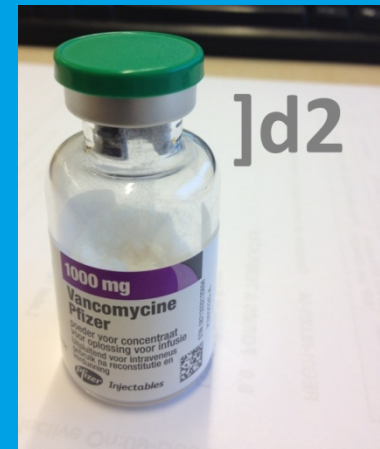


An industry perspective on medicines barcoding and bedside scanning

- Chris Dierickx
- Manager Business Development - Pfizer Global Supply – Puurs



Monday the 14th of October 2013

Content



- **Introduction**
 - Pfizer Global Supply Puurs and Business Development
- **Unit Dose**
 - Customer Requirement
 - Approach
 - Scope
 - HUD (Hospital Unit Dose) Process Review
 - GTIN and Barcode Basics, Coding and Examples

Our Company: Pfizer worldwide



- **Founded in 1849**
- **CEO: Ian Read**
- **Headquarters: New York, NY (USA)**

A Medicine Portfolio That Helps Prevent Disease and Promote & Improve Better Health and Well Being at Every Stage of Life

PGS Puurs

Pfizer Global Supply



Our Company: Puurs history



- 1962: First European Upjohn plant in Puurs
- 1995: Pharmacia & Upjohn
- 2000: Pharmacia
- 2003: Pfizer (Warner Lambert – 1999)
- 2009: Pfizer acquires Wyeth

Upjohn



**Pharmacia
& Upjohn**



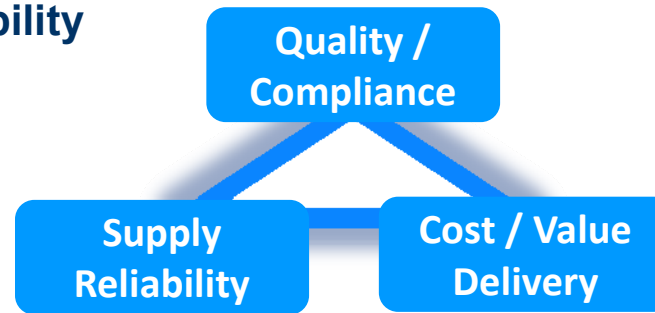
PHARMACIA

Wyeth

Our Company: Pfizer Global Supply Vision



- Deliver quality products to customers in most responsive way (100% supply assurance)
- Cost- competitive
- Adding value by innovation & sustainability



- Robust and Right First Time processes
- State-of-the-art manufacturing & packaging technologies
- Continues improvement

Content



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- Pfizer Global Supply Puurs and Business Development

- **Unit Dose**

- Customer Requirement
- Approach
- Scope
- HUD (Hospital Unit Dose) Process Review
- GTIN and Barcode Basics, Coding and Examples

Customer Requirement



- **Increase patient safety and compliance** by introducing technologies to allow **bedside scanning**

Approach



- **HUD (Hospital Unit Dose) as an integral component of the overall hospital strategy**
- **A pan-European/Worldwide approach for all Markets and Pfizer Global Supply**
- **Globally recognized standards for 2D Barcodes exist (GS1)**
- **Standards will promote**
 - **Consistent application across manufacturers**
 - **Simplified adoption for Healthcare providers**

Type barcodes



Code 128



Code 39



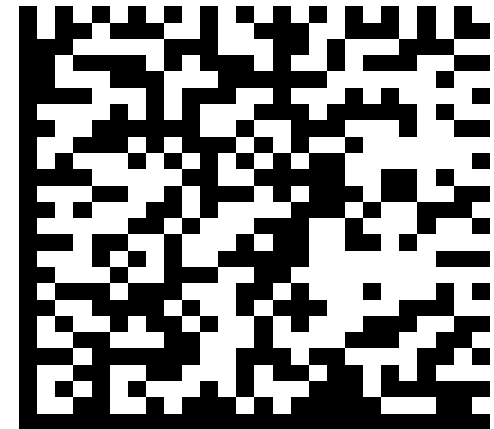
Code 93



DataMatrix



2D



PDF417



UPC - A





Why is Data Matrix Code popular?



