

Naming, labelling and packaging of medicines put patients at risk.

Experiences from SPAIN

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ISMP-Spain

National Medication Error Reporting & Learning System

The screenshot displays the ISMP-Spain website interface. At the top, it reads 'Instituto para el Uso Seguro de los Medicamentos' and 'Delegación Española del Institute for Safe Medication Practices'. A navigation menu on the left includes links for 'Inicio', 'Quiénes somos', 'Cómo contactar con nosotros', 'Direcciones de interés', and a section for 'SISTEMA DE NOTIFICACIÓN Y APRENDIZAJE DE ERRORES DE MEDICACIÓN' with sub-links for 'Errores de medicación', 'Notificación de errores al ISMP-ESPAÑA', 'Boletines', and 'Alertas'. The main content area is titled 'SISTEMA DE NOTIFICACIÓN Y APRENDIZAJE DE ERRORES DE MEDICACIÓN' and includes the text 'Adherido al Programa Internacional de Medicamentos Seguros del Instituto para el Uso Seguro de los Medicamentos'. Below this, it asks for a 'DESCRIPCIÓN DEL INCIDENTE' with 'Campos obligatorios' and 'Gravedad del incidente' options: 'Error potencial' (selected) and 'Error real'. It also includes a question '¿Cuándo sucedió el incidente?' with a dropdown menu for 'Tiempo conocido' set to 'Si' and a 'Fecha' field.

- ❑ Objective: “**Learning effectively from failures**”
- ❑ Supported by the Spanish Ministry of Health through its **Patient Safety Strategy**.
- ❑ Collaborate with the Spanish Medication Agency
- ❑ Reporting ways:
 - Web-based reporting form
 - Electronic reporting from local organizations through a computer application
 - Other systems: E-mail, telephone

ISMP-Spain & Spanish Agency of Medicines (AEMPS) Collaboration



▶ **Since 2001. Collaboration agreement between AEMPS and ISMP-Spain:**

Send medication error reports (without & with harm) filtered and analyzed, with proposals for solutions, about errors related to:

- **Labelling and packaging**, naming, product information, administration devices, shortages, etc.

Major Naming, Labelling and Packaging Problems

▶ Look-alike sound-alike drug names

- Brand names
- INN names
- Brand names and INN names

▶ Similarities in packaging and labelling appearance

- Different drugs
- Different dosage strengths of the same product

▶ Unclear, ambiguous or incomplete labelling

- Unclear strength designation
 - Use of percentages, use of concentration, etc.
- Poor readability of label information
 - Cluttered labelling, small font, lack of adequate background contrast, etc.

Examples of naming problems

▶ Look-alike sound-alike drug names

▣ Confusion between brand names

- Aricept- Azilect
- Luminal- Sumial
- Humalog- Humalog basal- Humalog mix
- Oxynorm-Oxycontin

▣ Confusion between generic names

- doxorubicina- epirubicina
- hidroxycarbamida- hidroxocobalamina
- metamizol- metronidazol
- metotrexato- metronidazol

▣ Confusion between brand and generic names

- Rohipnol-ropirinol
- Sandostatin- somatostatina

National Medication Error Reporting & Learning System

Feedback: LASA drug names list, TML list, name finder and recommendations

Recomendaciones para prevenir los errores causados por confusión en los nombres de los medicamentos

ISMP-España

ISMP

La confusión en los nombres de los medicamentos es una de las causas más comunes de errores de medicación. Algunos errores de medicación, de los que aumentan en frecuencia en los países con un alto nivel de desarrollo, son: el uso de nombres genéricos, nombres similares de medicamentos, etc.

El ISMP y otros organismos de la OMS recomiendan que se eviten los nombres que puedan causar confusión en los países de habla hispana.

Prácticas para evitar la confusión en los nombres de los medicamentos:



Las prácticas para evitar la confusión en los nombres de los medicamentos se refieren a las acciones que se deben tomar para evitar errores de medicación.



