Safeguarding public health

Regulatory tools for managing the risk of medication errors – labelling & patient information

Jan MacDonald
Medicines and Healthcare products Regulatory Agency

- Legal provisions and regulatory objectives
- MHRA Guidance on packaging for safety
- Key findings
- Examples

Regulatory objectives - labelling

- Medicines legislation is set out in Council Directive 2001/83/EC [as amended]
- Information should provide a high degree of consumer protection – [Recital 40]
- Labelling should be clear, legible and unambiguous [Article 56]
- Provide detailed information for the safe use of the product [Article 54]
- Medicines can be selected and used safely

CSM Labelling Group – Key findings

No substitute for reading the label

Certain information critical for safe use

Presentation of information is important

Similarity in packaging can confuse

Look alike/sound alike names cause problems

Medicines labelling can be improved

Critical Information

- Name of medicinal product
  – followed by common name

- Strength

- Route of Administration

- Posology

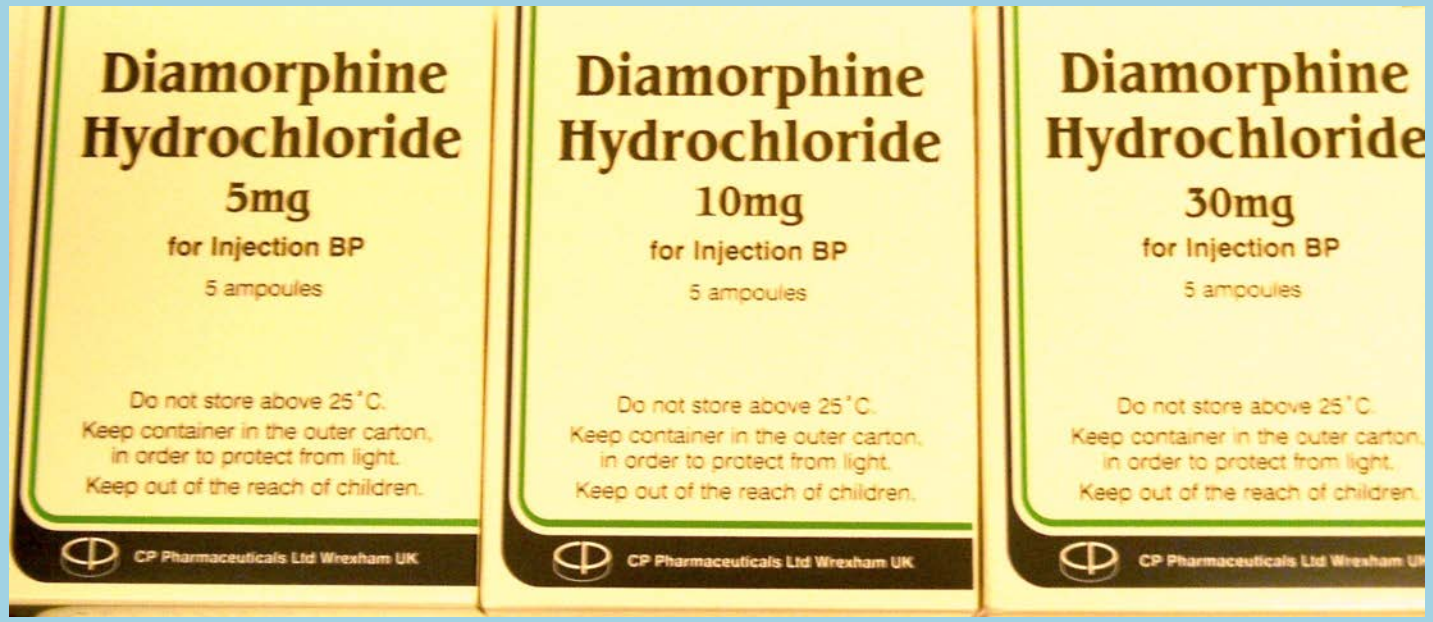
- Warnings

Principles to be applied

- Critical information located together on the pack in the same field of view
- Large font
- Name on three non-opposing faces of the pack
- Common name should be given due prominence
- Innovative pack design and judicious use of colour

Similarity in packaging (1)

Similarity in Packaging (2)



Similarity in Packaging (3)

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Similarity in Packaging (4)

