

LABELING AND PACKING OF PARENTRAL PREPARATIONS

BY

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Labeling

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Packing

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LABELING

- ✓ The term labeling designates all labels and other written, printed or graphic matter on or in any package or wrapper in which it is enclosed.
- ✓ The rules of the labelling made under **the drugs and cosmetic act 1940**.
- ✓ No person cannot distribute (or) sell the any drug with out labelling including **patent (or)proprietary medicine**.
- ✓ Label states the name of the preparation, percentage content of drug of a liquid preparation, the amount of active ingredient of a dry preparation, the route of administration, a statement of storage conditions and expiry date. also label must indicate the name of manufacturer or distributors and carry an identifying lot numbers



FIG-1



FIG-2

name(s) and amount of the active ingredient

NDC number

NAME OF THE PRODUCT

Directions for use

*Each mL contains 2 mg Doxorubicin Hydrochloride, USP, Sodium Chloride 0.9% (to adjust tonicity) and Water for Injection q.s.; pH adjusted to 3 using Hydrochloric Acid.

Contains no preservative. Discard unused portion.

USUAL DOSAGE: See package insert for complete prescribing information.

WARNING: Severe cellulitis, vesication and tissue necrosis will occur if doxorubicin is extravasated during administration.

Store in a refrigerator, 2°C to 8°C (36°F to 46°F).

Protect from light. Retain in carton until contents are used.

Storage information

Product strength

NDC 62756-827-40
DOXOrubicin Hydrochloride Injection, USP

200 mg/100 mL (2 mg/mL*)

ROA

FOR INTRAVENOUS USE ONLY
STERILE ISOTONIC SOLUTION
CAUTION: CYTOTOXIC AGENT

warning

MULTIPLE DOSE VIAL

Rx only
100 mL MULTI-DOSE VIAL

Logo information



Bar coding of product



Distributer information



Distributed by:
Caraco Pharmaceutical Laboratories, Ltd.
1150 Bijah McCoy Drive, Detroit, MI 48202

Manufacturer information

Manufactured by:
Sun Pharmaceutical Ind. Ltd.
Acme Plaza, Andheri-Kurla Road,
Andheri (East), Mumbai-400 059, India.

Batch information

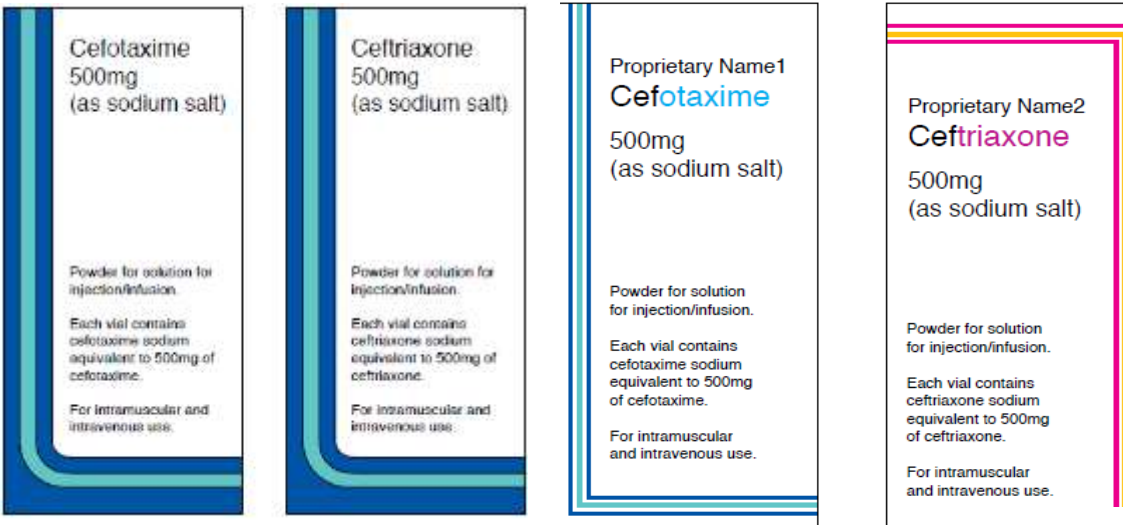
PJLB1415 PJLB1415 PJLB1415 PJLB1415
ISS: 02/2012
GUJDRUGS/28396

Expiry information

Batch No.:
Exp.:

RECOMMENDATIONS FOR PARENTAL LABEL DESIGN

FIG-3



Issues

- When the medicine name is printed horizontally around the vial or ampoule, similar names can be more easily confused with one another.

ISSUE: Similar names can be easily mistaken for each other
RECOMMENDATION: Highlight the differences between the generic drug names.

Recommendation:

Print the medicine name longitudinally, along the length of the ampoule.