Instituto para el Uso Seguro de los Medicamentos

LISTA DE NOMBRES SIMILARES DE MEDICAMENTOS QUE SE PRESTAN A CONFUSIÓN

A	Anafanti ↔ enalapril
Acabei ↔ Acovil	Angiotol ↔ Akineton
Acabei ↔ Actonel	Apocard ↔ Aprovel
ácido fólico ↔ ácido fólico	Apocard ↔ Atacand
ácido fólico ↔ ácido fólico	Aprovel ↔ Aprovel
Acovil ↔ Acabei	Aprovel ↔ Atrovent
Acovil ↔ Daonil	Aprovel ↔ Seroquel
Acovil ↔ Actonel	Aranesp ↔ ARIcept
Actiq ↔ Actia	Aranesp ↔ Avonex
Actra ↔ Actiq	Arava ↔ Axura
Actonel ↔ Acabei	Aramis ↔ Aerius
Actonel ↔ Acsai	Aramis ↔ Arimidex
Actonel ↔ Adofen	ARIcept ↔ Aranesp
Actonel ↔ Astudal	ARIcept ↔ AZILact
Adalat ↔ Adolonta	Arimidex ↔ Ameride
Adalgru ↔ Adalquir	Arimidex ↔ Aramis
Adiro ↔ Adimon	Artelid ↔ Astudal
Adiro ↔ Cidine	Astonin ↔ Daalocin
Adimon ↔ Adiro	Astoim ↔ Daalocin
Adofen ↔ Actonel	Astutal ↔ Actonel
Adolonta ↔ Adalat	Astutal ↔ Artelid
Adolonta ↔ atenolol	Atacand ↔ Apocard
Adolquir ↔ Adalquir	Atarax ↔ Alimax
ADRENalina ↔ Aleudrina	atenolol ↔ Adolonta
ADVAgraf ↔ PROgraf	Atrovent ↔ Aprovel
Aerius ↔ Aramis	Auxina E ↔ Axura
Aflunon ↔ Euglucon	Avonex ↔ Aranesp
Akineton ↔ Angiotol	Axura ↔ Arava
Alapryl ↔ Amaryl	Axura ↔ Auxina E
Alapryl ↔ enalapril	azaTiOprina ↔ aZitromicina
Aldactone ↔ Alisactone	AZILact ↔ ARIcept
Aldactone ↔ Aldactone	azitromicina ↔ azaTiOprina
Aleudrina ↔ ADRENalina	
Aligridol ↔ Aligridin	Bactil ↔ Bactil
Aligridol ↔ Orfidol	Beloken ↔ Dolofren
Aligridin ↔ Aligridol	Beloken ↔ Seroquel
Alimax ↔ Atarax	Beneftan ↔ Bestiran
alopurinol ↔ haloperidol	Bestiran ↔ Benestán
Amaryl ↔ Alapryl	Biceti ↔ Bactil
Amaryl ↔ Ameride	Bol-k ↔ Borea
Ameride ↔ Amaryl	Borea ↔ Bol-k
Ameride ↔ Arimidex	Briatazol ↔ Dilitol

Tabla 2. Relación de nombres de medicamentos similares con letras mayúsculas resaltadas

Par o grupo de nombres similares de medicamentos	Fuente/s
ADRENalina-ATROPina	ISMP-España
ADVAgraf-PROgraf	ISMP-España
ARIcept-AZILact	
azaCITIDina-azaTiOprina	
BUPivacaína-MEPivacaína-ROPivacaína	
cefAZOLina-cefTRIAXona-cefTAZidima-cefOXitina/cefOTAXima	
CISplatino-CARBOplatino	
cloTIApina-cloZAPina	
cloTRIMazol-cloMETIazol	
DACTINomicina-DAPTOmicina	
DASATinib-LAPAtinib/SUNItinib-SORAFenib	
DAUNORubicina-DOXOrubicina/IDARubicina/EPIdubicina	
DOBUTamina-DOPamina	
DOCETaxel-PACLitaxel	
DOLQuine-DEPAkine	
EbIXA-EVISTA	
eFEDrina-EPINEFrina/FENILEFrina	
EmCONcor-EnTOcord	
FLUoxetina-DULoxetina-PARoxetina	
FOSamax-TOPamax-IOPImax	
gliPIZIida-gliBENCLAMida/gliCLAZIida-gliMEPIRida	
hidRALAZina-hidroXizina	
HumALOG-HumALINA	
ISOTretinoína-tretinoína	
loRAtadina-loVAsStatina	
metAMIZol-metroNIDazol	
mitoXANTRONA/ mitoMICHINA	
MOXicil-mOXNurol-MAGNurol	
niCARdipino-niFEdipino/nimODipino	
NovoRAPID-NovoMX	
OKcarbazepina-carBAMazepina	
predniSONA-predniSolONA	
ProZAC-ProSCAR	
quiNINA-quiNIDina	
riTUXimab-inFLIXimab	
RoflUProl-roPINol	
SandIMMUN-SandoSTATIN	
SiNOGan-SinEQJan	
sulfaDIAZina-sulfaSALAZina	
SUmial-LUminal	
TIAPRIZal-TRILEPTal-TryPTIzol	
UroSOCHol-UroTROl-UroLOSIN	
vaIAciclovir-vaGANCiclovir	
vinBLAStina-vinCRIStina/vinFLUNina-vinORELBina	

Búsqueda de nombres de medicamentos con similitud ortográfica o fonética.

