

Global Patient Safety Considerations with Pharmaceutical Product Labeling

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Some important labeling and packaging problems

- Dangerous abbreviations
- Look-alike labeling
- Inconsistent and unclear expression of strength
- Cluttered labeling
- Highly stylized label graphics
- Overemphasis on company name and logos
- Lack of contrast on glass ampuls
- Inadequate prominence of reminders and warnings

Dangerous abbreviations and dose designations



60 Regular INSULIN NOW

New Zealand



Exelon®
(rivastigmine tartrate)
Capsules

equivalent to

3.0 mg 100 Capsules
base

See bottom panel for lot number and
expiration date.

Look alike labeling

Belize



Canada

5 PATCHES/
PATCHS

DIN 02249391

N RAN™-FENTANYL TRANSDERMAL SYSTEM

25

PATCH DE FENTANYL PATCH

Each patch contains 2.5 mg fentanyl for nominal *in vivo* delivery of 25 mcg/h fentanyl for 72 hours.

Chaque patch renferme 2.5 mg de fentanyl pour une administration nominale *in vivo* de 25 mcg/h de fentanyl pendant 72 heures.

OPIOID ANALGESIC/ANALGÉSIQUE OPIOÏDE

RANBAXY

5 PATCHES/
PATCHS

DIN 02249421

N RAN™-FENTANYL TRANSDERMAL SYSTEM

75

PATCH DE FENTANYL PATCH

Each patch contains 7.5 mg fentanyl for nominal *in vivo* delivery of 75 mcg/h fentanyl for 72 hours.

Chaque patch renferme 7.5 mg de fentanyl pour une administration nominale *in vivo* de 75 mcg/h de fentanyl pendant 72 heures.

