Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Enhancing Medication Safety: Insights into Medication Errors Reporting and Handling by the Saudi Food and Drug Authority (SFDA)

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Medication Errors Department
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Saudi Food and Drug Authority

Outline

- Saudi Vigilance Reporting system
- Draft Guidance on Medication Errors Reporting
- Medication Error Reports Handling

Saudi Vigilance

Saudi Vigilance

SCAN ME

Medication Error Reporting

- Introductory Statement
- Contact Information
- Trade and Generic Name
- Strength
- Dosage Form
- Description of the medication error
- Images?

Medication Error Report

Reporting Purpose

Saudi Food and Drug Authority (SFDA) relies on your reports of Medication Errors related to the naming, labeling, packaging, and design that are associated with drug products, including circumstances such as look-alike container labels or confusing prescribing information that may cause or lead to a medication error, to drive safer practices and prevent patients harm

Contact Information

Email	Email	Mobile	9665xxxxxxxx

Request Information

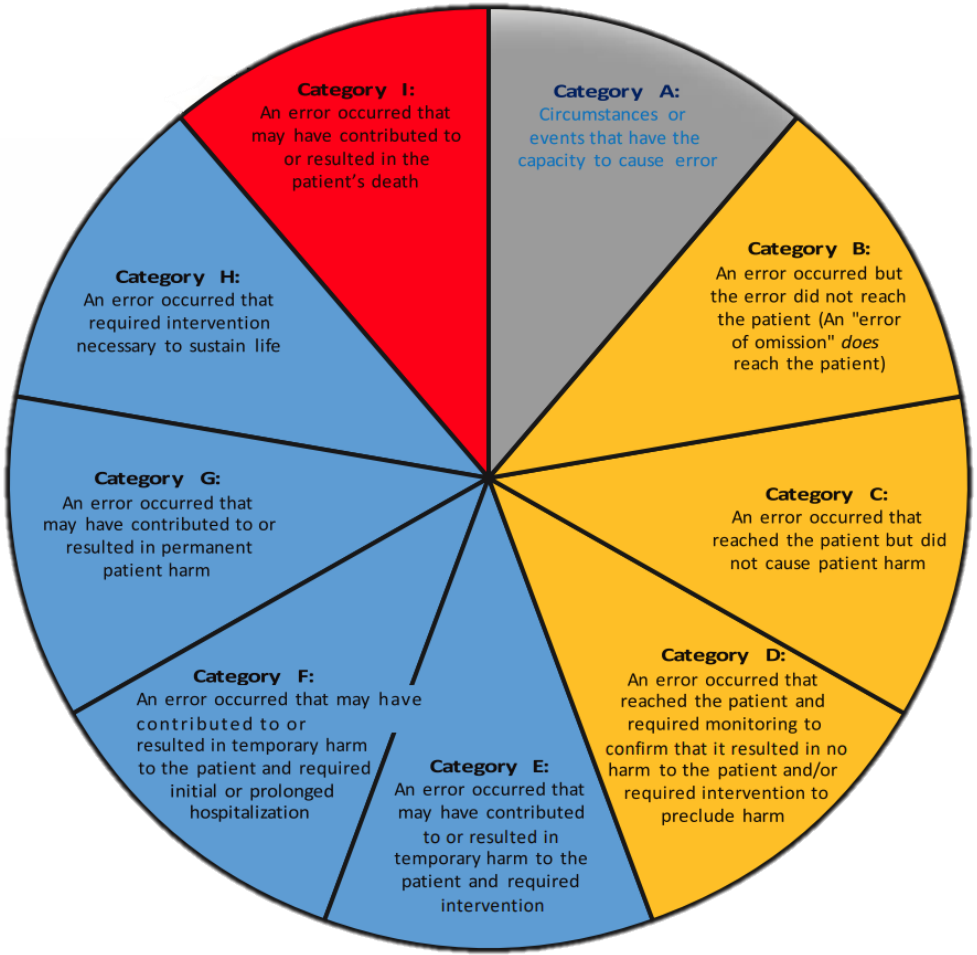
Trade Name	Trade Name in English
Generic Name	Generic Name
Strength	Strength ---Select---
Dosage Form	---Select---
Batch Number	Batch Number
Is this report to inform about similarity between medication names, products, inappropriate, or missing and misleading information in packaging and labeling	○ Yes ◉ No

Medication Error Definition

"A medication error is any **preventable** event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use."

The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)

NCC MERP Index for Categorizing Medication Errors



Contributing Factors?

