

*Spotlight on medication safety:
Designing safe packaging and labeling*

*Global Patient Safety
Considerations
for
Pharmaceutical Product
Labeling*

International Medication Safety Network
www.intmedsafe.net

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**International Medication Safety
Network**

■ Australia	■ Morocco
■ Brazil	■ Netherlands
■ Canada	■ New Zealand
■ Denmark	■ Saudi Arabia
■ France	■ Singapore
■ Hong Kong	■ Spain
■ Iran	■ Suriname
■ Ireland	■ Sweden
■ Israel	■ United States
■ Mexico	■ United Kingdom

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**Some important labeling and
packaging problems**

■ Look-alike labeling	■ Inadequate prominence of reminders and warnings
■ Inconsistent and unclear expression of strength	■ Unsafe application of color coding
■ Cluttered labeling	■ Packaging that fails to take human factors into account
■ Highly stylized label graphics	
■ Overemphasis on company name and logos	

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Read labels carefully - 3 times!

- When obtaining package
- When using package
- When discarding package or returning to storage

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Confirmation bias

Accept information that agrees with our hypothesis; reject information that does not

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Look alike labeling

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Canada
Former packaging Herceptin
and Rituxan



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Canada
Newer packaging Herceptin
Rituxan



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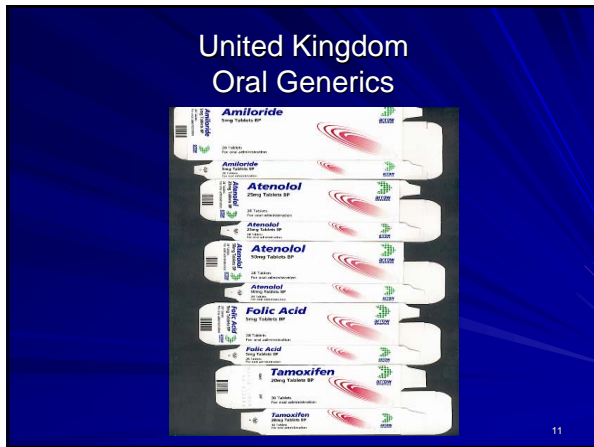
The new Roche Family Design



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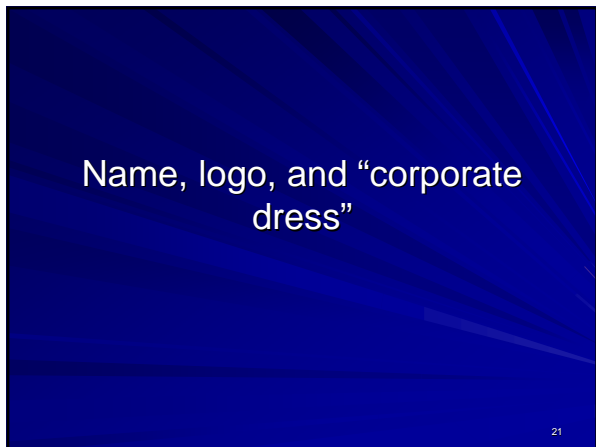




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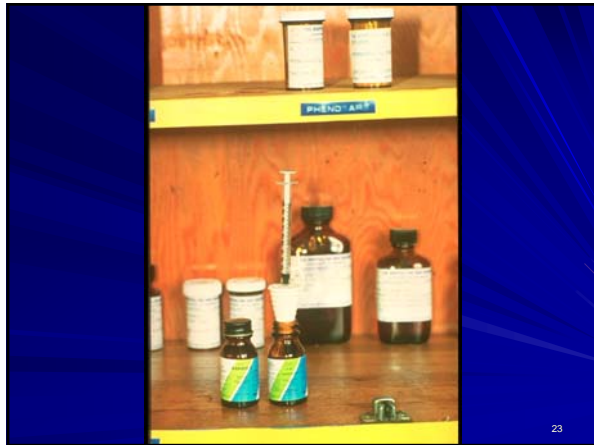