OPIOID ANALGESIC/ANALGÉSIQUE OPIOÏDE

RANBAXY

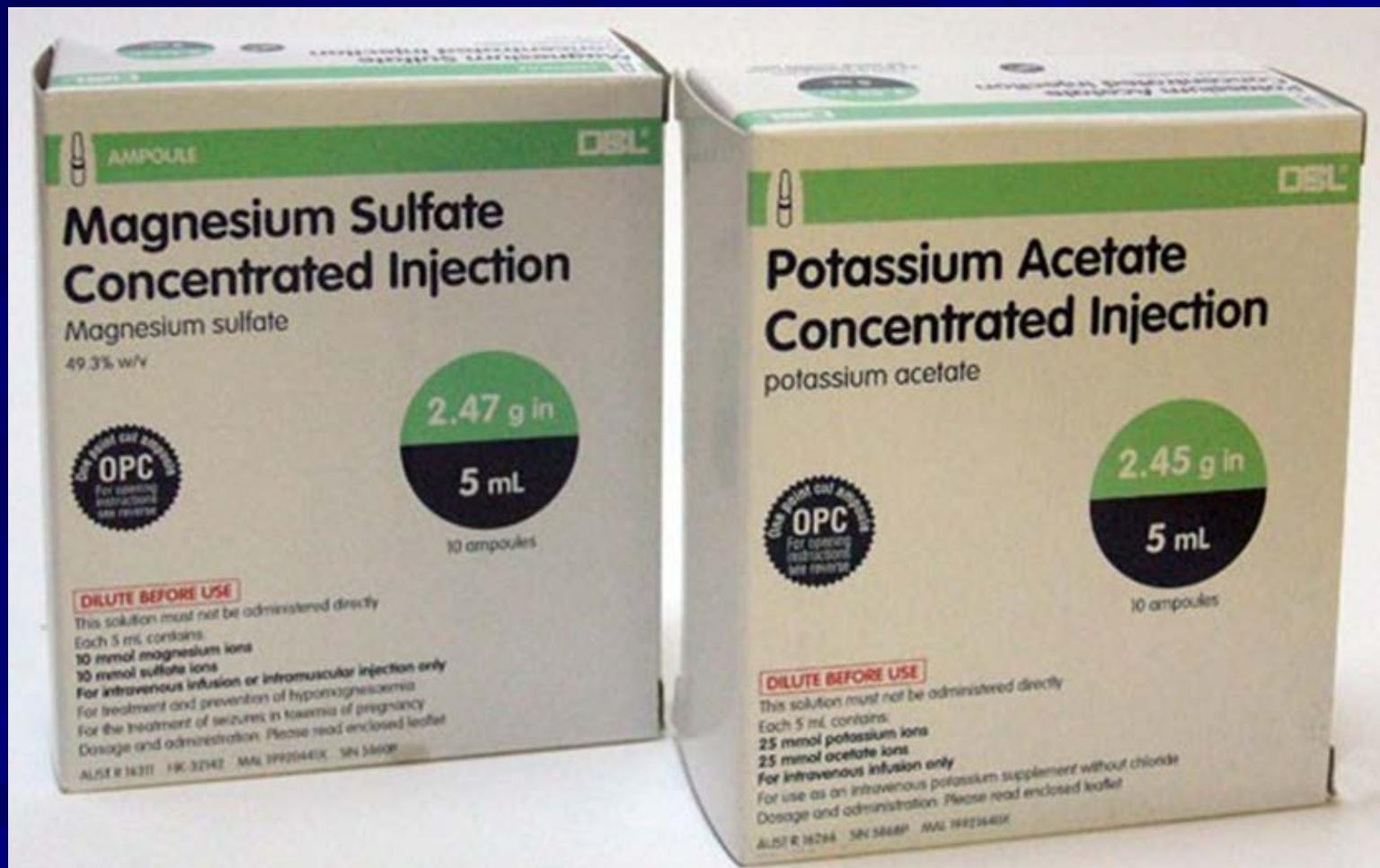
United Kingdom Oral Generics



Latin America - Colombia



Australia



Denmark



Contrast on glass ampuls

Spain



Note lack of label background – no contrast
upon dark background

Australia

One of these things is not like the others...

Sulfate
Injection
ephedrine
sulfate
30 mg in 1 mL
Sulfate
Injection
ephedrine
sulfate
30 mg in 1 mL
Ephedrine
Sulfate
Injection
ephedrine
sulfate
DBL
Ephedrine
Sulfate
Injection
ephedrine
sulfate
DBL
HEPARIN
SODIUM
(porcine mucous)
5,000 I.U. in
0.2 mL
injection BP
DBL
Ephedrine
Sulfate
Injection
ephedrine
sulfate

Making a serious drug error shouldn't be this easy
Join the campaign to make medication packaging safer
EZDrugID.org

Ampule labeling

Serious medication errors with ampules of bupivacaine and tranexamic acid

- <https://www.ejmanager.com/mnstemps/83/83-1444637751.pdf>
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3371494/>
- https://www.apsf.org/newsletters/html/2010/spring/02_inject.htm
- <https://dokumen.tips/documents/01-danger-of-wrong-drug-administration-during-subarachnoid-blockpdfpdfcompressor.html>



Figure 1. Look-alike ampoules:
Tranexamic acid and bupivacaine.

