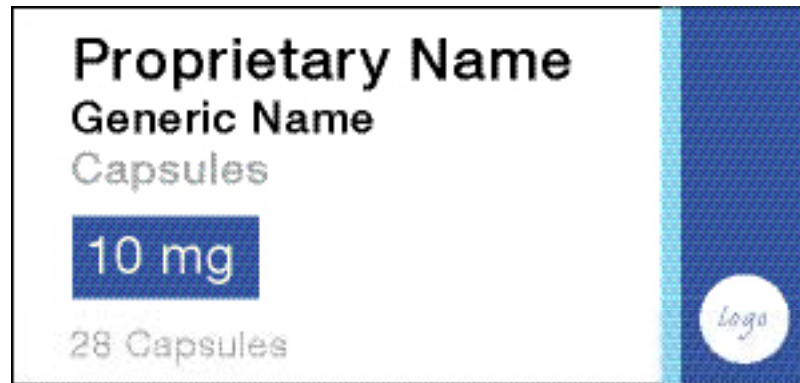


Recommendation

Do not squash lines of text closer together or adjust the space between letters

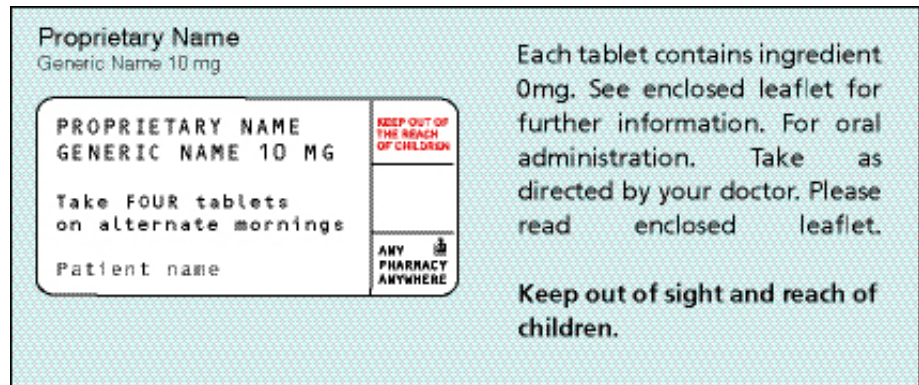
Do not squash lines of text closer together. If text is in 12 point size, the leading should be 16 point. If text is in 14 point size, the leading should be 18 point.

Do not adjust the space between letters unless doing so will enhance legibility.



Issue

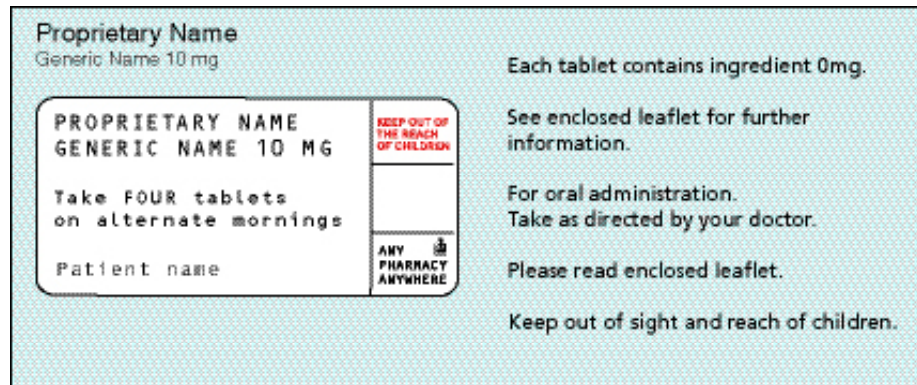
An irregular amount of space between words affects legibility.



Recommendation

Align text to the left

Align text to the left hand margin and do not justify text.



Issue

Fitting text around or over images or logos breaks the flow of information.