Este sistema de búsqueda es una herramienta de consulta para que los profesionales sanitarios y los pacientes puedan acceder a los nombres de los medicamentos que se ha detectado que pueden causar errores de medicación.

Escriba el nombre del medicamento que desea consultar. Si ha causado un error por confundirse con el nombre de otro u otros medicamentos, éstos aparecerán a continuación.

Comience a escribir un nombre para acceder a los nombres registrados

Resultados para: HumaLOG

HumaLOG

HumaLOG basal
HumaLOG mix
HumuLINA

Buscar Limpiar

Advertencia: Esta información se ha elaborado exclusivamente a partir de los errores de medicación recogidos en el ISMP-España. Por ello no es

Examples of labelling and packaging problems

- ▶ Similarities in packaging and labelling (different drugs)/ inadequate prominence of manufacturer name:



Examples of labelling and packaging problems

- ▶ Similarities in packaging and labelling (different drugs)/ poor readability:



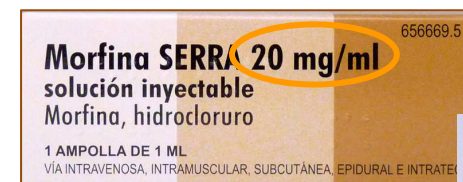
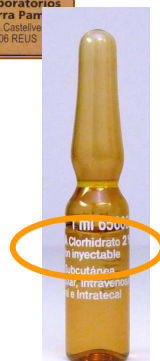
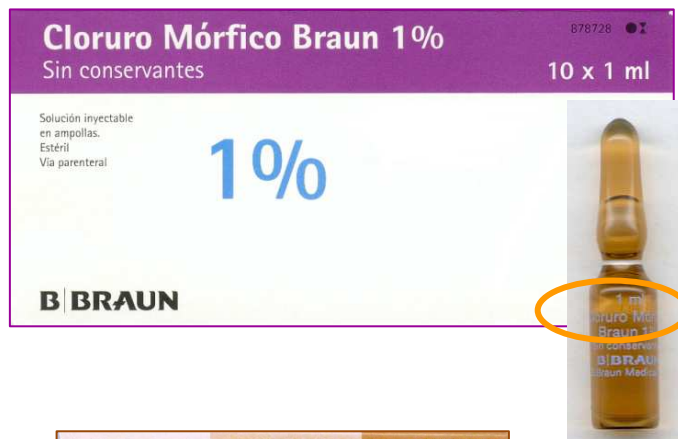
Examples of labelling and packaging problems

▶ Similarities in packaging and labelling (different dosage strengths)