Germany

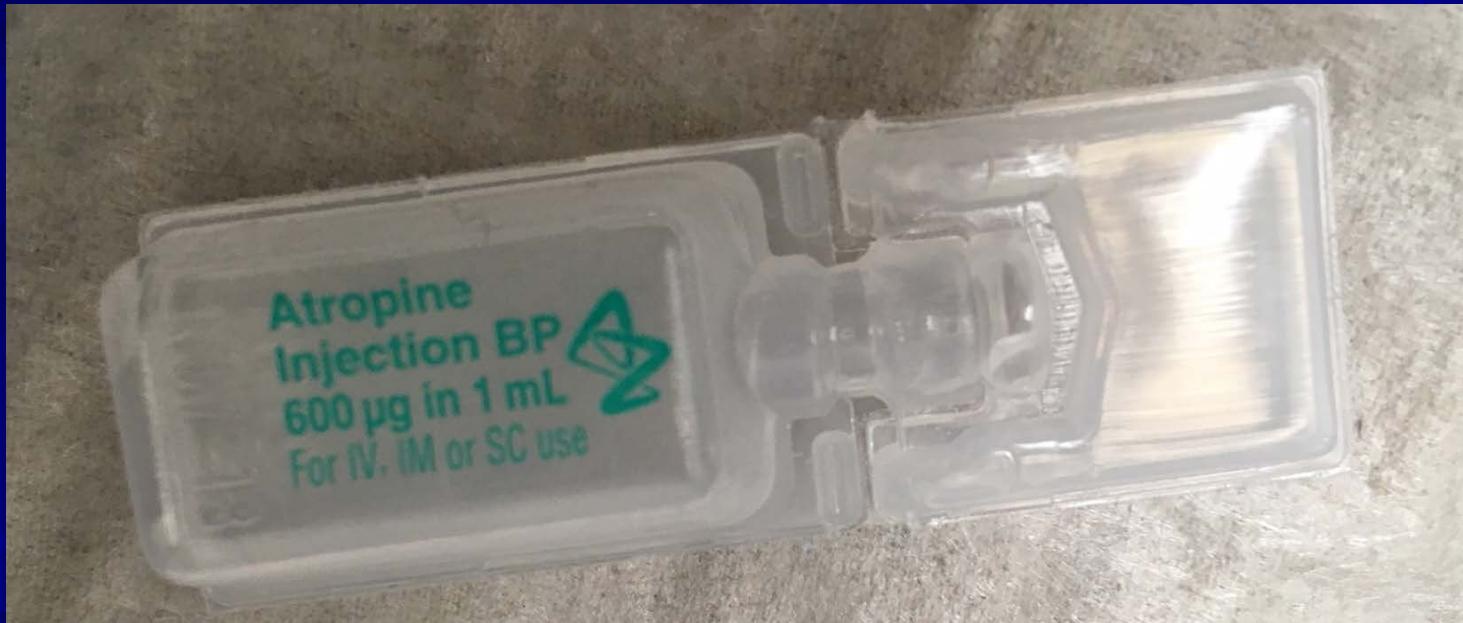
■ Label position on ampuls and syringes



US ampul label for comparison

Readability of information on polypropylene ampules

New Zealand



Germany

■ Label position on ampuls and syringes

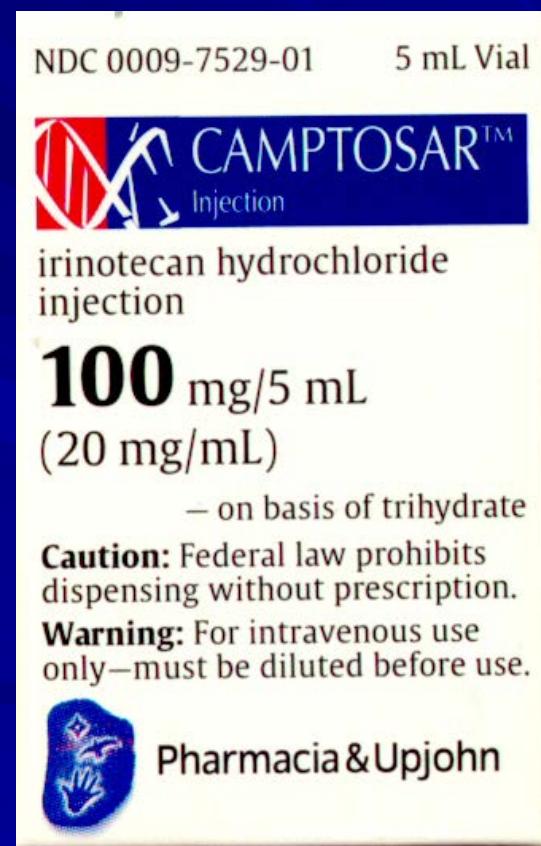


US ampul label for comparison



Expression of concentration and strength

Before and after – both are same strength



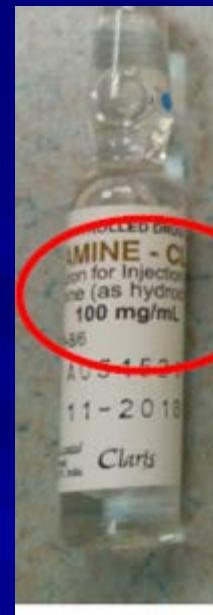
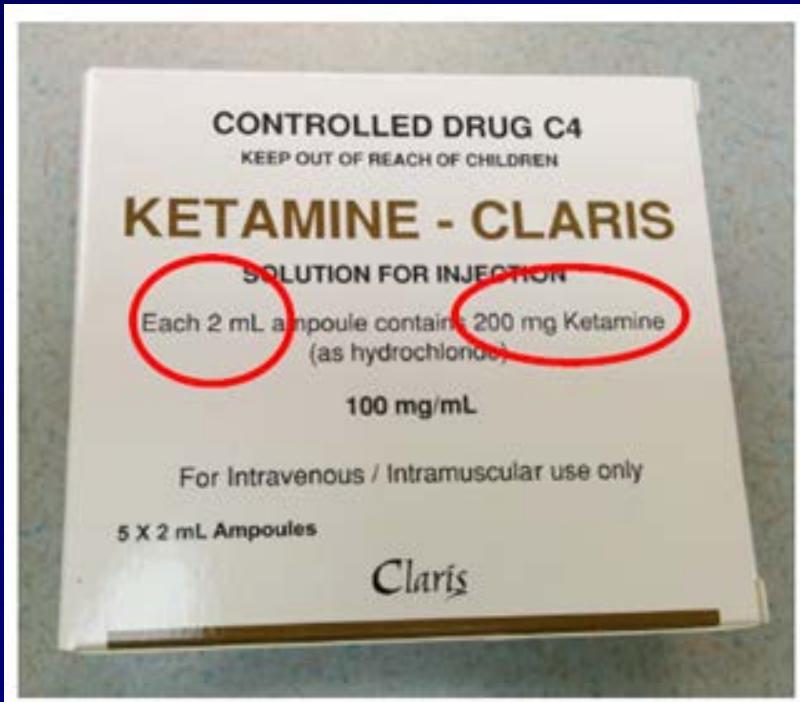
USA



Singapore



New Zealand





August 6, 2007

Direct Healthcare Professional Communication on Kaletra® (lopinavir/ritonavir) oral solution and accidental overdose in children

Dear Healthcare Professional,

Summary

Abbott was recently notified of an accidental overdose when an infant received a significantly large dose of Kaletra (lopinavir/ritonavir) Oral Solution. The infant subsequently died.

Abbott is reminding you that:

- Kaletra Oral Solution is highly concentrated, containing 80 mg lopinavir and 20 mg ritonavir per mL (not per bottle).
- Children dosages are calculated based on body weight. A child should receive **less** than 5 mL oral solution per dose unless they are also receiving certain concomitant antiretroviral medicines. Reference should be made to the attached prescribing information.

Further information on the safety concern

- The accidental overdose occurred in a 44-day-old infant, born at 30 weeks gestation with HIV, who was given approximately 6.5 mL of Kaletra Oral Solution (this is about 10 times the calculated volume). The infant died nine days later of cardiogenic shock.
- Special attention must be paid to accurate calculation of the dose, transcription of the instructions to minimize errors, and be made to the attached recommendations in

Please see accompanying full prescriber information.