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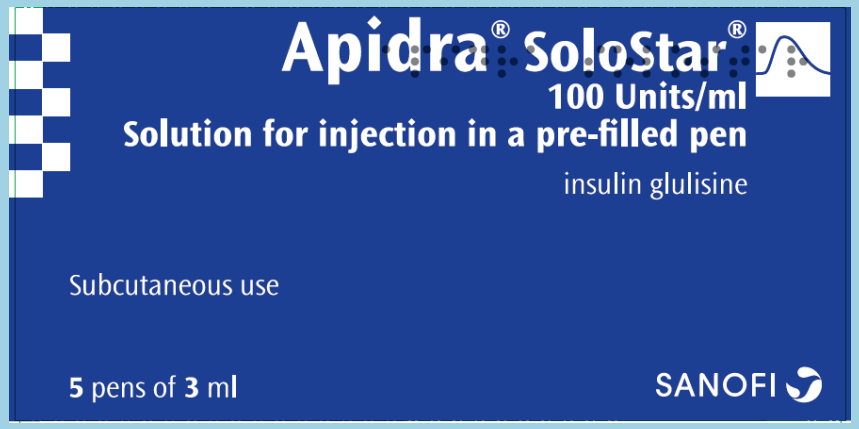
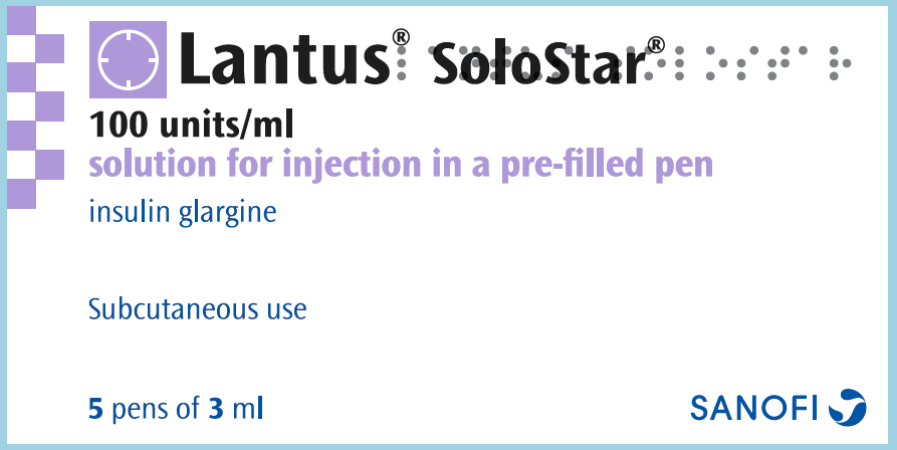
Look Alike Sound Alike Common Names





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Factors to consider in redesigning packaging

- How will the medicine be stored
- Will medicines be co-prescribed
- Differentiation is required both between products and between strengths
- Product name should appear above the space allocated for the dispensing label