- # 4 Drug name, label, packaging problem?
  (e.g., look-/sound-alike names, look-alike packaging, unclear/absent labeling, faulty drug identification)

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ISMP. Key Elements of Medication Use and ASSESS-ERR ® Worksheet (2021)

Types of Medication Errors

Product-related Medication Errors

- Name Similarity
  - Look-alike / Sound-alike
- Unclear labels
  - Lack of Critical Information on products packaging
  - Strength Expression
  - Discrepancies (translation/ packaging and labeling)
- Design similarity
  - Unified themes
  - Look-alike Packaging

Guidance for Medication Error Reporting

- Draft was released for public comments on July 23, 2023 for two (2) months
- Explains the importance of Med error reporting
- Steps to follow when reporting through the Saudi vigilance reporting system

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Medication Error Reporting Impact

Med Error Report Handling

Product Details (Optional)

Package Size	Package Size		
Manufacturer			
Distributor/Vendor			
Manufacturing Date	Manufacturing Date	End Date	End Date
Has the manufacturer been informed?	○ Yes ◉ No		

Contact Information

Name		Email	
Mobile		Profession	
Region			
Healthcare Provider Name			

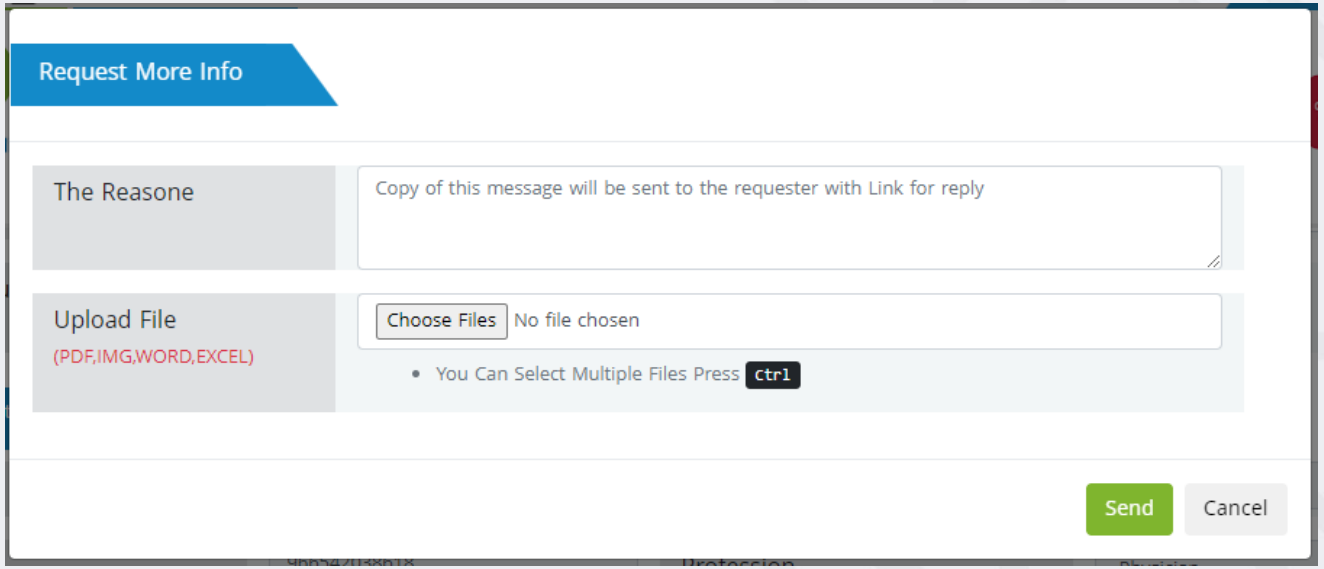
Save Change

Accept Request | Request More Info | False Report | Transfer Request

Accepted Request

- Feedback to Report Submitter

Request More Info



Interactions with Qualified Person Responsible for Pharmacovigilance (QPPV)

- Med.drug@sfda.gov.sa
- Event description with images
- Recommendations
  - Product Modification (Trade name & artwork amendments)
  - Dear Health Care Provider Letter (DHCL)
  - Patient Education Materials
- Submit Variation Request

Examples

What's Wrong?


ach 100 ml contains :
albutamol (as sulphate) 0.5 gm
arcolin Respirator Solution is to be
used with a respirator or nebulizer
only, under the direction of the
physician.
It should not be injected or
administered orally.
The contents should be used within
three months after opening.
Store below 25° C, away from light.
Keep out of the reach of children.
Made in Egypt
PHARCO
PHARMACEUTICALS
Alexandria
محلول تنفسى
RESPIRATOR SOLUTION
Each 20 ml contains :
Salbutamol sulphate 0.121 gm
Store below 25° C, away from light.
Batch No.: 2128
Mfg. Date : 09 20
Exp. Date : 09 22

Dear Pharco Pharmaceuticals QPPV,

A medication error report was received through the Saudi Vigilance System (تيقظ) with the concern of strength discrepancy between the outer package labeling (carton label) and inner package labeling of Farcolin (salbutamol sulfate) 0.5% Respirator Solution — attached