FIG-5

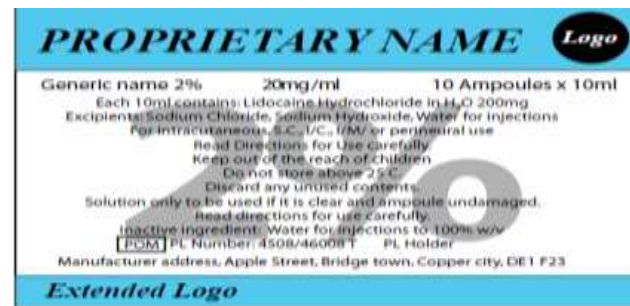


FIG-4



Issue Different representations of concentration can create confusion. **Recommendations** Display concentration in total quantity/total volume, even if other units of concentration such as percentage and ratios are also present.

MATERIALS USED IN LABELLING

The following types of labels are. Such as

- ❖ Paper
- ❖ Foil
- ❖ Fabric

FIG -6 PAPER



FIG -7 FOIL



FIG -8 FABRIC



PACKING

- Packing is a process that a bulk material must undergo to become a finished product.
- packaging preserves the **stability** and **quality** of medicinal products and protects them against all forms of spoilage and tampering which ensure product safety through the intended shelf life for the parenterals.



FIG -9

TYPES OF PACKING

PRIMARY PACKAGING:

primary packaging components are in direct physical contact with the product(e.g. bottles, vials, closures, blisters)



SECONDARY PACKAGING:

Secondary packaging is not in direct contact with the product (e.g. aluminum caps, cardboard boxes).

TYPES OF PACKING MATERIALS

GLASS:

Glass is one of the old and cheapest materials using for the packing of various types of pharmaceutical formulations, especially for the parenteral formulations.

Advantages	DISADVANTAGES
<ul style="list-style-type: none">✓ Excellent barrier properties✓ High chemical resistance✓ High transparency✓ light protection with amber glass✓ Reputation as high-grade material	<ul style="list-style-type: none">• Danger of breakage• Part of free alkali oxide• Traces of heavy metal• costly manufacturing

TYPES OF PACKING MATERIALS

Classification of Glass:

The classes are based on the degree of chemical or hydrolytic resistance of these glasses to water attack.

Type-I Highly resistant borosilicate glass: These can be used for parenteral purpose.

Type-II Treated soda lime glass: These are also used parenteral liquids as well as powders.

Type-III Soda lime glass: This type can also used for packing of parenteral products.

Type-IV General purpose soda-lime glass: These are **not used in parenteral products packing.**

FIG -10



TYPES OF PACKING MATERIALS

PLASTIC:

- Plastic containers are meant for using to packing of various types of sterile dosage forms
- Plastic containers are made up with thermoplastic polymers of high molecular weight

ADVANTAGE	DIS ADVANTAGE
✓ Simple and clean manufacturing process	• Low temperature resistance
✓ Blow-Fill-Seal	• Minor transparency with some polymers
✓ Break resistant	• Barrier properties inferior to glass
✓ Design flexibility	• Interaction of material/additives
✓ very strict dimensional	• Moulds necessary
✓ Cheap	

The commonly useful polymers in parenteral packaging are

- Polpropylene
- Poly ethylene and poly ethylene teraphthalate
- Poly vinyl chloride

TYPES OF PACKING MATERIALS

Rubber : The rubber closures are used to seal the openings of cartridges, vials and bottles, providing a material soft and elastic enough to permit entry and withdrawal of a hypodermic needle without loss of integrity of the sealed container.

Aluminum: The material mainly used for seal the vials.

Paper: The paper cart boards are mainly used for final packing of parenteral products. This packing is known as secondary packing.



FIG -11



FIG -12



FIG -13

CONTAINERS

Parenteral preparations are usually supplied in

- Glass ampoules
- Bottles
- Vials
- Plastic bottles or bags
- Prefilled syringes



FIG -13



FIG -14

FIG -15



CONTAINERS

Containers used for packing parental are classified as

Well closed containers

- protect the contents from extraneous matter or from loss of the substance under normal conditions of handling

Tightly closed containers

- must protect the contents from extraneous matter, from loss of the substance

Hermetic containers

- must protect the contents from extraneous matter and from liquids, gases

CLOSURES:

Closures for parenteral preparation containers are equipped with a firm seal to prevent entry of microorganisms and other contaminants while permitting the withdrawal of a part or the whole of the contents without removal of the closure.

The closure, composed of

- ✓ Plastic materials
- ✓ Elastomers closures

FIG -16



FIG -17



CONCLUSION

16

- It is vital for any pharma product that it remains in its original form and maintains its quality until it reaches the hands of end users
- The products manufactured to resolve health issues would be of no use if they are not packed and labeled properly

Thank you!

The image features the words "Thank you!" in a highly decorative, bubbly font. Each letter is a different color and has a thick, textured outline. The word "Thank" is on the top line, and "you!" is on the bottom line. The letters are surrounded by several stylized flowers in various colors (blue, pink, purple) and a large blue exclamation point. The overall style is playful and celebratory.