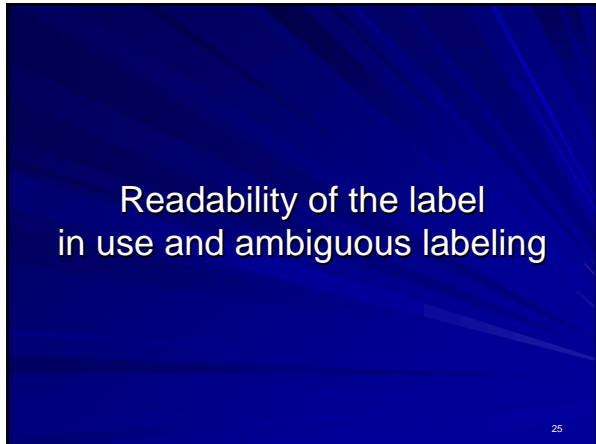
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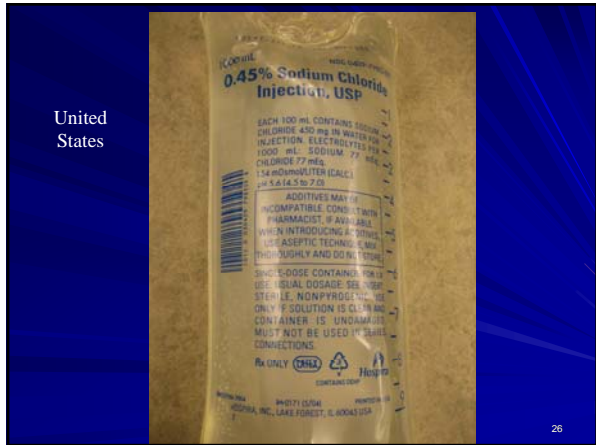






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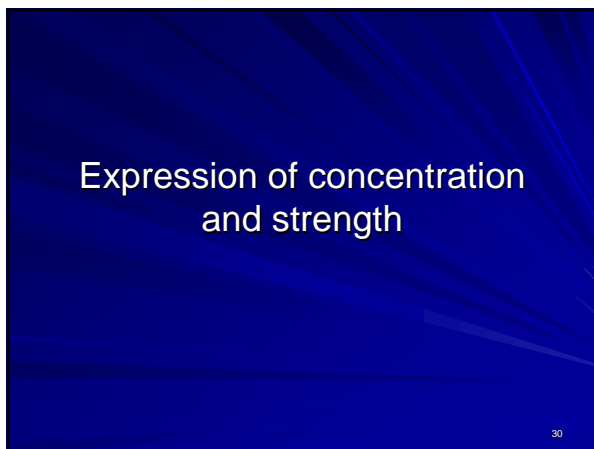




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August 6, 2007

United Kingdom

France and French speaking African country

Spain

Greece

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Australia

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United States

Before and after – both are same strength

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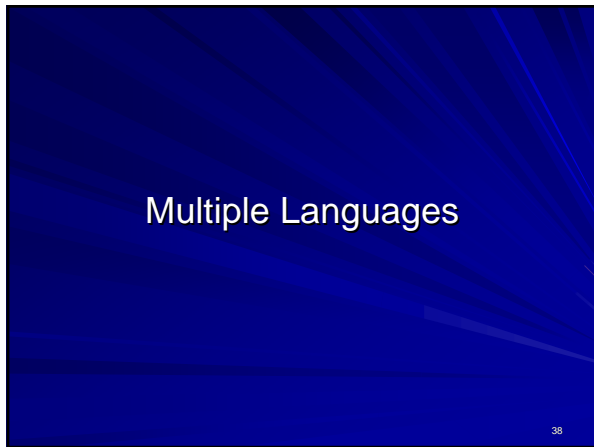
United States

2 tablets = 400 mg or 2 x 400 mg tablets?