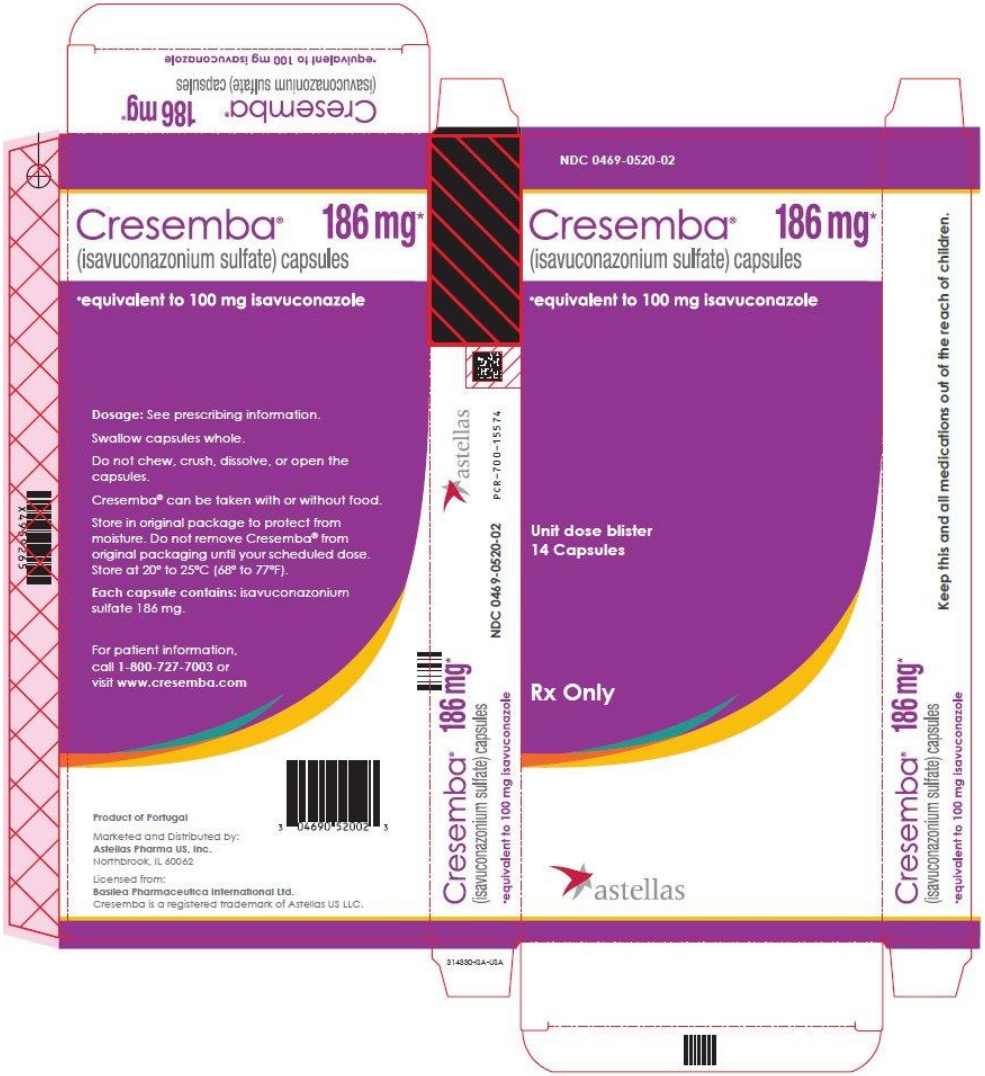
While currently used strength expression on outer package is matching the intended concentration of 0.5%, the inner package label does not. Calculating the amount of drug per mL using the information provided on outer package will result in the following concertation (5 mg/mL) which is different from the result of calculating amount per mL strength using inner label data (120 mg (0.121 g)/ 20 mL → 6.05 mg/mL)

However, using any of the currently present strength expressions are discouraged, as they are confusing and require healthcare providers to calculate the dose upon prescribing which is subject to medication error.

Use of a common expression for Salbutamol nebulization solution as 0.5% accompanied by the amount per mL (5 mg/mL) is advised; to follow the innovator (Ventolin®) and since it matches usual prescribed doses of Salbutamol nebulization solution.

Kindly ensure using consistent strength expression across product packaging and labeling (primary and secondary packaging label, SPC, PIL,…etc.) in accordance to aforementioned recommendations, and availability of all critical information on principal display panel of outer packaging label to avoid any medication errors.

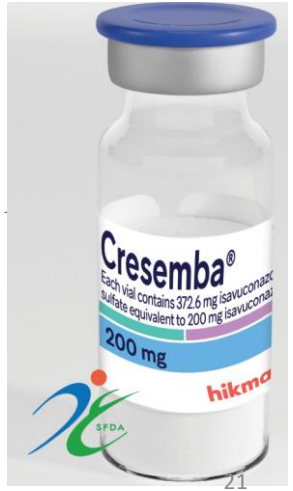
Regards,



Salt/Prodrug
(Isavuconazonium sulfate)
Vs. active moiety
(Isavuconazole)