Pack Design

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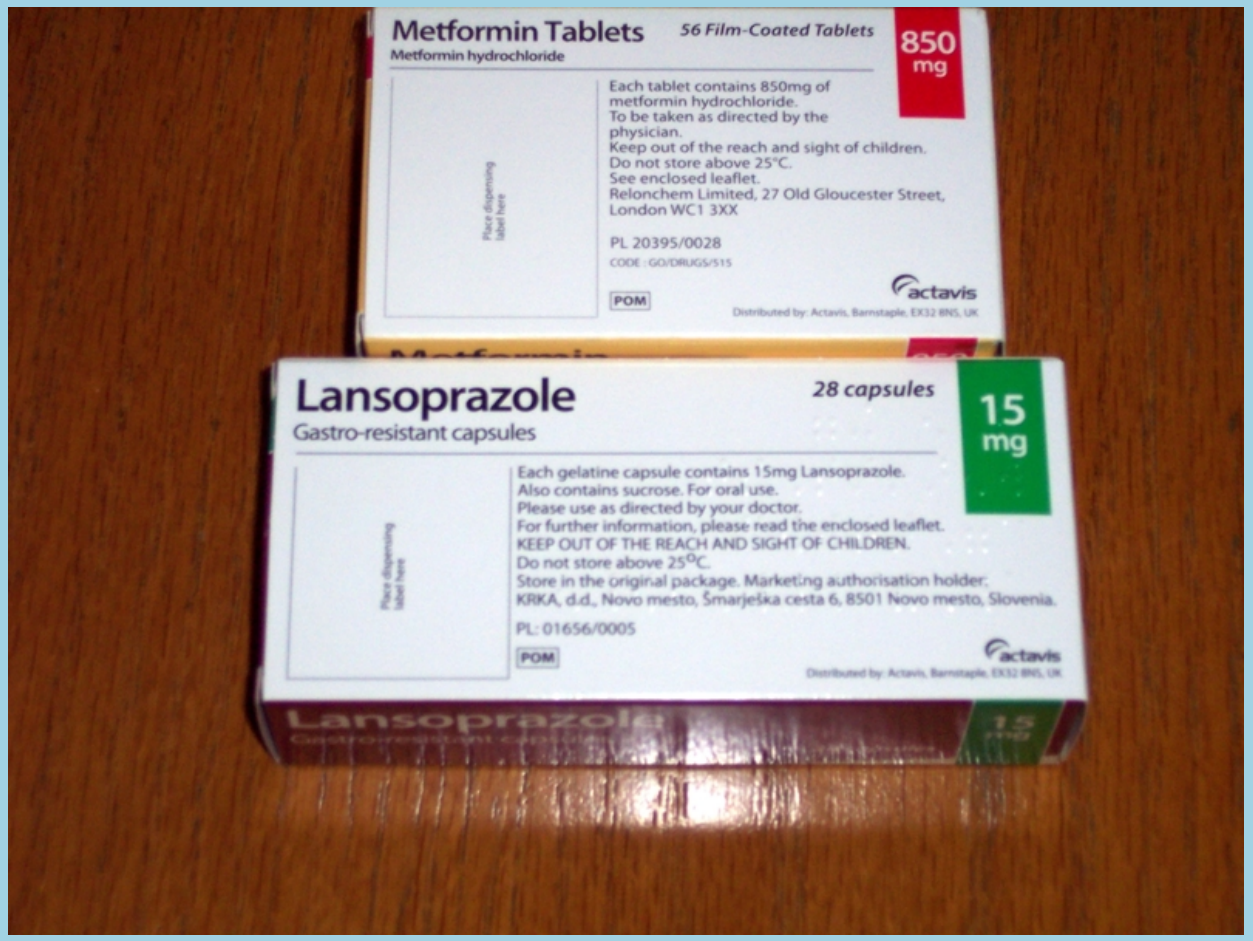
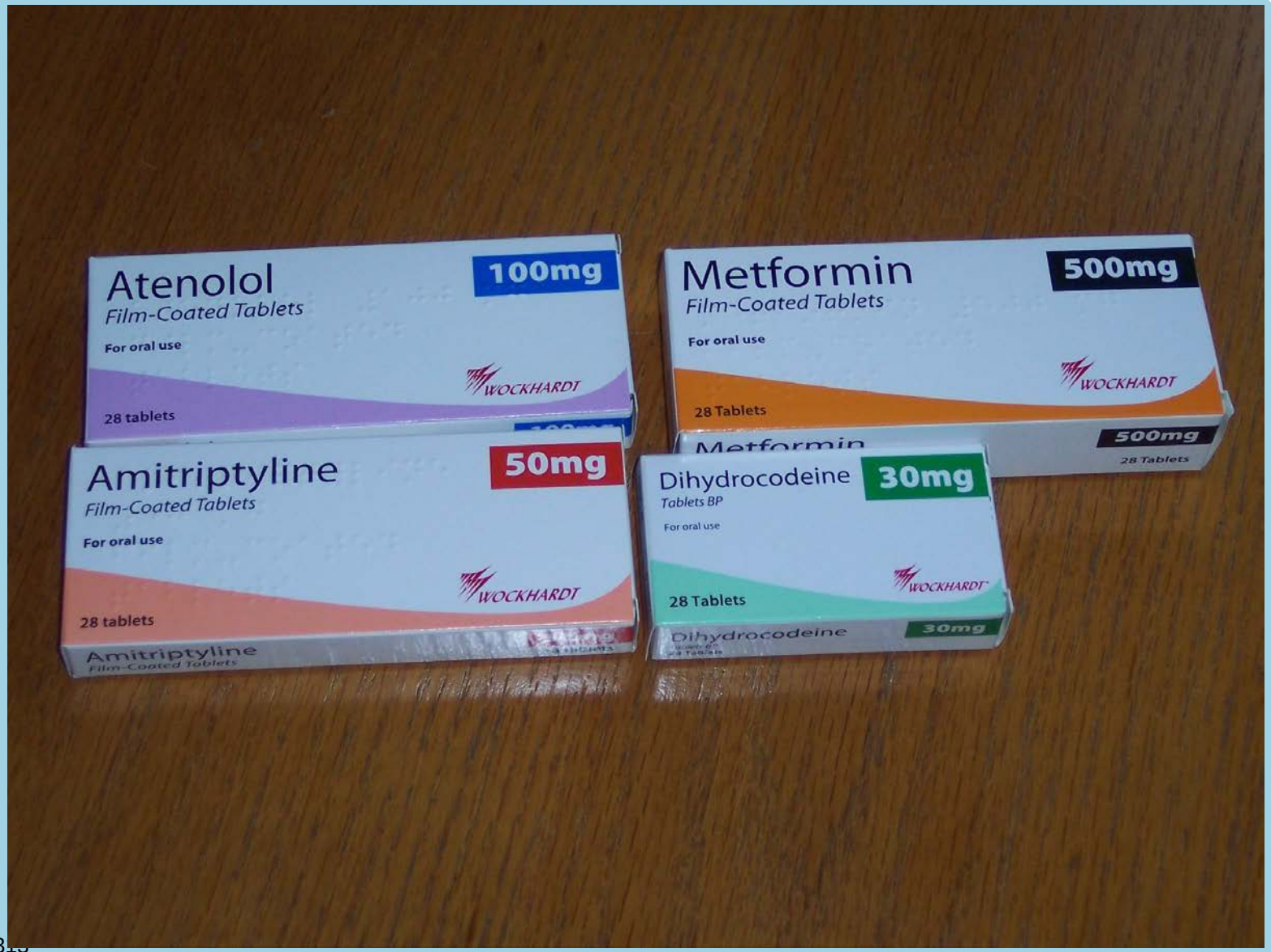
Pack Design