36

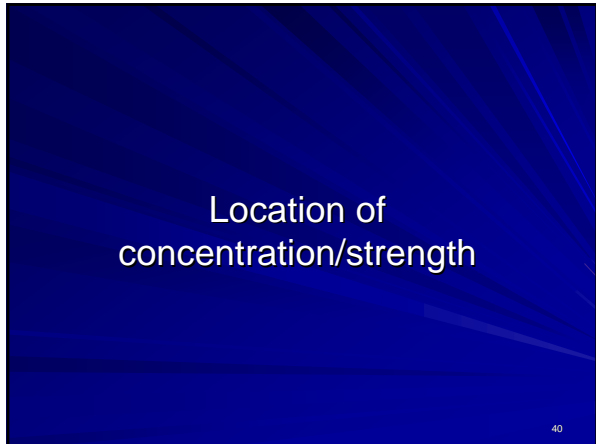
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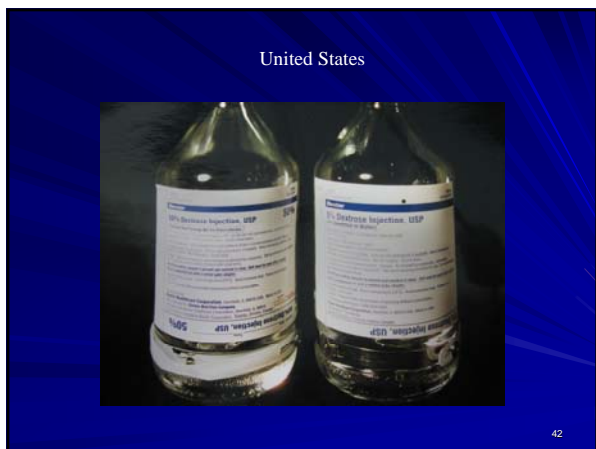




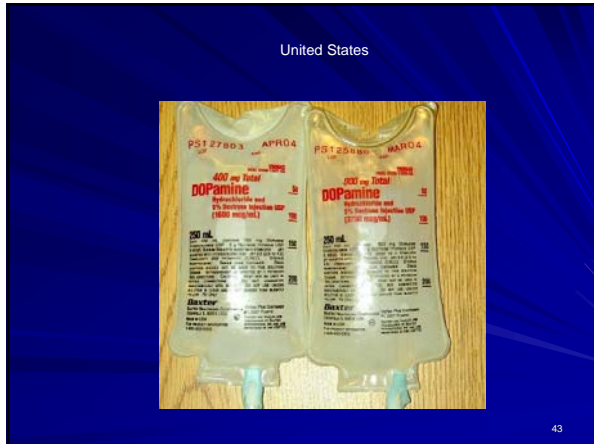
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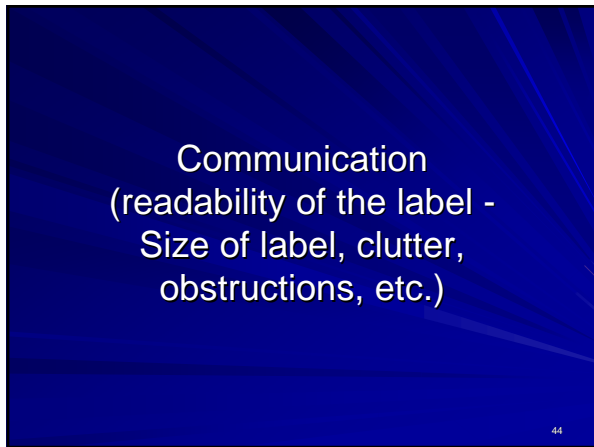






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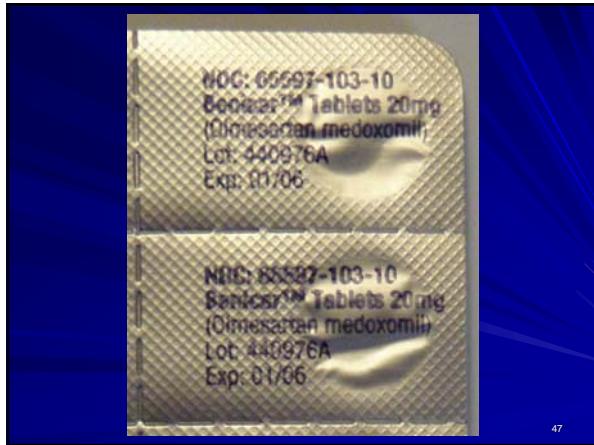