United Kingdom



France and French speaking African country



French label above

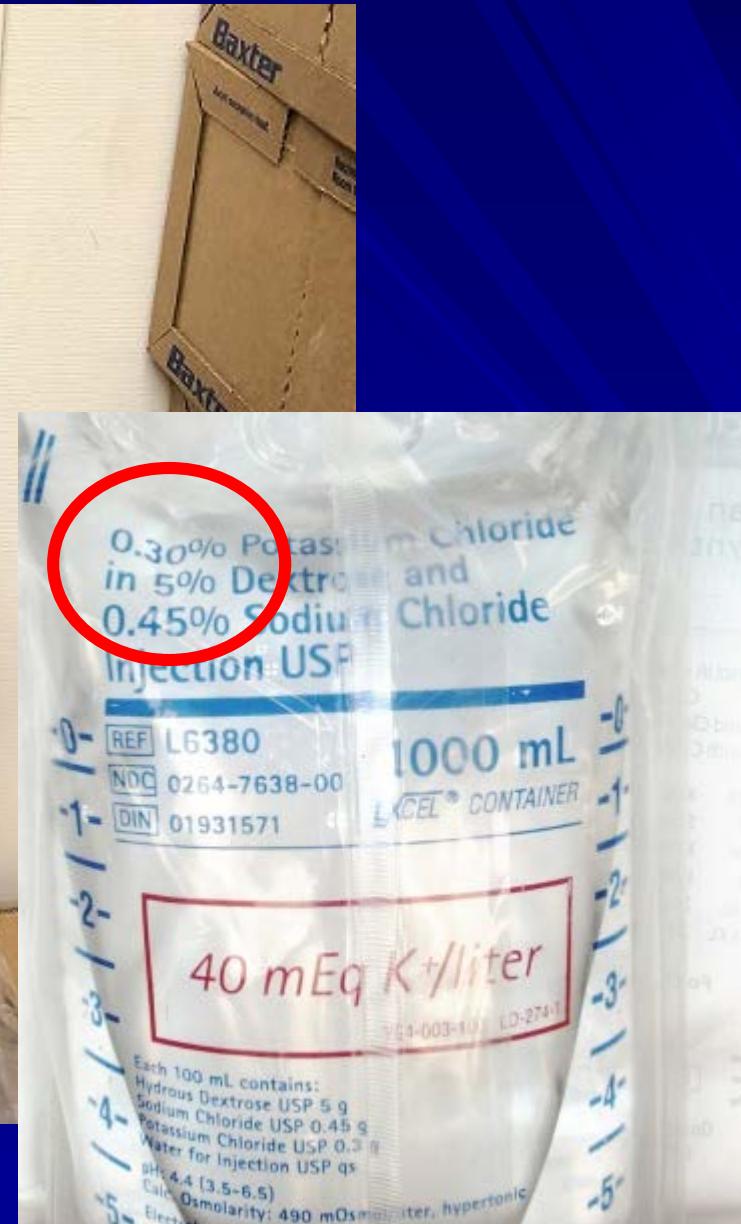
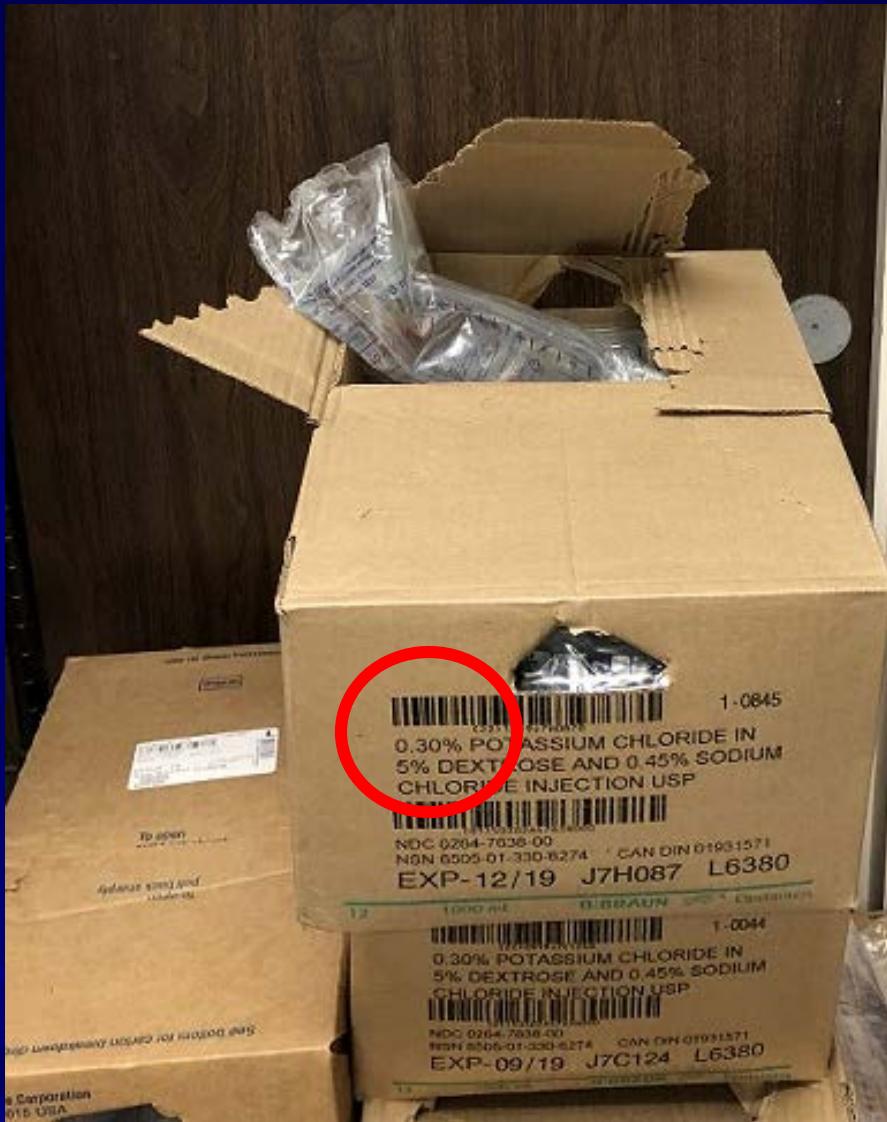
Spain