Examples of labelling and packaging problems

► Unclear strength designation: use of percentages



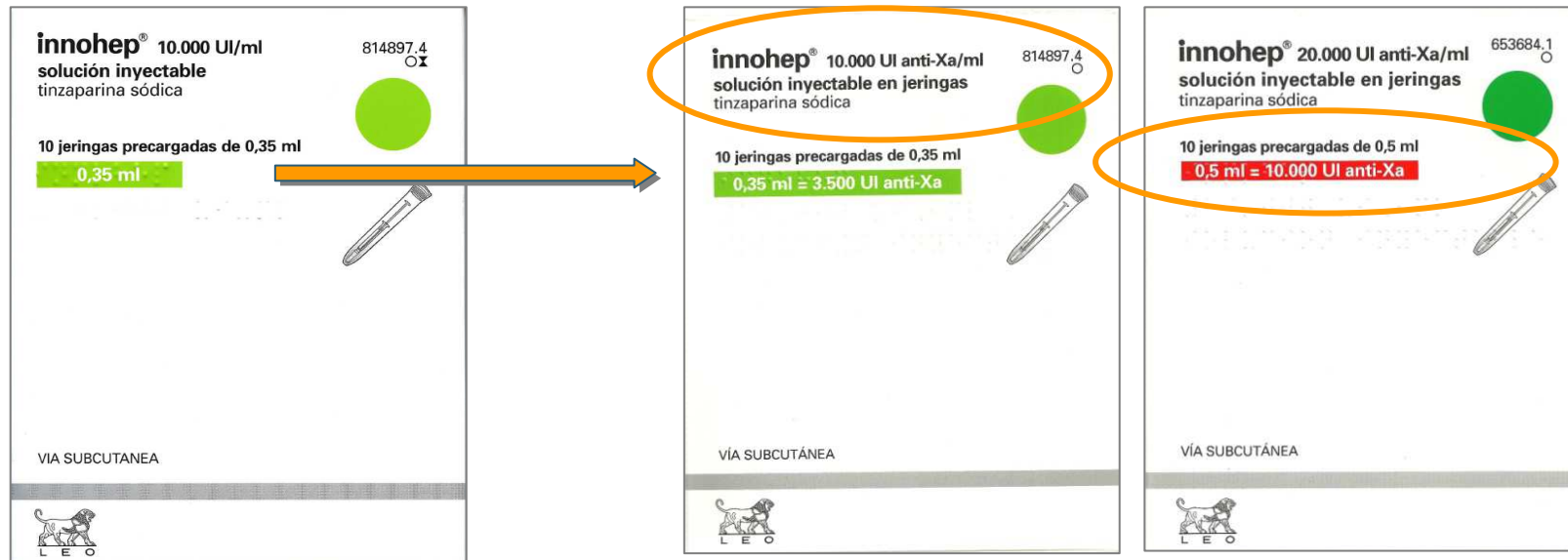
Examples of labelling and packaging problems

► Unclear strength designation: use of concentration



Examples of labelling and packaging problems

► Unclear strength designation: use of concentration



Examples of labelling and packaging problems

► Unclear strength designation: use of concentration

TINZAPARIN LABEL CHANGES IN RESPONSE TO MEDICATION INCIDENT REPORTS

Two cases from the database of the Institut Medication Practices Canada (ISMP Canada) illustrate medication packaging problems with labelling for tinzaparin.

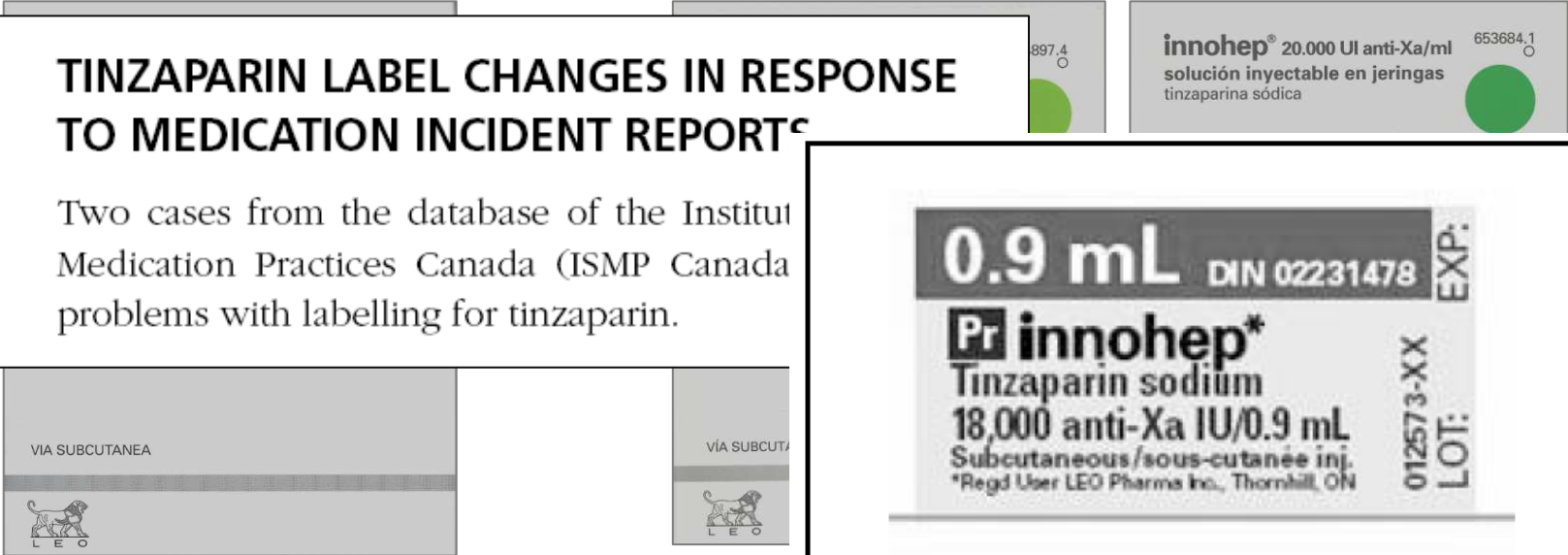
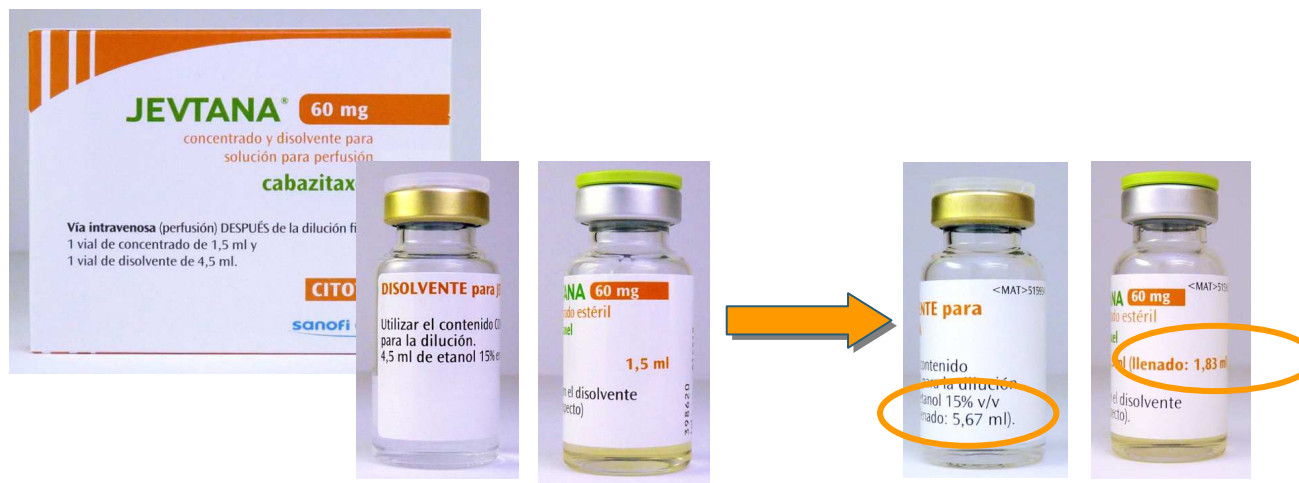