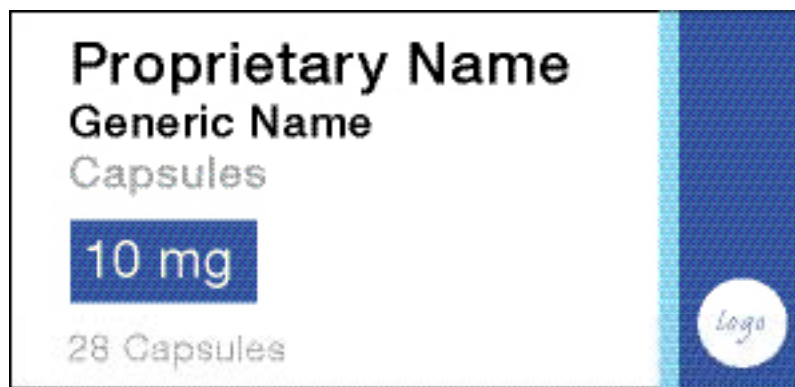


Recommendation

Do not place text over images or logos

Text should remain unbroken.

Images or logos should be placed at the beginning or end of the text.



Issue

Insufficient contrast between the background and the type reduces legibility.

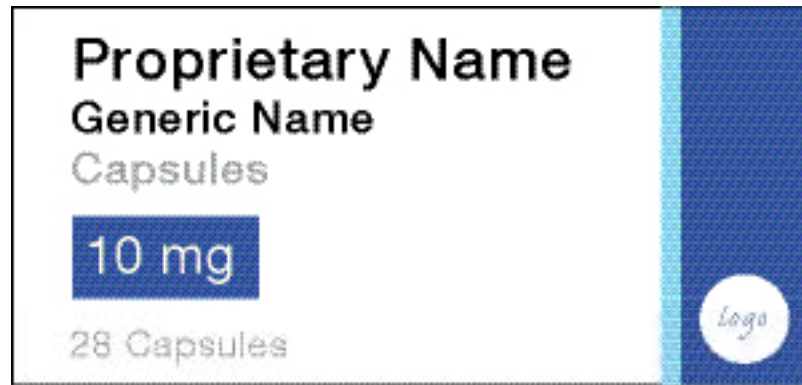


Recommendation

Create a strong contrast between type and background colour

There should be a strong contrast between the type and background colours.

Dark coloured type (e.g. black, dark blue) should be on a light coloured background (e.g. white, pale pink, pale yellow).



Using colour

Colour can help correctly identify, classify and differentiate between medicines. However, relying totally on colour to do this can lead to mistakes. This is because colours look different in different lighting conditions; people have different perceptions of colour; and colour blindness means some people see colours differently.

4

If a single colour is used for a whole range of medicines it can be difficult to identify a specific product. This is compounded if medicines with similar names are stored next to one another.

If a patient is prescribed a number of medicines with the same colour packaging, there is an increased chance of them taking the wrong one.

Colour coding

A colour coding system allows people to memorise a colour and match it to a function. However, creating a shortcut for identifying a medicine without having to read the label can lead to mistakes. No colour coding system could differentiate between all 12,000 medicines authorised in the UK. Furthermore, in the absence of a national or international colour code, any UK system could become a barrier to trade.

One exception is the medicine warfarin, which is universally colour coded brown for strengths of 1mg, blue for strengths of 3mg, and red for strengths of 5mg.

Colour differentiation

Colour differentiation is the recommended method. It uses colour to make features on a packet stand out or to help distinguish one item from another. The chosen colour is not associated with a particular feature. It is important that there is no pattern in the colour scheme.

Issue

Colour differentiation is inadvertently associated with a particular feature.



Recommendation

Use colour differentiation to highlight information

Do not colour code packaging.

Use colour to distinguish between, for example, different strengths of the same medicine and between similarly named medicines.



Issue

The use of colour does not help distinguish between products in a manufacturer's range.