ABCDEFGHIJKLMNOPQRSTUVWXYZ



ABCDEFGHIJKLMNOPQRSTUVWXYZ

Less space required



These damaged symbols are still readable

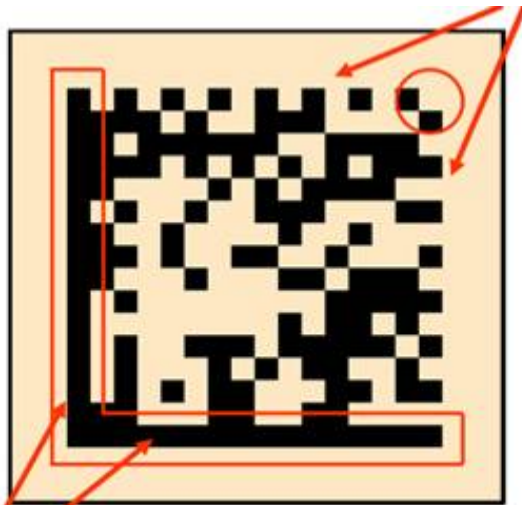


Omni-directional reading

DataMatrix ECC200

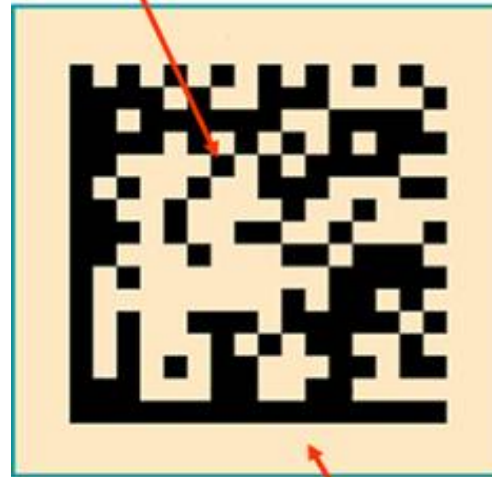


Lege hoek



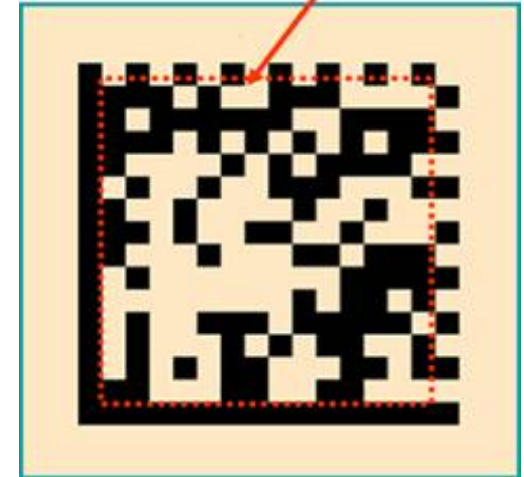
L-profiel

Module



Quiet zone

Data



Scope



- Implementing a 2D barcode with **static data** (unique product identification code or Global Trade Identification Number - GTIN)
 - All Hospital products
 - Injectables and orals
 - Primary Container
 - All Pfizer Branded, Established and inlicensed products
- Implementation of a 2D barcode with **variable data** (GTIN, Batch #, expiration date) is not in scope