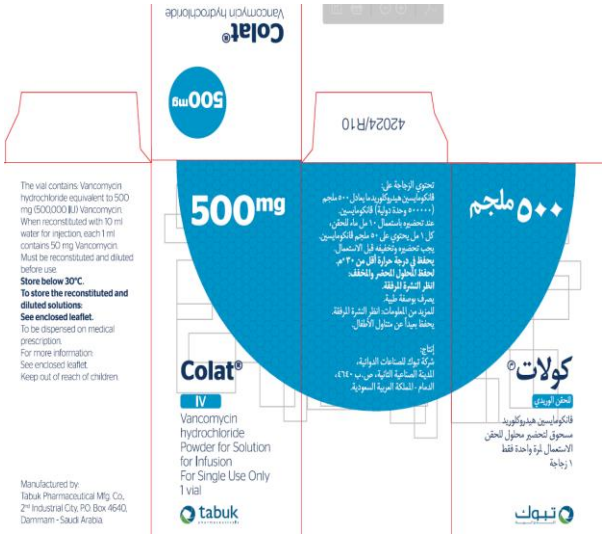

Cresemba®
Isavuconazole
(Isavuconazonium sulfate)
100 mg
For Oral Use
hikma.
14 Hard Capsules
GTIN : 06285101003875
Batch No.:
Mfg. date :
Exp. date :
Cresemba® 100 mg
كريسيمبا®
إيزافوكونازول
(سلفات الإيزافوكونازونيوم)
١٠٠ ملغم
للاستخدام عن طريق الفم
١٤ كبسولة صلبة
Cresemba®
Isavuconazole (Isavuconazonium sulfate)
100 mg
14 Hard Capsules
Prescription-only medicine.
Keep out of reach and sight of children.
Do not store above 30°C.
Store in the original package in order to protect from moisture.
Read enclosed leaflet for further information.


Prescription-only medicine.
Keep out of reach and sight of children.
Store in a refrigerator (2-8°C).
Store in the original package.
After reconstitution and dilution with the compatible diluents, it can be stored for 24 hours at 2 to 8°C or 6 hours at room temperature.
Read enclosed leaflet for further information.
Cresemba®
Isavuconazole (Isavuconazonium sulfate)
200 mg
For Intravenous Use
hikma.
1 Vial
Powder for Concentrate for Solution for Infusion
GTIN : 06285101003868
Batch No.:
Mfg date. :
Exp. date :
Cresemba® 200 mg
Each vial contains 372.6 mg isavuconazonium sulfate equivalent to 200 mg isavuconazole.
Excipients: Mannitol and sulfuric acid.
MAH and Batch release: Jazeera Pharmaceutical Industries, Riyadh - Saudi Arabia
Bulk manufacturer: Baxter Pharmaceutical Solutions, LLC, Indiana-USA.
Under licensed from: Basilea Pharmaceutica International Ltd., Basel-Switzerland
Rev: 12/2020 AE
Cresemba®
Isavuconazole (Isavuconazonium sulfate)
200 mg
1 Vial
كريسيمبا®
إيزافوكونازول
(سلفات الإيزافوكونازونيوم)
٢٠٠ ملغم
للاستخدام الوريدي
hikma.
زجاجة واحدة
مسحوق لتشكيل المركز
ثم التخفيف قبل التسريب


Cresemba®
Each vial contains 372.6 mg isavuconaz
sulfate equivalent to 200 mg isavuconaz
200 mg
hikma
SFDA

Thoughts?


500mg
Colat®
IV
Vancomycin hydrochloride
Powder for Solution for Infusion
For Single Use Only
1 vial
tabuk
1g
Zidime®
IM/IV
Ceftazidime for Injection
1 Vial
tabuk
500mg
Colat®
IV
Vancomycin hydrochloride
Powder for Solution for Infusion
For Single Use Only
1 vial
tabuk