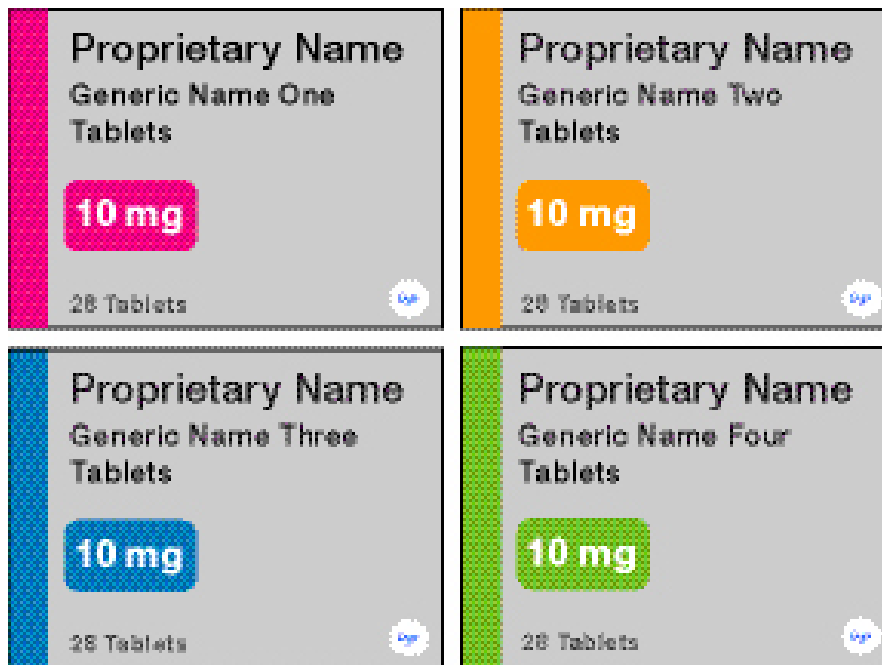


Recommendation

Use opposing, meaningless colours

Use opposing, meaningless colours to distinguish between medicines with similar names in a manufacturer's range.

An awareness of users with limited colour perception should be developed.



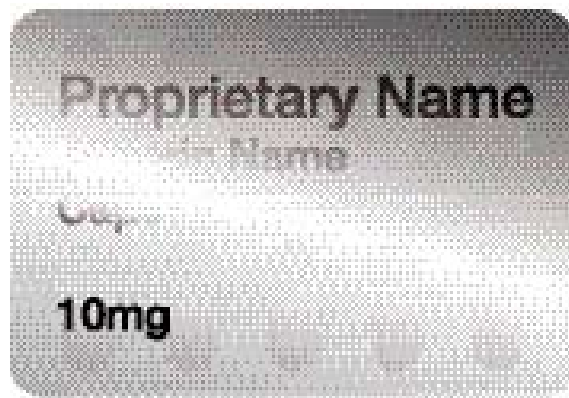


Design recommendations for primary packaging

Issue

Blister strips are commonly sealed with reflective foil. Glare can easily be caused by light reflecting on the foil.

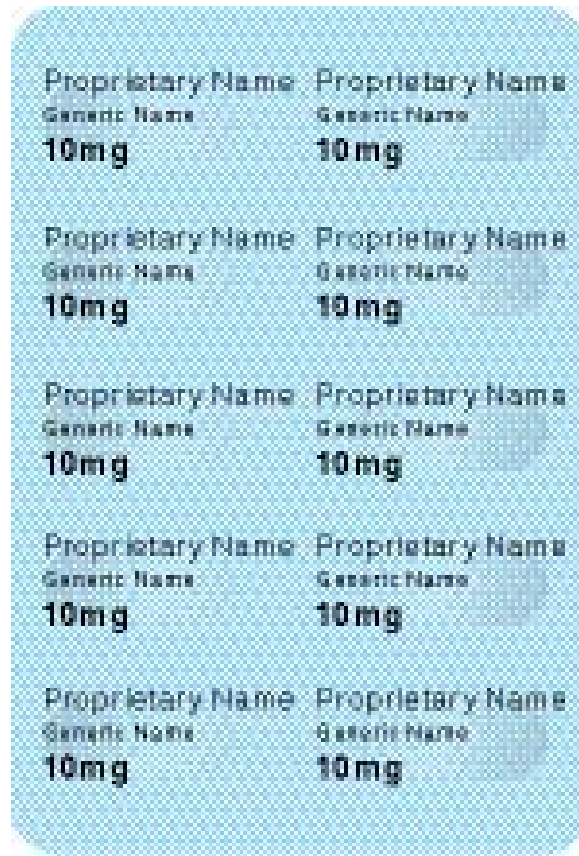
This can reduce the legibility of any information printed on the foil. If type is in a light colour or lightweight font, legibility can be further reduced.