2D on carton – different scope

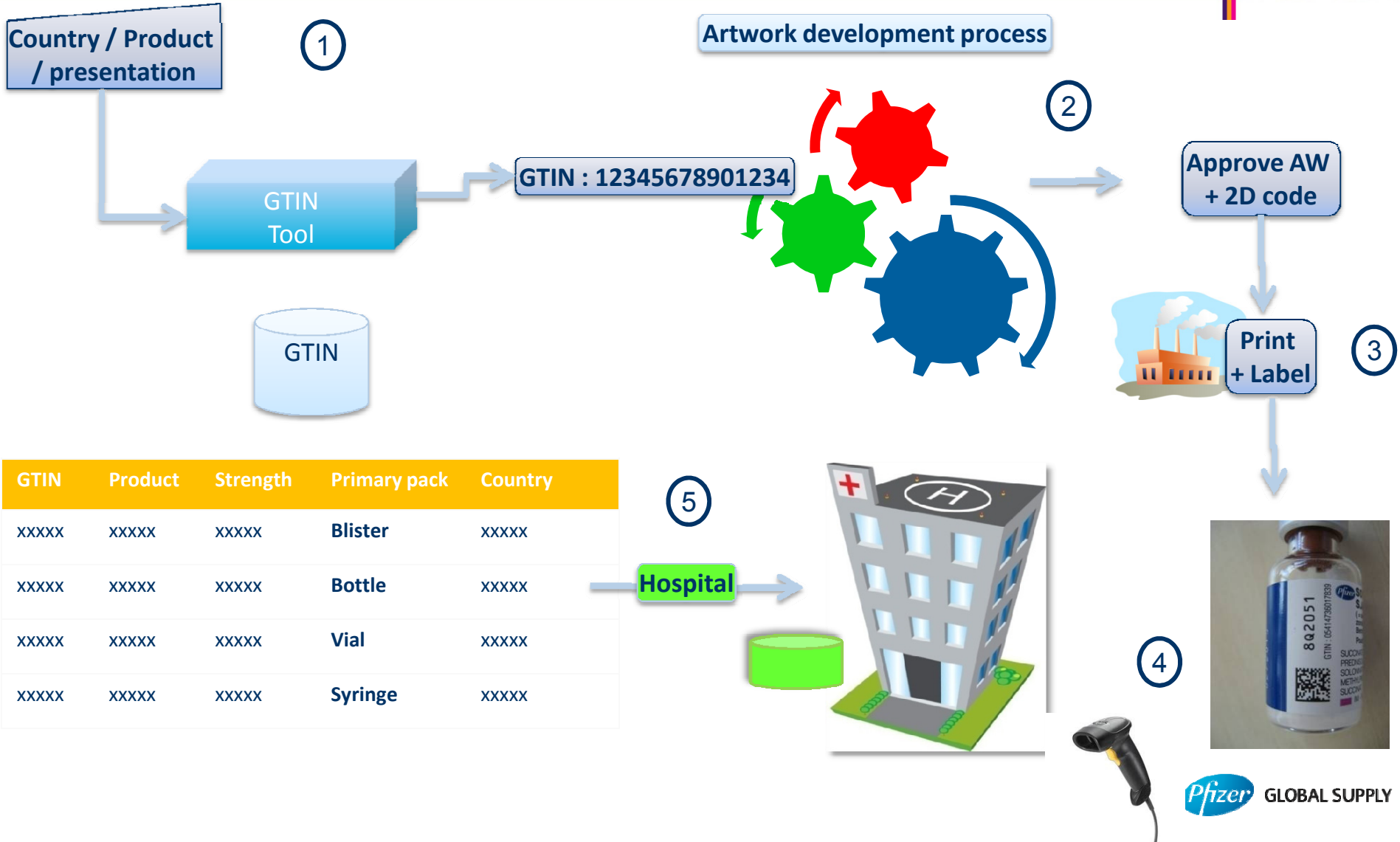


Utg.dat./Käyt.viim.:
Batchnr/Eränro:

HB0120
10/2005
07046264542569



HUD (Hospital Unit Dose) Process Overview



GTIN	Product	Strength	Primary pack	Country
XXXXX	XXXXX	XXXXX	Blister	XXXXX
XXXXX	XXXXX	XXXXX	Bottle	XXXXX
XXXXX	XXXXX	XXXXX	Vial	XXXXX
XXXXX	XXXXX	XXXXX	Syringe	XXXXX