Figure 3. The manufacturer's new label for the prefilled syringe now includes the generic drug name (tinzaparin sodium).

Examples of labelling and packaging problems

► Incomplete information (overfilling)



6.5 Nature and contents of container

One pack contains one vial of concentrate and one vial

- Concentrate: 1.5 ml of concentrate in a 15 ml clear glass vial (type I) closed with a grey chlorobutyl rubber closure sealed by an aluminium cap covered with a light green plastic flip-off cap.
- Solvent: 4.5 ml of solvent in a 15 ml clear glass vial (type I) closed with a grey chlorobutyl rubber closure sealed by a gold colour aluminium cap.



6.5 Nature and contents of container

One pack contains one vial of concentrate and one vial of solvent:

- Concentrate: 1.5 ml of concentrate in a 15 ml clear glass vial (type I) closed with a grey chlorobutyl rubber closure sealed by an aluminium cap covered with a light green plastic flip-off cap. Each vial contains 60 mg cabazitaxel per 1.5 ml nominal volume (fill volume: 73.2 mg of cabazitaxel/1.83 ml). This fill volume has been established during the development of JEVTANA to compensate for liquid loss during preparation of the premix. This overfill ensures that after dilution with the entire content of the accompanying solvent for JEVTANA, there is a minimal extractable premix volume of 6 ml containing 10 mg/ml JEVTANA which corresponds to the labelled amount of 60 mg per vial.
- Solvent: 4.5 ml of solvent in a 15 ml clear glass vial (type I) closed with a grey chlorobutyl rubber closure sealed by a gold colour aluminium cap covered with a colourless plastic flip-off cap. Each vial contains 4.5 ml nominal volume (fill volume: 5.67 ml). This fill volume has been established during the development and the overfill ensures after the addition of the entire

Examples of labelling and packaging problems

► Initial labelling in USA:



A closing thought



Medicine labelling & packaging should speak a universal language, however there are international variations which may have important implications for patient safety.

► It is essential to establish international standards for labelling & packaging, and to promote and reinforce international cooperation and information sharing.

Thank you

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