Recommendation

Use non-reflective foil.

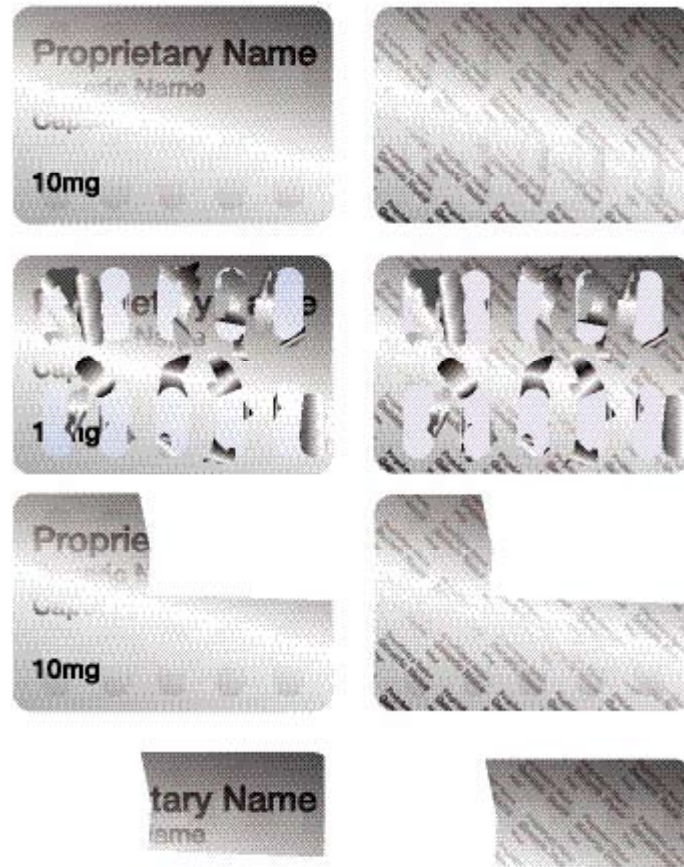
Use non-reflective, matt foil.



Issue

Blister strips are taken out of the secondary packaging to access the medicine and may not be returned.

Single blister pockets, which hold one dose of the medicine, can be cut from the strip leaving insufficient information about the medicine. If the name and strength are printed across the entire blister strip, the text is damaged when the medication is removed.

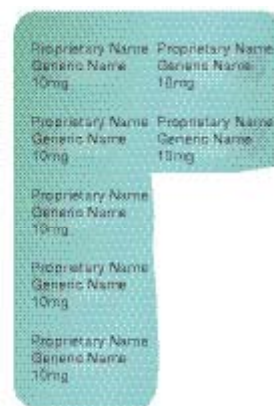
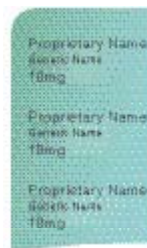
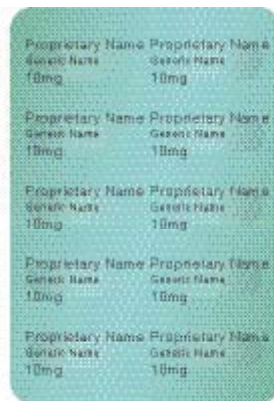