HUD (Hospital Unit Dose) Process Overview

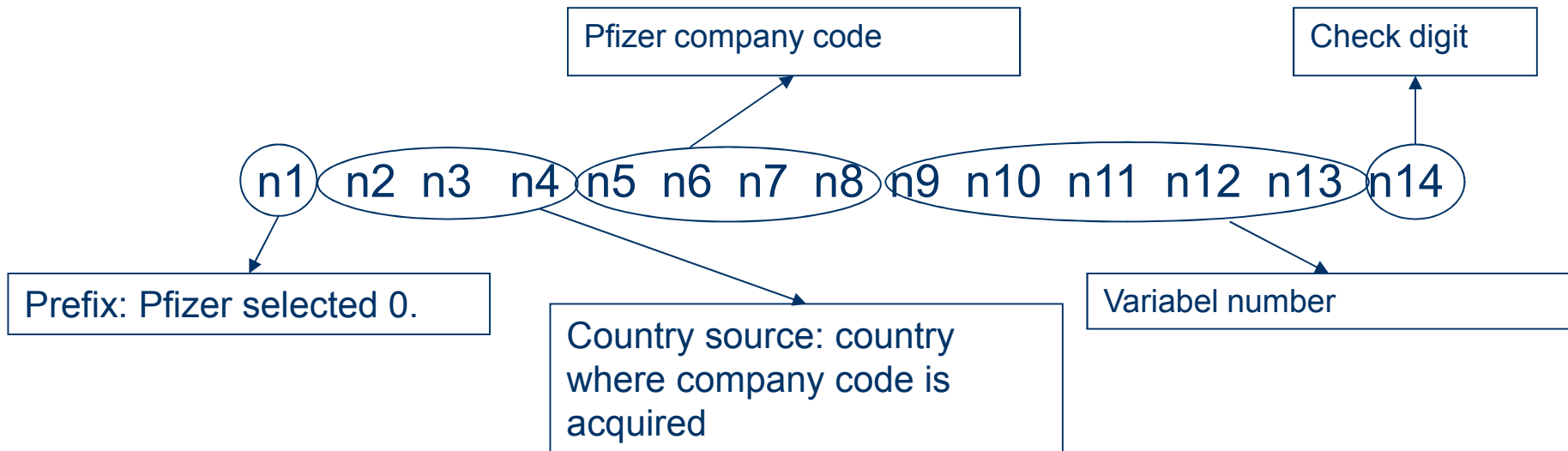


1. Based on country/product / strength/presentation information a unique code is created: GTIN = a 14 digit code
2. The GTIN is translated in a 2D matrix barcode and included in the standard artwork design and approval process
3. New (approved) artwork is printed and used for labeling in manufacturing
 - *Verification of 2D (Content, GS1 Compliance)*
 - *ISO Grade of 2D minimum standard*
4. Relationship GTIN code – product, Country, presentation is maintained in the GTIN database
5. Incoming goods control at hospital & Scanning at bedside

GTIN and Barcode Basics

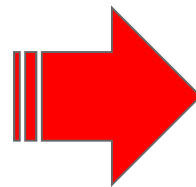


- **GTIN = Global Trade Identification Number**



- **Data Carrier: GS1 2D DataMatrix Barcode**

Desired HUD Data & Barcode



Human Readable*



*It is permissible to omit the HRI of the GTIN if there is insufficient space on the component.

GTIN coding

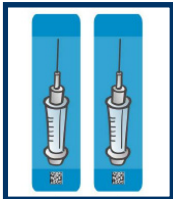


1.



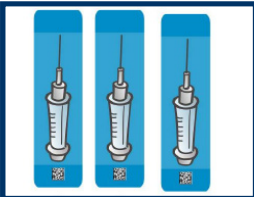
Artwork Creation & GTIN assignment: GTIN 1*

2.



Item 1: It uses the Artwork & GTIN 1*

3.



Item 2: It uses the same Artwork & GTIN 1*

Once an GTIN is assigned to the formulation/container/country combination the GTIN remain unchanged when changing the Artwork/label

*Different GTIN required on the unit of sale required for the varying counts or multiplicity of unit doses

GS1?



- international standard and enables interoperability
- therefore anyone can interpret, since the composition of the string of characters is uniquely defined
- contains check points or references for verification on data accuracy
- Can contain more info than the linear barcode (2D and compact)
- GS compliance is a prerequisite for correct reading and interpretation in the hospitals and customers