Metformin Tablets
56 Film-Coated Tablets
Metformin hydrochloride
850 mg
Each tablet contains 850mg of metformin hydrochloride.
To be taken as directed by the physician.
Keep out of the reach and sight of children.
Do not store above 25°C.
See enclosed leaflet.
Relonchem Limited, 27 Old Gloucester Street, London WC1 3XX
PL 20395/0028
CODE : GO/DRUGS/515
POM
actavis
Distributed by: Actavis, Barnstaple, EX32 8NS, UK
Place dispensing label here
Lansoprazole
28 capsules
Gastro-resistant capsules
15 mg
Each gelatine capsule contains 15mg Lansoprazole.
Also contains sucrose. For oral use.
Please use as directed by your doctor.
For further information, please read the enclosed leaflet.
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.
Do not store above 25°C.
Store in the original package. Marketing authorisation holder:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia.
PL: 01656/0005
POM
actavis
Distributed by: Actavis, Barnstaple, EX32 8NS, UK
Lansoprazole
15 mg

Pack Design


Atenolol
Film-Coated Tablets
100mg
For oral use
28 tablets
WOCKHARDT
Metformin
Film-Coated Tablets
500mg
For oral use
28 Tablets
WOCKHARDT
500mg
28 Tablets
Amitriptyline
Film-Coated Tablets
50mg
For oral use
28 tablets
WOCKHARDT
Amitriptyline
Film-Coated Tablets
Dihydrocodeine
Tablets BP
30mg
For oral use
28 Tablets
WOCKHARDT
Dihydrocodeine
30mg

Pack design


Atenolol 100mg Tablets x 28 tablets
Affix Dispensing Label Here
5 012727 903507
Each tablet contains 100mg of atenolol
Contains E110
Read the package leaflet for further information
Do not take this medicine if you have a history of wheezing or asthma
Do not stop taking this medicine except on your doctor's advice
Dose: As directed by your doctor
Do not store above 25°C
Store in the original container
Read the package leaflet before use
Keep out of the reach and sight of children
POM
PL 29831/0019
Marketing Authorisation Holder:
Wockhardt UK Ltd, Ash Road North,
Wrexham, LL13 9UF, UK
Amitriptyline 50mg Tablets x 28 tablets
Affix Dispensing Label Here
5 012727 904771
Do not store above 25°C
Keep out of the reach and sight of children
Dose: As directed by your doctor
Read the package leaflet before use
Each tablet contains 50mg of amitriptyline hydrochloride
Contains E464, E171 and E172
Read the package leaflet for further information
POM
PL 29831/0009
Marketing Authorisation Holder:
Wockhardt UK Ltd, Ash Road North,
Wrexham, LL13 9UF, UK.
Metformin 500mg Film-Coated Tablets x 28 Tablets
Affix Dispensing Label Here
5 012727 902968
CP1
Do not store above 25°C
Keep out of the reach and sight of children
Dose: As directed by your doctor
Read the package leaflet before use
Each tablet contains 500mg metformin hydrochloride
Contains sodium. Read the package leaflet for further information
POM
PL 29831/0133
Marketing Authorisation Holder:
Wockhardt UK Ltd, Ash Road North,
Wrexham, LL13 9UF, UK