Recommendation

Put medicine name and strength clearly on each pocket

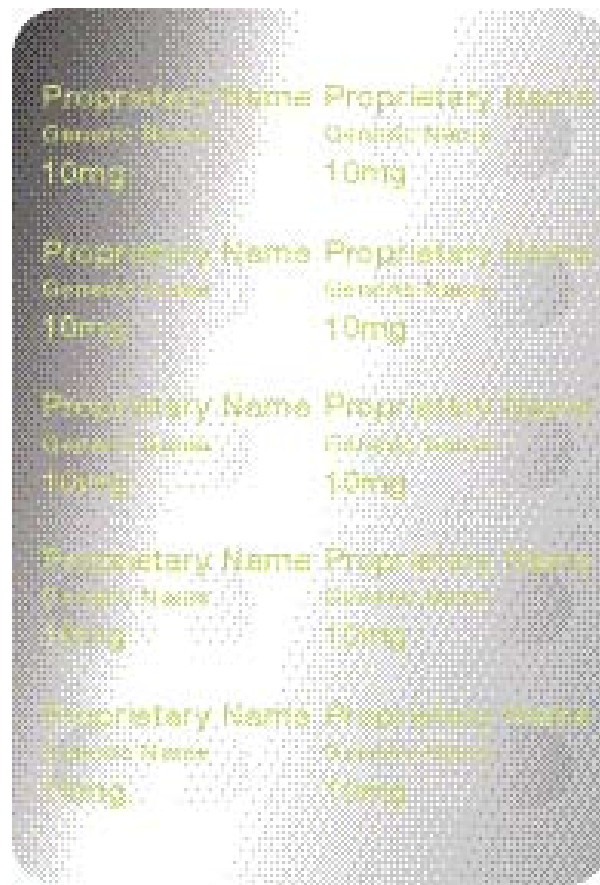
The medicine name and strength should appear on each pocket of the blister strip.

If the size of the pocket is too small, the information should be repeated in a pattern across the entire strip.



Issue

Legibility can be reduced by the combined effect of the foil material, a small type size and a background colour that does not sufficiently contrast with the type colour.