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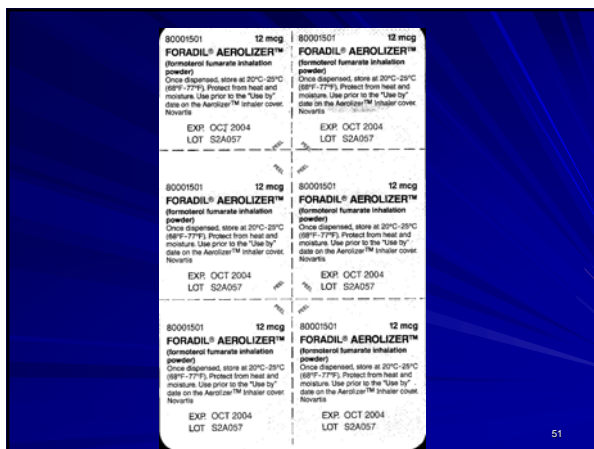




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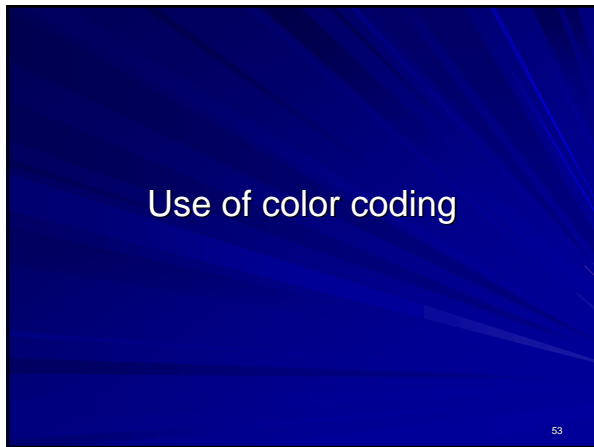






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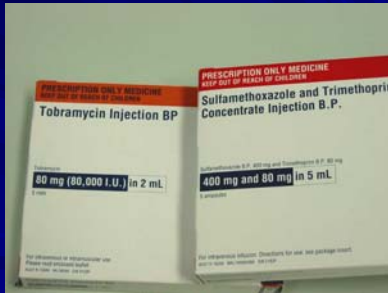






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Australia



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Label reminders and warnings; communication of important information

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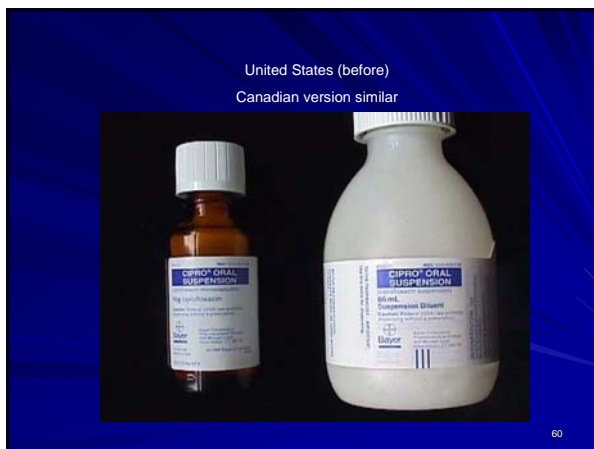


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Spotlight on medication safety: Designing safe packaging and labeling








Spotlight on medication safety: Designing safe packaging and labeling

United States (after)



855310 NDC 0306-8553-36
Diluent for Cipro® 10% Oral Suspension
(ciprofloxacin suspension)
86 mL Suspension Diluent
R Only
Bayer Corporation
Pharmaceutical Division
400 Morgan Lane
West Haven, CT 06516

INACTIVE INGREDIENTS: Medium chain triglyceride, lecithin, lecithin, water and knowlesby flavor.
DOSEAGE: See accompanying literature for complete information on dosage and administration.


RECOMMENDED STORAGE: Store at room temperature (20° C to 25° C) or in the refrigerator (5° C to 15° C).
Protect from freezing. Store upright.