Pack design


Amitriptyline
10 mg Tablets
10 mg
28 Tablets
Bendroflumethiazide
2.5 mg Tablets
2.5 mg
28 Tablets
Bumetanide
1 mg Tablets
1 mg
28 Tablets
Bumetanide 1 mg Tablets
Nazdol MR
30 mg Modified-Release Tablets
Gliclazide
30 mg
Simvastatin
40 mg Film-Coated Tablets
For Oral Administration
40 mg
28 Calendar Pack Tablets
Loratadine
10 mg Tablets
Non-Drowsy
Fast acting
10 mg
Amlodipine
10 mg Tablets
amlodipine maleate
Oral Use
10 mg
28 Calendar Pack Tablets
Levothyroxine
Tablets BP 50 mcg
For Oral Administration
50 mcg
28 Tablets
Lisinopril
20 mg Tablets
For Oral Administration
20 mg
28 Calendar Pack Tablets
Simvastatin
80 mg Film-Coated Tablets
For Oral Administration
80 mg
28 Calendar Pack Tablets
Levothyroxine
Tablets BP 100 mcg
For Oral Administration
100 mcg
28 Tablets
Clomipramine
10 mg Capsules
For Oral Administration
10 mg
28 Calendar Pack Capsules

Pack Design


Each tablet contains 10 mg of amlodipine (as maleate).
DOSAGE:
Use as directed by the doctor.
Please read the enclosed package leaflet before use.
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN
Do not store above 25°C.
Store in the original package.
Amlodipine 10 mg Tablets
Each tablet contains 55.5 mcg of Levothyroxine Sodium BP equivalent to 50 mcg of levothyroxine. Also includes lactose.
DOSAGE:
Use as directed by the physician.
Please read the enclosed leaflet.
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.
Do not store above 25°C.
Store in the original package.
Levothyroxine Tablets BP 50 mcg
Each capsule contains 10 mg of clomipramine hydrochloride. Also includes lactose.
DOSAGE:
Use as directed by the physician.
Please read the enclosed leaflet.
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.
Do not store above 25°C.
Store in the original package.
Clomipramine 10 mg Capsules
Each tablet contains 80 mg of simvastatin. Also includes lactose.
DOSAGE:
Use as directed by the physician.
Please read the enclosed leaflet.
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.
There are no special storage instructions.
Simvastatin 80 mg Film-Coated Tablets

Case Example

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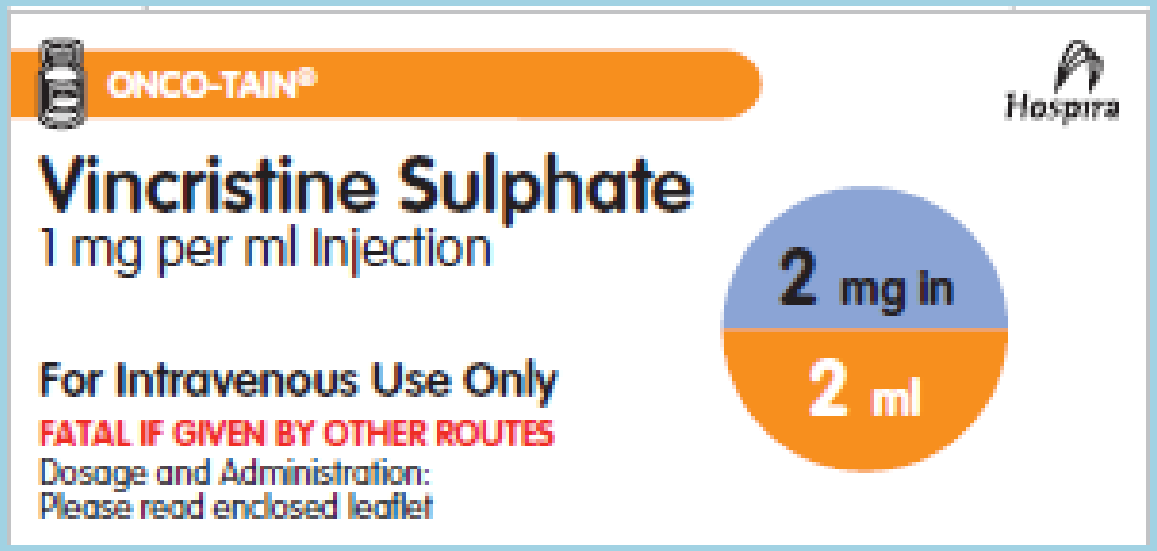
- Change in legislation to require child-resistant packaging