GS1 – on unit of dose



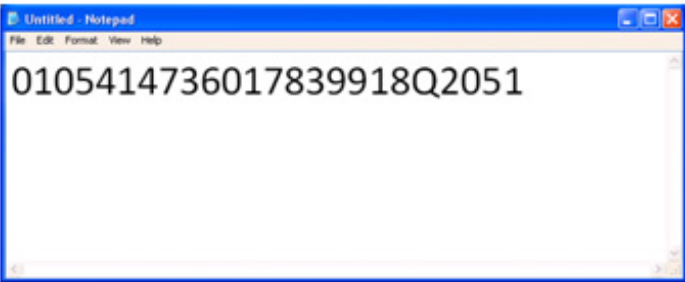
- **coding exist of:**
 - function codes (FNC1 – ascii code <232>)
 - application identifiers (AI)
 - data
- **function code determines if the datamatrix is GS1 compliant: is the start of every code**
 - cannot be printed and is invisible with a non programmed scanner
- **application identifiers used:**
 - 01: GTIN (the first AI – fixed length of numerical characters of 14 positions)
 - 243: Packaging Component Number or PCN (91)

GTIN & Barcode Basics

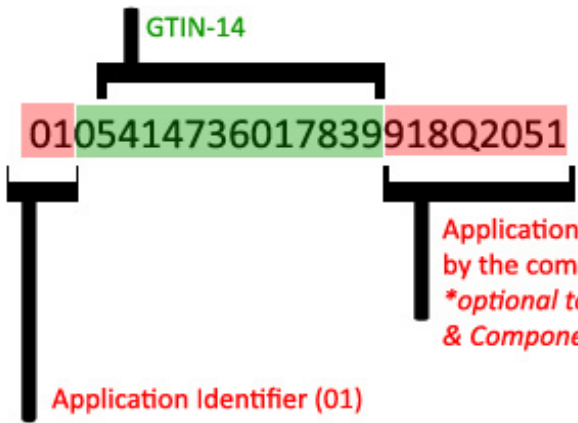


- **Reading the 2D code with Unprogrammed and Programmed Scanners**
 - **A Programmed 2D Scanner will often output the ISO code Identifier at the beginning of the data contained in the code**
 - **An Unprogrammed scanner will simply output the GTIN Application Identifier at the beginning of the data contained in the code**
- **See example on Next Slide**

Unprogrammed 2D Handheld Scanner Output:
Raw Data Defined



Unprogrammed 2D Handheld Scanner Output:
Raw Data Defined



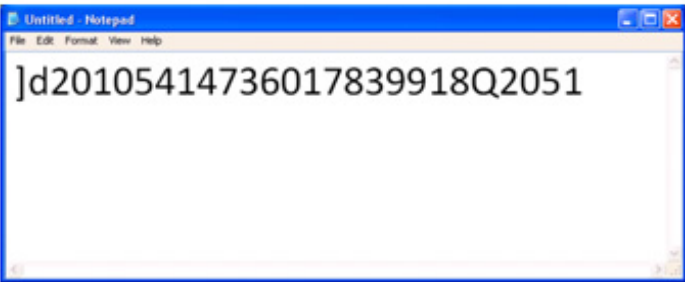
AI (91) will be replaced by AI (243)



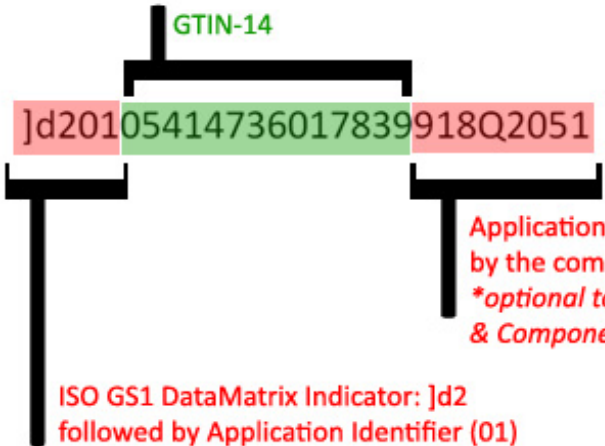
Unprogrammed Output
01087133321241789110000226-02
Programmed Output
]d201087133321241789110000226-02

GTIN: 08713332124178
Pfizer by 10000226-02

Programmed 2D Handheld Scanner Output:
Raw Data Defined



Programmed 2D Handheld Scanner Output:
Raw Data Defined



Application Identifier (91) followed by the component code *optional to use AI(91) & Component code in the 2D

ISO GS1 DataMatrix Indicator:]d2 followed by Application Identifier (01)

Examples



Exp./Chargenr.:




8Q2625
GTN : 08713332123737

CYKLOKAPRON®
100 mg/ml
TRANEXAMINEZUUR

1 ampul à 5 ml
oplossing voor injectie
voor intraveneuze
toediening

LOT/EXP.:



Pfizer SOLU-MEDROL
40 mg
Solution injectable/Oplissing voor injectie/ Injektionslösung
SUCCINATE SODIQUE DE METHYLPREDNISOLONE/
METHYLPREDNISOLONNATRIUMSUCCINAAT/
METHYLPREDNISOLON-NATRIUMSUCCINAT

1 ml Acl-O-Vial
IM - IV

8Q0954

LOT/EXP.:

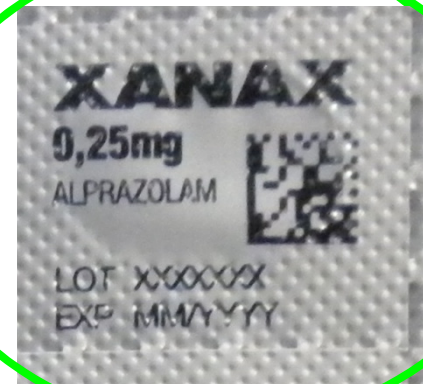
8Q2051
GTN : 0541478617000

Pfizer SOLU-MEDROL
S.A.B. 40 mg
(= sans alcool benzyllique/
zonder benzylalcohol/ohne
Benzylalkohol)
Poudre/Poeder/Pulver

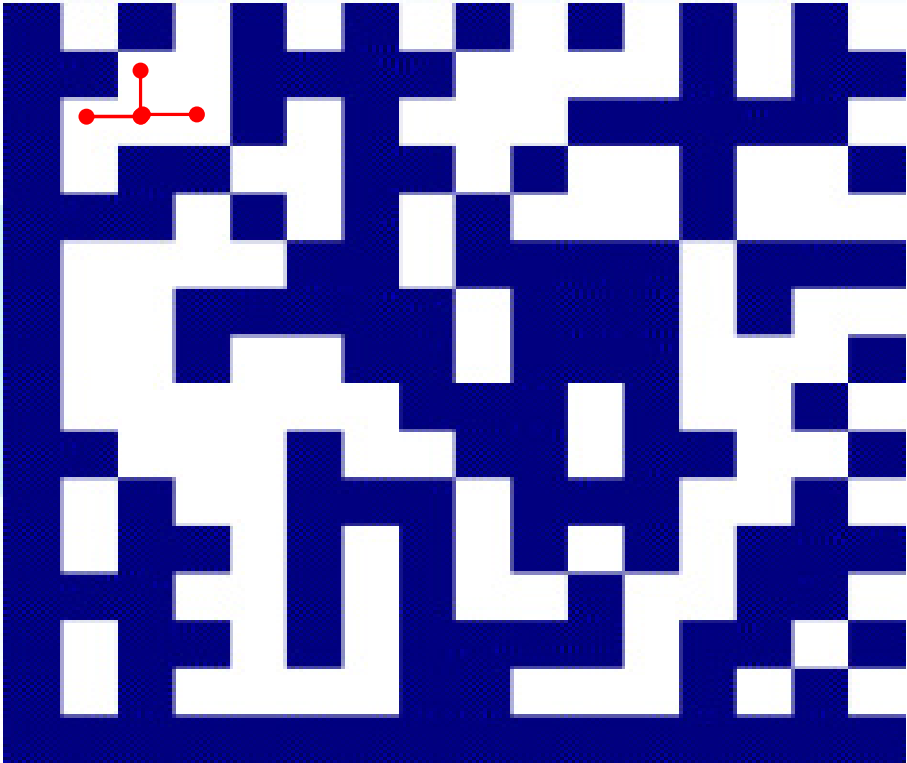
SUCCINATE SODIQUE DE METHYLPREDNISOLONE/
METHYLPREDNISOLONNATRIUMSUCCINAAT/
METHYLPREDNISOLONNATRIUMSUCCINAT

IM - IV

Examples



GS1 Standard



Examples



Exp./Chargenr.:



8Q2625
GTIN : 08713332123737

CYKLOKAPRON®
100 mg/ml
TRANEXAMINEZUUR

1 ampul à 5 ml
oplossing voor injectie
voor intraveneuze
toediening

0108713332123737918Q2625

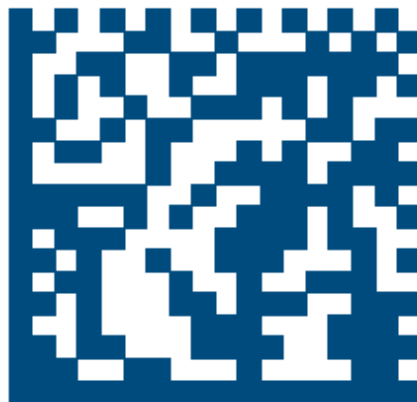
Exp./Chargenr.:



8Q2625
GTIN : 08713332123737

CYKLOKAPRON®
100 mg/ml
TRANEXAMINEZUUR

1 ampul à 5 ml
oplossing voor injectie
voor intraveneuze
toediening



Examples



LOT/EXP:

8Q0789

Pfizer Dynastat™
40 mg

Poudre pour solution injectable
Poeder voor oplossing voor injectie
Pulver zur Herstellung einer
Injektionslösung - Voies IV/IM - i.v./i.m.
Parécoxib (sel de sodium)
Parecoxib (als parecoxibnatrium)
Parecoxib (als Parecoxib-Natrium)

Lire la notice avant utilisation/
Voor gebruik de bijsluiter lezen/
Gebrauchsinformation beachten.

No GS1 DM
"8Q0789"



LOT/EXP:

05414736018355

Pfizer Dynastat™
40 mg

Poudre pour solution injectable
Poeder voor oplossing voor injectie
Pulver zur Herstellung einer
Injektionslösung - Voies IV/IM - i.v./i.m.
Parécoxib (sel de sodium)
Parecoxib (als parecoxibnatrium)
Parecoxib (als Parecoxib-Natrium)

Lire la notice avant utilisation/
Voor gebruik de bijsluiter lezen/
Gebrauchsinformation beachten.

8Q1927

GS1 DM
"(01)05414736018355(91)8Q1927"

Examples



LOT/EXP.:

Pfizer SOLU-MEDROL 40 mg
Solution injectable/Opløsning voor injectie/ Injektionslösung
SUCCINATE SODIQUE DE METHYLPREDNISOLONE/
METHYLPREDNISOLONNATRIUMSUCCINAAT/
METHYLPREDNISOLON-NATRIUMSUCCINAT

1 ml Act-O-Vial
IM - IV

8Q0954

No GS1 DM
"8Q0954"

LOT/EXP.:

8Q1707
GTIN: 054147-36017822

Pfizer SOLU-MEDROL 40 mg
Solution injectable/Opløsning voor injectie/ Injektionslösung
SUCCINATE SODIQUE DE METHYLPREDNISOLONE/
METHYLPREDNISOLONNATRIUMSUCCINAAT/
METHYLPREDNISOLON-NATRIUMSUCCINAT

1 ml Act-O-Vial
IM - IV

GS1 DM
"(01)05414736017822(91)8Q1707"

LOT/EXP.:

8Q0949

Pfizer SOLU-MEDROL S.A.B. 40 mg
(= sans alcool benzylique/
zonder benzylalcohol/ohne
Benzylalkohol)
Poudre/Poeder/Pulver

SUCCINATE SODIQUE DE METHYLPREDNISOLONE/
METHYLPREDNISOLONNATRIUMSUCCINAAT/
METHYLPREDNISOLONNATRIUMSUCCINAT

IM - IV

No GS1 DM
"8Q0949"

LOT/EXP.:

8Q1708
GTIN: 05414736017839

Pfizer SOLU-MEDROL S.A.B. 40 mg
(= sans alcool benzylique/
zonder benzylalcohol/ohne
Benzylalkohol)
Poudre/Poeder/Pulver

SUCCINATE SODIQUE DE METHYLPREDNISOLONE/
METHYLPREDNISOLONNATRIUMSUCCINAAT/
METHYLPREDNISOLONNATRIUMSUCCINAT

IM - IV

GS1 DM
"(01)05414736017839(91)8Q1708"

An industry perspective on medicines bar coding and bedside scanning



Thank You – Q&A



Chris