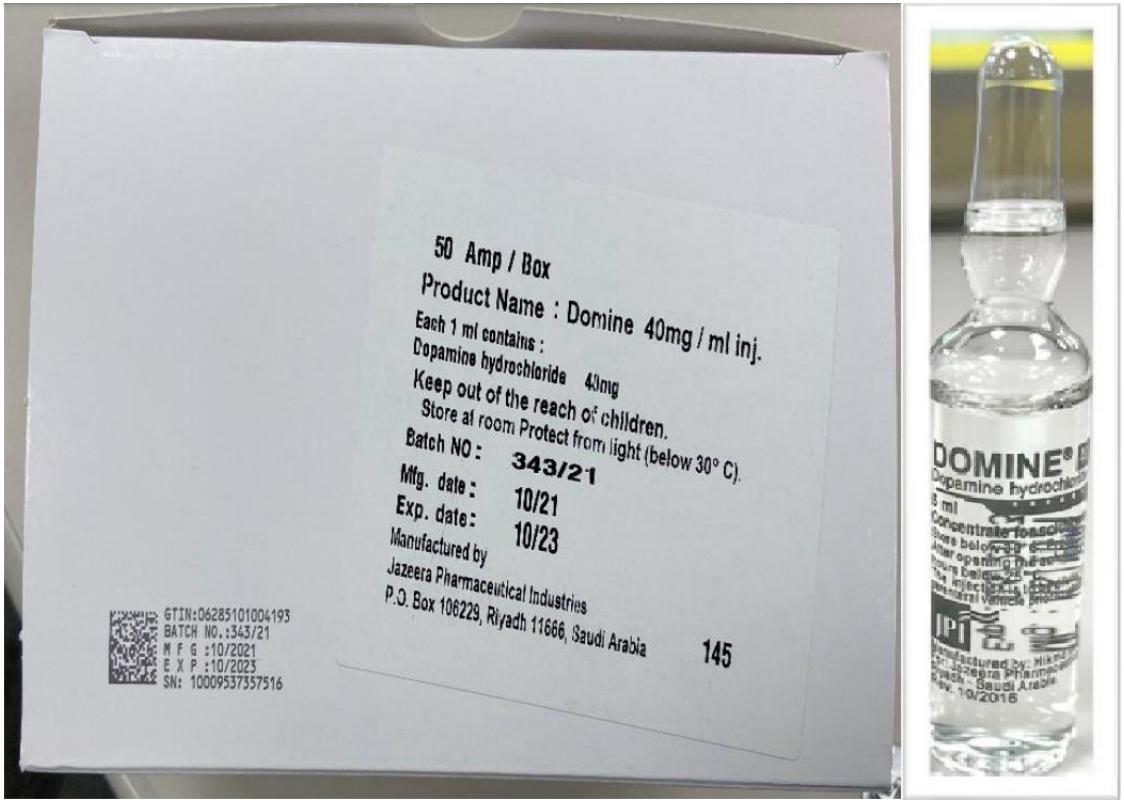

Colat®
Vancomycin hydrochloride
500mg
4202/R10
500 ملجم
Colat®
Vancomycin
hydrochloride
500mg
IV
Powder for Solution
for Infusion
For Single Use Only
1 Vial
tabuk
كولات®
فانكومايسين هيدروكلوريد
٥٠٠ملجم
للحقن الوريدي
مسحوق لتحضير
محلول للحقن
الاستعمال لمرة واحدة فقط
١ زجاجة
تبوك
The vial contains: Vancomycin hydrochloride equivalent to 500 mg (500,000 IU) Vancomycin.
When reconstituted with 10 ml water for injection, each 1 ml contains 50 mg Vancomycin.
Must be reconstituted and diluted before use.
Store below 30°C.
To store the reconstituted and diluted solutions:
See enclosed leaflet.
To be dispensed on medical prescription.
For more information:
See enclosed leaflet.
Keep out of reach of children.
Manufactured by:
Tabuk Pharmaceutical Mfg. Co.,
2nd Industrial City, P.O. Box 4640,
Dammam - Saudi Arabia.
تحتوي الزجاجة على:
فانكومايسين هيدروكلوريد ما يعادل
٥٠٠ ملجم (٥٠٠٠٠ وحدة دولية) فانكومايسين.
عند تحضيره باستعمال ١٠ مل ماء
للحقن، كل ١ مل يحتوي على ٥٠ ملجم
فانكومايسين.
يجب تحضيره وتخفيفه قبل
الاستعمال.
يحفظ في درجة حرارة أقل من ٣٠°م.
لحفظ المحلول المحضر والمخفف:
انظر النشرة المرفقة.
يصرف بوصفة طبية.
للمزيد من المعلومات:
انظر النشرة المرفقة.
يحفظ بعيداً عن متناول الأطفال.
إنتاج:
شركة تبوك للصناعات الدوائية،
المدينة الصناعية الثانية، ص.ب ٤٦٤٠،
الدمام - المملكة العربية السعودية.


IV
500mg
Colat®
كولات®
للحقن الوريدي
Vancomycin hydrochloride
Powder for Solution for Infusion
For single use only
فانكومايسين هيدروكلوريد
The vial contains: Vancomycin hydrochloride equivalent to 500 mg (500,000 IU) Vancomycin • After reconstitution: Each 1 ml contains 50 mg Vancomycin. Must be reconstituted and diluted before use • Store below 30°C. To store the reconstituted and diluted solutions: See enclosed leaflet • To be dispensed on medical prescription • For more information: See the leaflet
44696/R2
B. No:
Mfg:
Exp:
tabuk
Tabuk Pharmaceutical Mfg. Co.,
Dammam - Saudi Arabia


IV
500mg
Colat®
كولات®
للحقن الوريدي
Vancomycin hydrochloride
Powder for Solution for Infusion
For Single Use Only
فانكومايسين هيدروكلوريد
The vial contains: Vancomycin hydrochloride equivalent to 500 mg (500,000 IU) Vancomycin • After reconstitution: Each 1 ml contains 50 mg Vancomycin • Must be reconstituted and diluted before use • Store below 30°C • To store the reconstituted and diluted solutions: See the leaflet • To be dispensed on medical prescription • For more information: See the leaflet • Keep out of reach of children
44696/R10
B. No:
Mfg:
Exp:
tabuk
Tabuk Pharmaceutical Mfg. Co.,
Dammam - Saudi Arabia


Panadol
COLD+FLU
كولد+ فلو
بانادول
استنشاق البخار
+ مزيل للإحتقان
VAPOUR RELEASE
+ DECONGESTANT
Rapid effective relief from:
Headache & body ache
Blocked & runny nose
Sore throat
Fever
HOT LEMON AND HONEY
10 SACHETS
Menthol Sensation
Cold&Flu
Vapour Release
+ Decongestant
Contains Vitamin C
Powder for Oral Solution
10 Sachets
HOT LEMON AND HONEY
NPA007451

What's Wrong?