- International standards:
  - BS EN ISO 8317
  - BS EN 14375

Case Example



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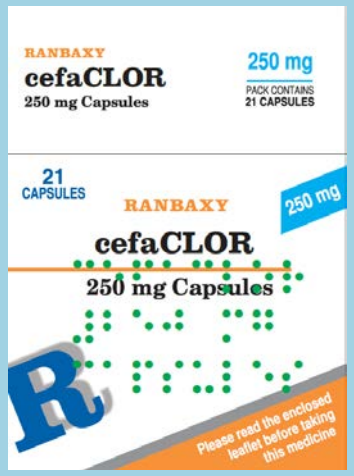
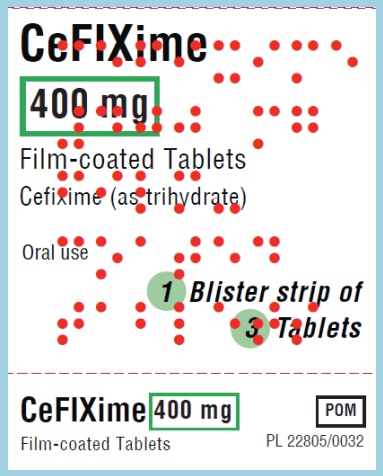
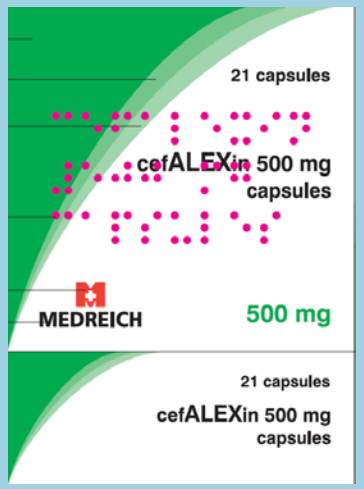
- Removal of “negative” statements
- Positive statements only
- All in same field of view
- Clinical guidance published