Greece





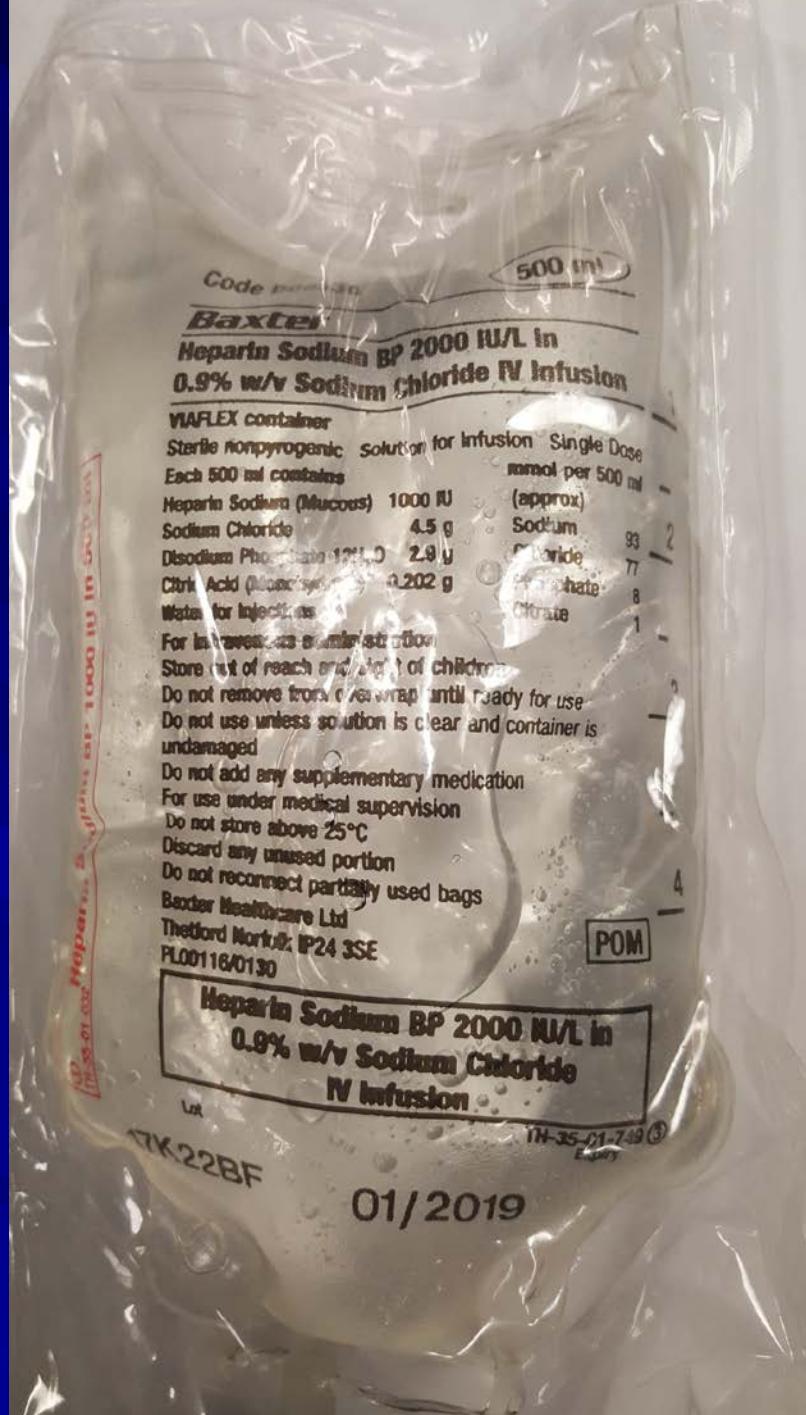
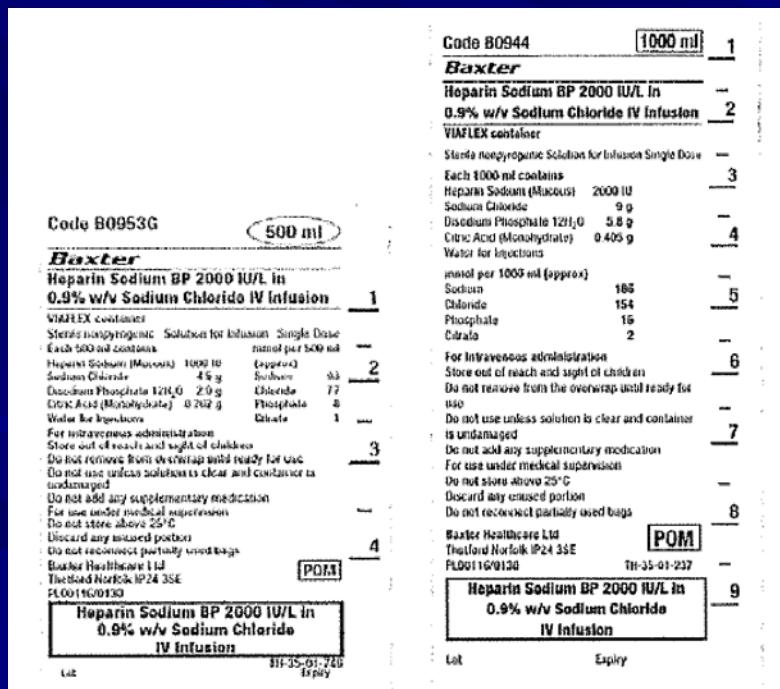


How much heparin?