50 Amp / Box
Product Name : Domine 40mg / ml inj.
Each 1 ml contains :
Dopamine hydrochloride 40mg
Keep out of the reach of children.
Store at room Protect from light (below 30° C).
Batch NO : 343/21
Mfg. date : 10/21
Exp. date : 10/23
Manufactured by
Jazeera Pharmaceutical Industries
P.O. Box 106229, Riyadh 11666, Saudi Arabia
145
GTIN:06285101004193
BATCH NO.:343/21
M F G :10/2021
E X P :10/2023
SN: 10009537357516
DOMINE®

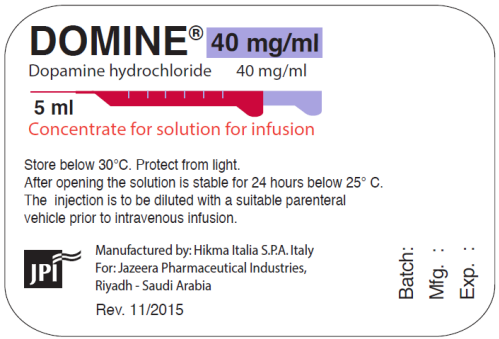
Good Day!

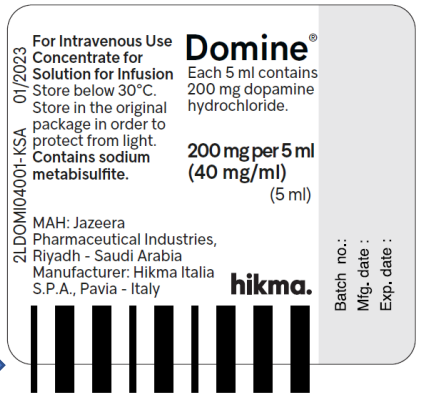
We have received report of possible mix-ups between Domine (Dopamine Hydrochloride) 200 mg/ 5 mL (40 mg/mL) concentrate for solution for infusion ampoule with products from different manufacturers which typically occur with small containers — refer to the attached image

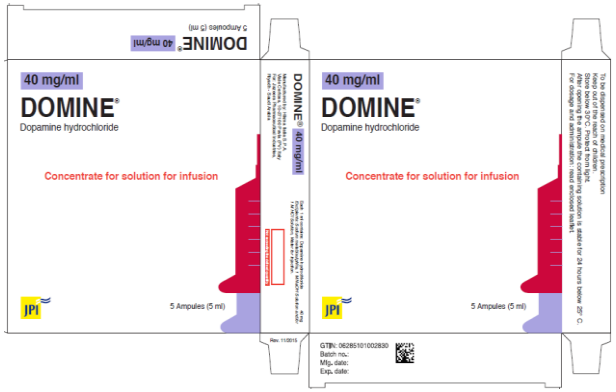
As per the SFDA Guidance for Graphic Design of Medication Packaging, the following amendments have to be considered to better differentiate various products and avoid any medication errors:

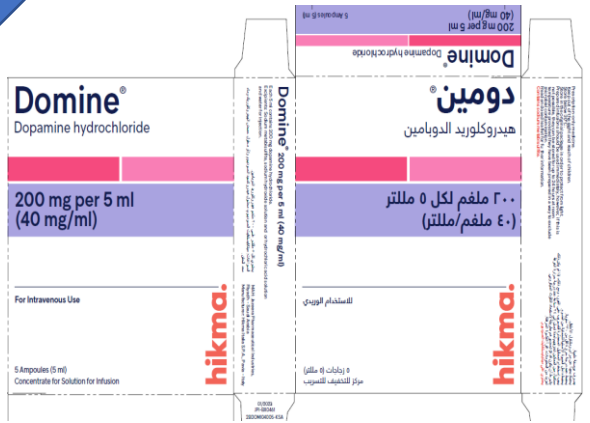
1. Use paper labeling where possible, and ensure that the label does not wrap completely around the ampoule to allow for inspection of contents. If clear plastic labeling must be used, highlight key information by inverting the text color.
2. Eliminate the overlapping text by keeping the information to minimum, as follow: proprietary name, nonproprietary name, strength, route(s) of administration, warnings or cautionary statements (if any), batch number, expiry date, and MAH.
3. Change the text orientation for the pharmaceutical information presented on the ampoule to be positioned longitudinally (vertically), along the length of the ampoule
4. The quantity per total volume should be the primary and prominent expression, followed in close proximity by quantity per milliliter enclosed by parentheses “i.e., 200 mg/5 mL (40 mg/mL)”.