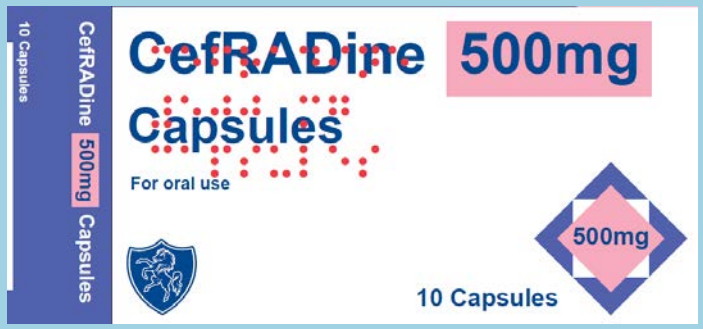
Case Example

- Tallman lettering

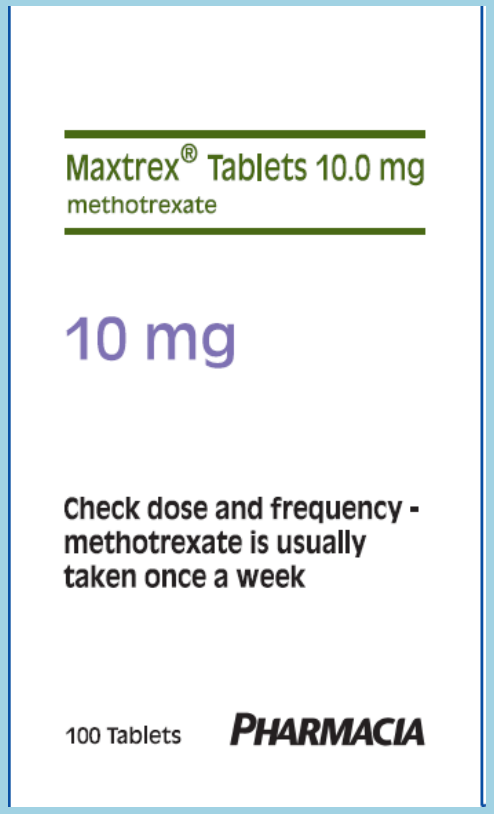








Case example



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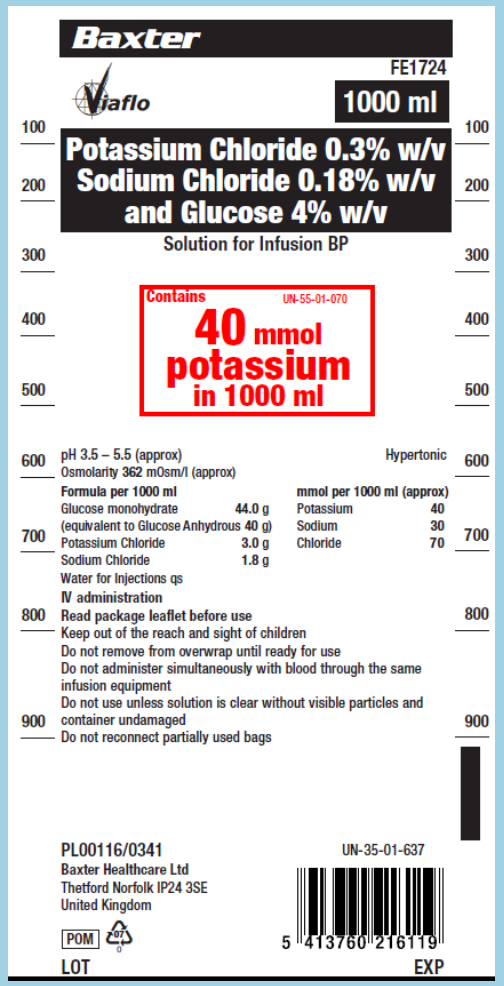
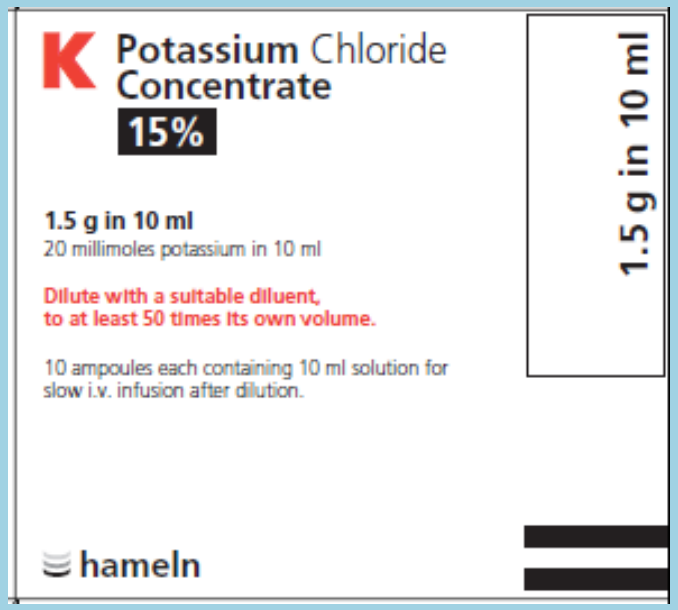
Case Example





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Case Example

Durogesic® *DTrans*® 50 mcg/hr
transdermal patch
fentanyl

One transdermal patch contains 8.4 milligrams of fentanyl
(absorption rate approx 50 micrograms/hour: active surface area 21.0 cm²)

FOR TRANSDERMAL USE
Each patch also contains: polyacrylate adhesive, polyethylene terephthalate/ethyl vinyl acetate film, green printing ink and siliconised polyester film.

POM

C.D.

for external use only

PL 00242/0193 © J-C 2010 GB - 978948

JANSSEN-CILAG Ltd
50-100 Holmers Farm Way
High Wycombe, Buckinghamshire HP12 4EG, UK

Batch No:

Read the leaflet before use. Dosage: as directed by the doctor.

Remove your old patch before applying a new one on a new area of skin. Apply a new patch every 3 days (72 hours).