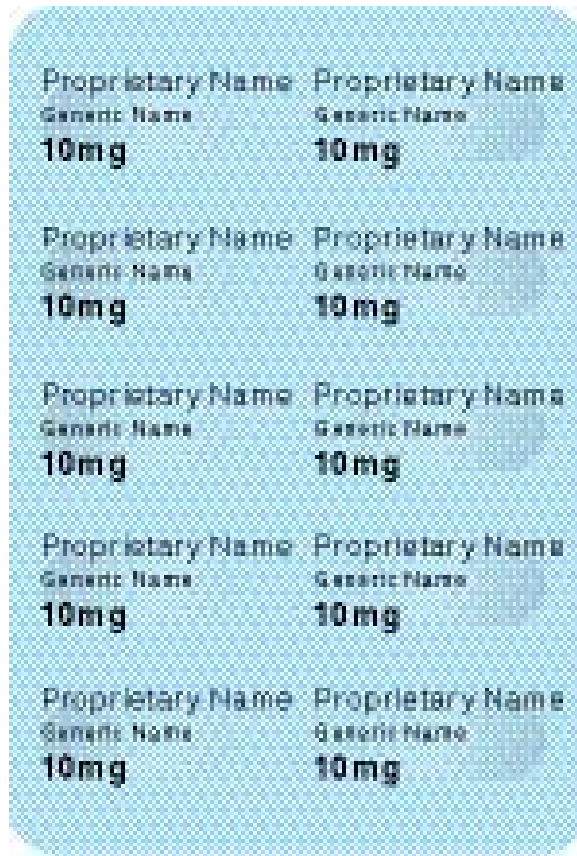


Recommendation

Create a strong contrast between type and background colour

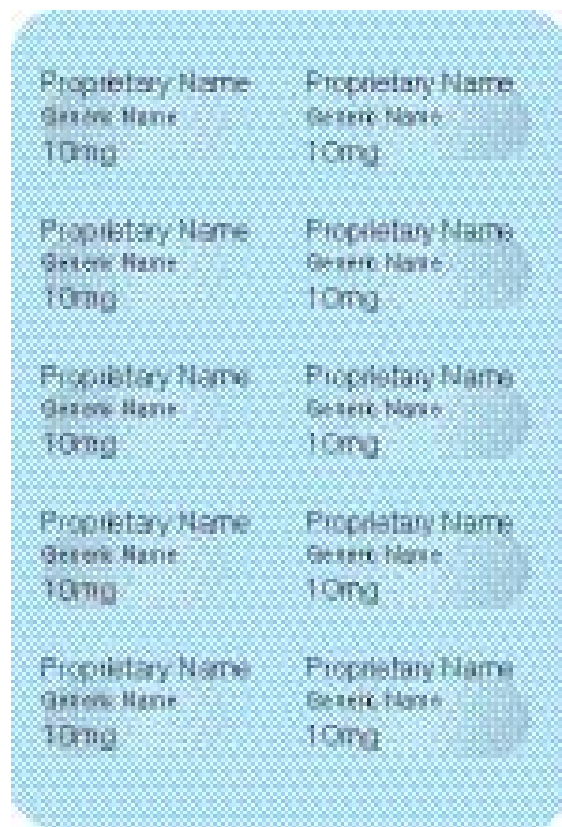
Type colour should contrast strongly with the background colour.

For example, black or dark blue type on a white, pale pink or pale yellow background. If text is reversed out of a background colour, use a bold typeface.



Issue

Small type size and a lightweight font on a foil background impairs legibility. Small type sizes are easier to read when set in a heavier weight typeface.

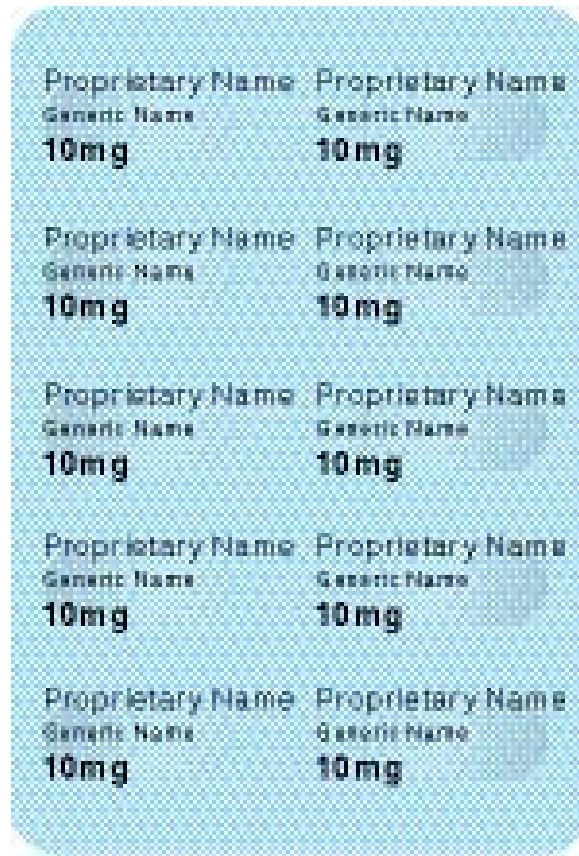


Recommendation

Use bold or semi-bold type

Use bold or semi-bold type and avoid lightweight type.

It is important to note, however, that too much bold or semi-bold type can also impair readability if in a very small point size.



Issue

Patients taking more than one medicine, or the same medicine 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 packages and blister strips up could lead to the patient taking the wrong medication or even overdosing.



Recommendation

Match the styles of primary and secondary packaging

A product's primary and secondary packaging should have an identical or linked visual style created through, for example, colour.





Further reading

Books

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Websites

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Almus Pharmaceuticals www.almus.com

Design Council www.designcouncil.org.uk

Helen Hamlyn Research Centre at the Royal College of Art www.hhrc.rca.ac.uk

Stein Lyftingsmo's personal website www.lyftingsmo.no

Brian Parkinson's personal website www.makingsense.co.uk

Medicines and Healthcare products Regulatory Agency www.mhra.gov.uk

National Association of Boards of Pharmacy (US) www.nabp.net

National Patient Safety Agency www.npsa.nhs.uk

Patient Packaging Audit www.patientpacks.com

Pharmacy Choice www.pharmacychoice.com

The National Patient Safety Agency

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