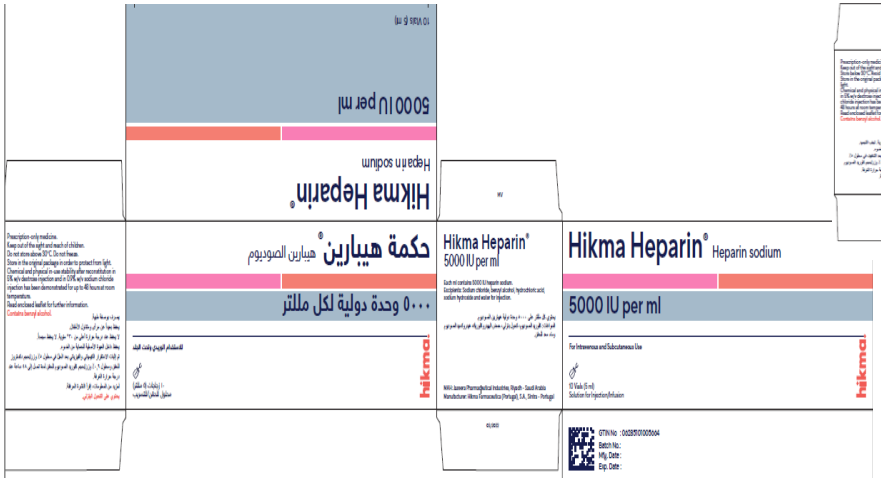
Kindly acknowledge receipt of this email and submit variation request with the new proposed artworks, ensuring the aforementioned recommendations are applied.


DOMINE® 40 mg/ml
Dopamine hydrochloride 40 mg/ml
5 ml
Concentrate for solution for infusion
Store below 30°C. Protect from light.
After opening the solution is stable for 24 hours below 25° C.
The injection is to be diluted with a suitable parenteral vehicle prior to intravenous infusion.
JPI
Manufactured by: Hikma Italia S.P.A. Italy
For: Jazeera Pharmaceutical Industries, Riyadh - Saudi Arabia
Rev. 11/2015
Batch: . .
Mfg. . .
Exp. . .

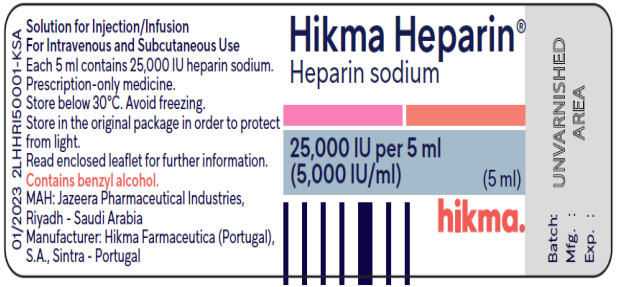

For Intravenous Use
Concentrate for Solution for Infusion
Store below 30°C.
Store in the original package in order to protect from light.
Contains sodium metabisulfite.
Domine®
Each 5 ml contains 200 mg dopamine hydrochloride.
200 mg per 5 ml (40 mg/ml)
(5 ml)
MAH: Jazeera Pharmaceutical Industries, Riyadh - Saudi Arabia
Manufacturer: Hikma Italia S.P.A., Pavia - Italy
hikma.
2LDOMI04001-KSA 01/2023
Batch no.:
Mfg. date :
Exp. date :

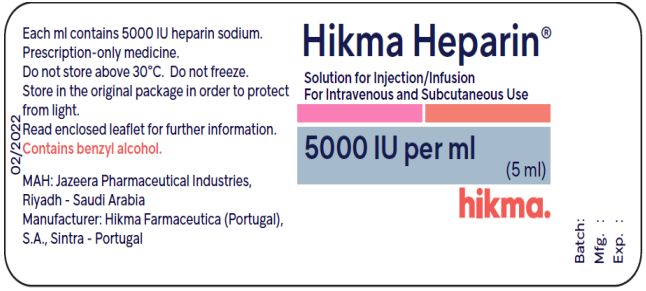

40 mg/ml
DOMINE®
Dopamine hydrochloride
Concentrate for solution for infusion
5 Ampoules (5 ml)
JPI
GTIN: 06285101002830
Batch no.
Mfg. date:
Exp. date:

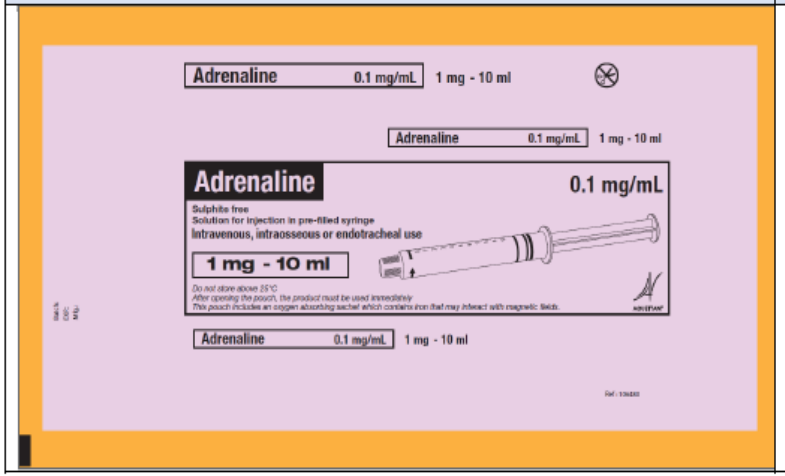

Domine®
Dopamine hydrochloride
200 mg per 5 ml
(40 mg/ml)
5 Ampoules (5 ml)
دومين®
هيدروكلوريد الدوبامين
٢٠٠ ملغم لكل ٥ ملتر
(٤٠ ملغم/ملتر)
For Intravenous Use
5 Ampoules (5 ml)
Concentrate for Solution for Infusion
hikma.


Hikma Heparin®
Heparin sodium
5000 IU per ml
حكمة هيبارين®
هيبارين الصوديوم
٥٠٠٠ وحدة دولية لكل ملليتر
Hikma Heparin® 5000 IU per ml
Hikma Heparin® Heparin sodium
5000 IU per ml
For Intravenous and Subcutaneous Use
10 Vials (5 ml)
Solution for Injection/Infusion
hikma


Hikma Heparin®
Heparin sodium
25,000 IU per 5 ml (5,000 IU/ml)
حكمة هيبارين®
هيبارين الصوديوم
٢٥٠٠٠ وحدة دولية لكل ٥ ملليتر (٥٠٠٠ وحدة دولية/ملليتر)
Hikma Heparin® 25,000 IU per 5 ml (5,000 IU/ml)
Hikma Heparin® Heparin sodium
25,000 IU per 5 ml (5,000 IU/ml)
For Intravenous and Subcutaneous Use
10 Vials (5 ml)
Solution for Injection/Infusion
hikma


Solution for Injection/Infusion
For Intravenous and Subcutaneous Use
Each 5 ml contains 25,000 IU heparin sodium.
Prescription-only medicine.
Store below 30°C. Avoid freezing.
Store in the original package in order to protect from light.
Read enclosed leaflet for further information.
Contains benzyl alcohol.
MAH: Jazeera Pharmaceutical Industries, Riyadh - Saudi Arabia
Manufacturer: Hikma Farmaceutica (Portugal), S.A., Sintra - Portugal
01/2023 2LHHRI50001-KSA
Hikma Heparin®
Heparin sodium
25,000 IU per 5 ml
(5,000 IU/ml) (5 ml)
hikma.
UNVARNISHED AREA
Batch:
Mfg. :
Exp. :


Each ml contains 5000 IU heparin sodium.
Prescription-only medicine.
Do not store above 30°C. Do not freeze.
Store in the original package in order to protect from light.
Read enclosed leaflet for further information.
Contains benzyl alcohol.
MAH: Jazeera Pharmaceutical Industries, Riyadh - Saudi Arabia
Manufacturer: Hikma Farmaceutica (Portugal), S.A., Sintra - Portugal
02/2022
Hikma Heparin®
Solution for Injection/Infusion
For Intravenous and Subcutaneous Use
5000 IU per ml (5 ml)
hikma.
Batch:
Mfg. :
Exp. :

Previous Aluminum artwork	Aluminum artwork updated (with highlights)
	


20 ml
Bronchovent
Salbutamol 5 mg/ml
(As Sulphate)
Nebulizer Solution
WARNING: DO NOT INJECT OR SWALLOW
nupco
Pharmaceutical Solutions Industry
Bronchovent
Salbutamol 5 mg/ml
(As Sulphate)
Nebulizer Solution


Each 100 ml contains :
Salbutamol (as sulphate) 0.5 gm
Farcolin Respirator Solution is to be used with a respirator or nebulizer only, under the direction of the physician.
It should not be injected or administered orally.
The contents should be used within three months after opening.
Store below 25° C, away from light.
Keep out of the reach of children.
Made in Egypt
PHARCO
PHARMACEUTICALS
Alexandria
محلـول تنفسـى
RESPIRATOR SOLUTION
Each 20 ml contains :
Salbutamol sulphate 0.121 gm
Store below 25° C, away from light
Batch No. : 2128
Mfg. Date : 09 20
Exp. Date : 09 22


FOR TOPICAL USE ONLY - DO NOT INJECT
RECOTHROM
Thrombin topical
(Recombinant)
5,000 units
Baxter
BD 5ml Syringe
DO NOT INJECT
THROMBIN, TOPICAL
(RECOMBINANT) SOLUTION
07-27-00-0732
Do Not Reshield Used Needles • Sterile • Do Not Reuse
REF 309646
Becton, Dickinson and Company
1 Becton Drive, Franklin Lakes, NJ 07417 USA
Made in USA
DGW81904
bd.com/symbols-glossary

The way Forward!

- Awareness about Medication Error Reporting
- Optional → Mandatory requirements!
- National Collaborations (CBAHI, SPSC)
- International Collaborations (IMSN)

Contact Us

Med.drug@sfda.gov.sa

Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Thank You