Opening Instructions

for external use only

- Gently tear or cut open the pouch at the tear notch, shown by the arrow, and remove the edge of the pouch completely (if you use scissors, cut close to the sealed edge of the pouch to avoid damaging the patch)
- Grasp both sides of the opened pouch and pull apart completely
- Take out the patch and use straight away
- Never divide or cut the patch. Do not use the patch if it looks damaged

Keep out of the reach and sight of children.

DISPOSAL AFTER USE: DO NOT throw the pouch away after removing the patch inside. Keep it to put your used patch in. As soon as you take the patch off, fold it firmly in half (sticky sides together) and put it back in the pouch. Put the pouch in the bin with your household rubbish.

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Open

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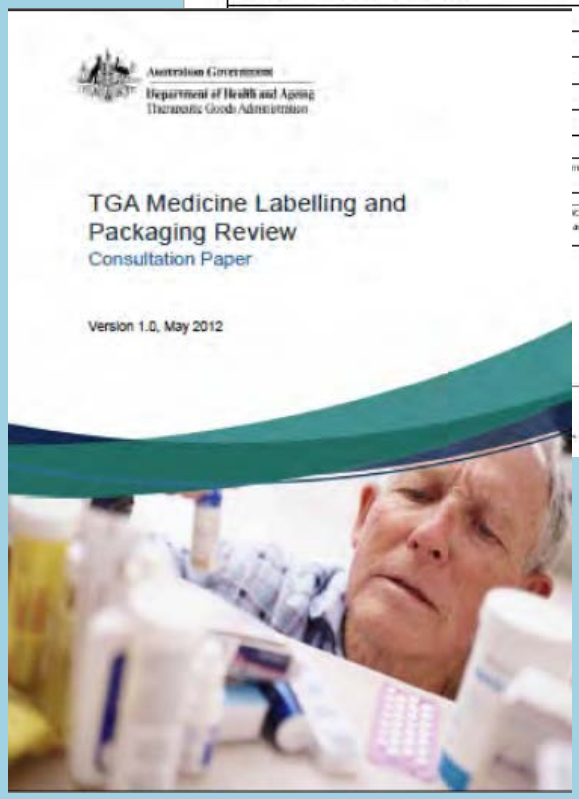
Don't **expose** the patch to **direct** heat such as **heating pads**, electric blankets, **hot-water bottles**, heated water beds, heat or tanning lamps, intensive sun bathing, prolonged hot baths, saunas or hot whirlpool spa baths. These may affect the way the medicine is absorbed through the skin

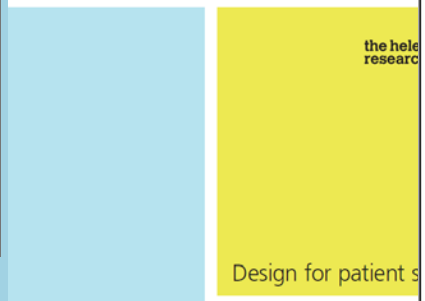
Using and changing the patches

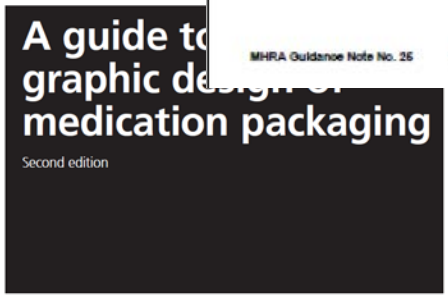
- There is enough medicine in each patch to last **3 days (72 hours)**
- You should change your patch every third day, unless your doctor has told you differently
- Always **remove** the old **patch** before applying a **new one**
- Always change your patch at the **same time** of day **every 3 days (72 hours)**
- If you are using more than one patch, change all your patches at the same time
- Make a note of the **day**, **date** and **time** you apply a patch, to remind you when you need to change your patch
- The following table shows you which day of the week to change your patch:

Apply your patch on		Change your patch at the same time on
Monday	⇨	Thursday
Tuesday	⇨	Friday
Wednesday	⇨	Saturday
Thursday	⇨	Sunday
Friday	⇨	Monday
Saturday	⇨	Tuesday
Sunday	⇨	Wednesday

Supporting others







Summary

- Issues are **global** – not local
- Primary purpose of labelling is the clear and unambiguous identification of the medicine and the conditions for safe use
- Certain items of information are vital for the safe use of the product
- All information must be presented in a legible and easily understood manner by all users
- Innovative pack design and the judicious use of colour can improve patient safety and reduce likelihood of error