IU

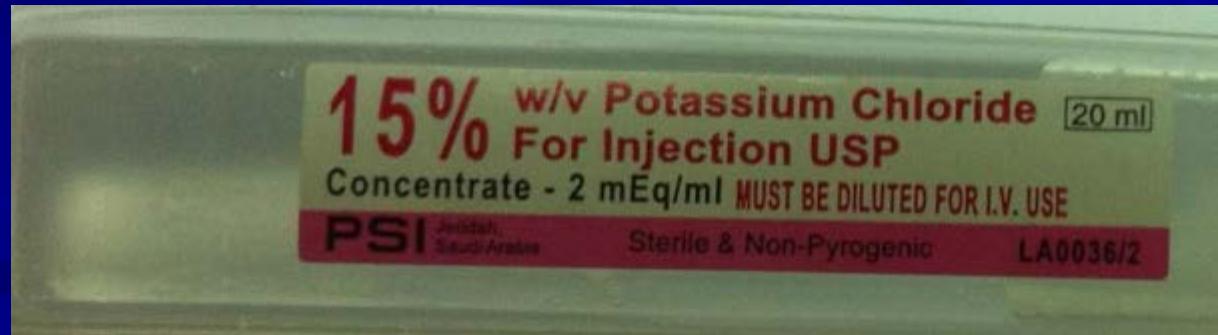
Bar code?

Heparin in title is per liter
while other heparin
mention and electrolytes
are per 500 mL





Units not standardized to mEq or mmol



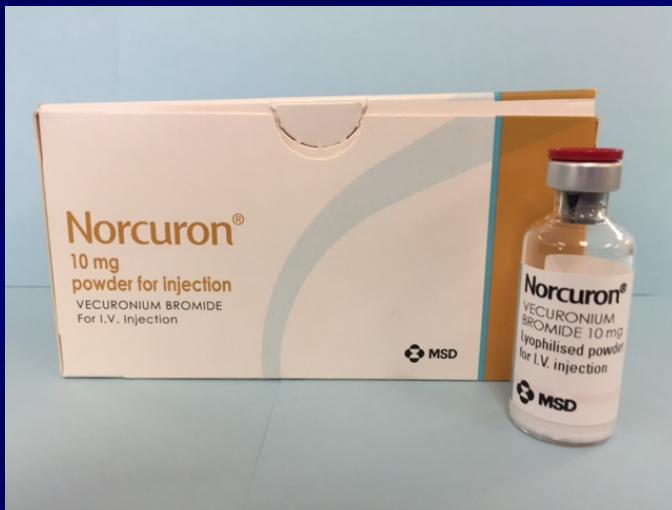
NDC: 65597-103-10
Sancsri™ Tablets 20mg
(Oimesartan medoxomil)
Lot: 440976A
Exp: 01/06

NDC: 65597-103-10
Sancsri™ Tablets 20mg
(Oimesartan medoxomil)
Lot: 440976A
Exp: 01/06



Label reminders and
warnings; communication of
important information

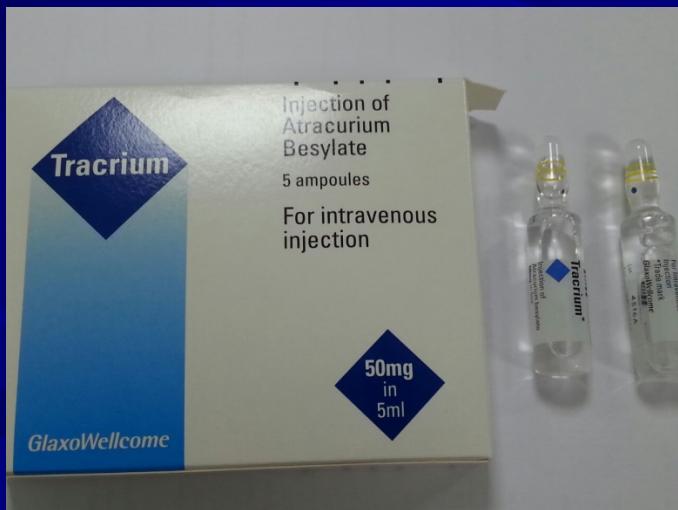
Neuromuscular Blockers



New Zealand



Unknown Country





Why warning paralyzing agent on US and Canadian labels only?

Neuromuscular Blocker look-alike New Zealand



USA and Canada Neuromuscular Blocker