RECONSTITUTION: Cipro Oral Suspension comes in two bottles; the smaller bottle contains 20 mL of ciprofloxacin suspension and the larger bottle contains the diluent.
1. Pour the microcapsules completely into the large bottle of diluent.
2. Do not add water to the suspension.
3. Remove the top label of the diluent bottle and affix the Cipro Oral Suspension label.
4. Shake the bottle vigorously for about 15 seconds.

P-500279 © 1999 Bayer Corporation (Made in USA)

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TO THE PHARMACIST: MINORITARIAN
Use this label for dispensing.



855310 NDC 0306-8553-36
Diluent for Cipro® 10% Oral Suspension
(ciprofloxacin suspension)
86 mL Suspension Diluent
R Only
Bayer Corporation
Pharmaceutical Division
400 Morgan Lane
West Haven, CT 06516

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Typography

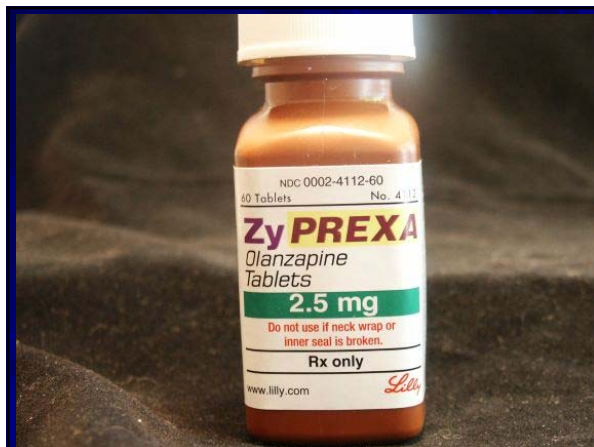
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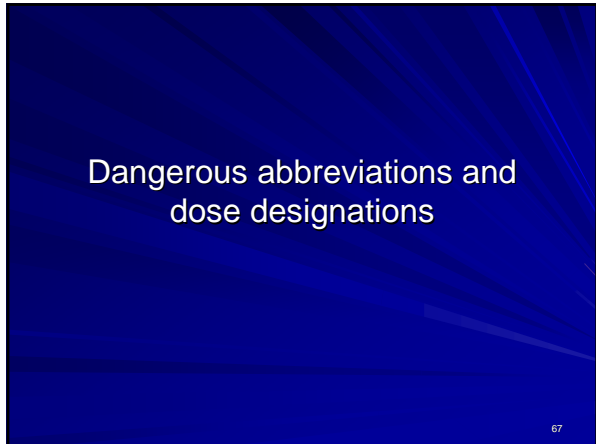
- Dobutamine 400 mg
- Dopamine 500 mg
- chlorpropamide 100 mg
- chlorpromazine 100 mg
- hydralazine 50 mg
- hydroxyzine 50 mg
- doBUTamine
- doPAMine
- chlorproPAMIDE
- chlOrproMAZINE
- hydrALazine
- hydrOXYzine

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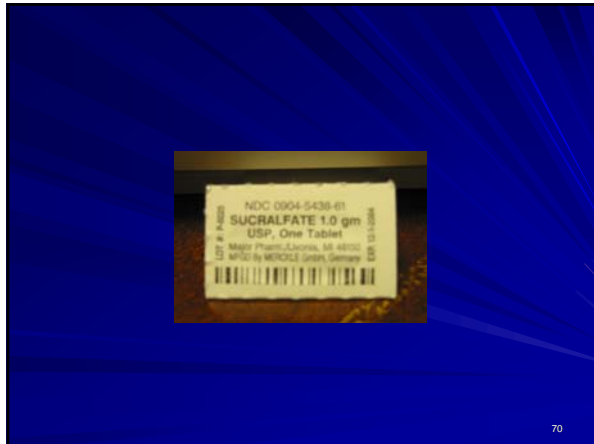
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Lack of response by
manufacturer when error is
reported

“This report has been brought to the attention of the appropriate Labeling/Regulatory personnel, and we have entered it into the [Company] Product Complaint System for monitoring purposes.”

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*Questions on labeling,
Packaging??*

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