Barcoding Reform

Rebecca Heland, Manager Barcoding Reform,
Health Provider Engagement

21 October 2015

NATIONAL BLOOD AUTHORITY
AUSTRALIA

Why ?

The adoption of the ISBT128 DataMatrix and GS1 DataMatrix aims to:

- ✓ Enhance safety and supply security
- ✓ Improve inventory management and financial sustainability
- ✓ Increase efficiencies
- ✓ Facilitate global compliance and benchmarking

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This is not a new discussion

- 2007 / 2008 – initial proposal to move to ISBT 128 and GS1, including a public meeting on the side of HAA
- 2012 – Public consultation on draft requirements for IBST128 DataMatrix and GS1 DataMatrix undertaken by NBA
- 2014 – Specifications approved by Jurisdictional Blood Committee (comprised of all Australian Governments)

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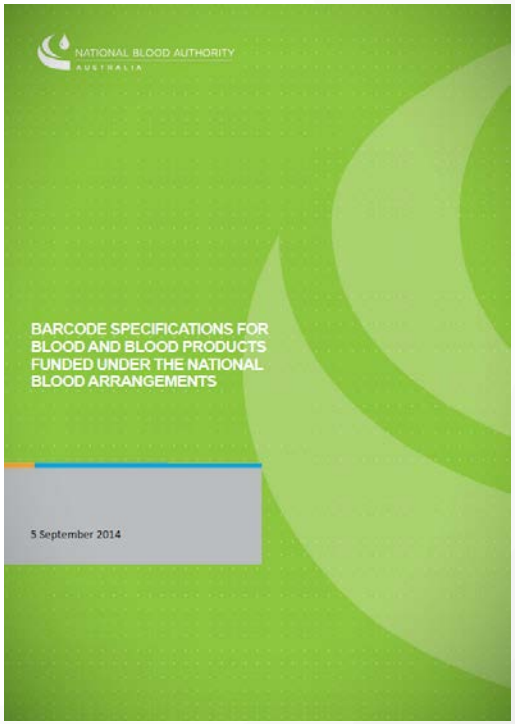
Barcoding Standard

- Mandatory for all blood products funded under the national blood arrangements
  - ISBT 128 DataMatrix for fresh products (red cells, platelets, FFP etc)
  - GS1 DataMatrix for all manufactured products
- Contractual obligations for all commercial suppliers to move to new symbologies



Why 2D rather than linear ?

- Two-dimensional is the standard for healthcare
- Ability to fit a great deal of information in a small barcode including multiple fields that can be read in a single scan

Comparative size of Code 128 and Data Matrix Symbols

The Data Matrix symbol on the left contains all of the information held in the five Code 128 symbols on the right.

Image from *ISBT 128 for Blood Components – An Introduction – 3rd Edition, ICCBBA*

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ISBT 128 DataMatrix

1. All data elements to be included in the DataMatrix

2. All units to be uniquely identifiable globally

3. All products with different characteristics shall be assigned different product codes

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ISBT 128 DataMatrix Timing

- July 2017 - Blood Service commence transition labelling (ie current and new symbologies)
- July 2019 – Blood Service can cease transition labelling (ie new symbologies only)
- The original timelines have been extended due to internal Blood Service technical issues

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GS1 DataMatrix

- Mandated use of the National Product Catalogue from NeHTA
- Once transition is complete, no linear barcodes only DataMatrix
- On the vial and the carton
- Serialisation

A GS1 DataMatrix can contain the following attributes:

Manufacturer Product Code (GTIN) - 14 digits
Expiry Date - 6 digits (YYMMDD)
Batch / lot Number - up to 20 alpha-numeric characters
Unique Serial Number (randomized) - up to 20 alpha-numeric characters

Example: Use of GS1 Standards for the identification of products using a GS1 DataMatrix

GTIN:	(01) 07046261398572
Expiry:	(17) 130331
Batch / lot:	(10) TEST5632
S/N:	(21) 19067811811

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GS1 DataMatrix Timing

- Jan 2016 – Transition labelling commences
- Jan 2017 – Serialisation commences
- Jan 2018 – Transition labelling can cease

Timings are for product off the manufacturing line, not distribution (add up to six months)

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Steps Health Services need to undertake now to get ready

1. Talk to software vendors
   - Talk to Health Service ICT – you already have 2D in your facility
2. If replacing barcode scanners, start buying 2D imaging scanners
3. Review business processes
4. Learn more and check for updates at www.blood.gov.au/barcoding

The Global Language of Business

GS1 Australia

GS1 DataMatrix
Supporting the NBA barcode requirements

Gary Russon – Senior Advisor, Healthcare

October 2015

THE GLOBAL LANGUAGE OF BUSINESS

110+ Member Organizations
Serving 2 Million Business Around the World
Over 5 billion barcodes scanned every day

Neutral & not for profit
User driven

Our purpose and beliefs

GS1 believes in the power of standards to transform the way we work and live

- We **create** a common foundation for business by uniquely identifying, accurately capturing and automatically sharing vital information about products, locations and assets.
- We **enable** visibility through the exchange of authentic data.
- We **empower** business to grow and to improve efficiency, safety, security and sustainability.

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THE GLOBAL LANGUAGE OF BUSINESS

GS1 Standards are the global language of business—

a language for **identifying**, **capturing**, and **sharing** information automatically and accurately, so that anyone who wants that information can understand it, no matter who or where they are.

The most broadly implemented supply chain standard in history.

Barcodes required

Suppliers and distributors to implement the following global barcode standards in relation to funded products

- ISBT 128 DataMatrix for all fresh blood products (Red Cells, Platelets, Clinical Fresh Frozen Plasma, Cryoprecipitate, Cryo-depleted Plasma and Serum Eye Drops)

- **GS1 DataMatrix** for all plasma, recombinant and diagnostic products at the level of unit packagingGS1 DataMatrix for all plasma, recombinant and diagnostic products at the level of unit packaging

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Barcodes on all levels of packaging

Packaging Hierarchy

- Both the unit and all levels of packaging (such as the unit/vial, pack, carton etc) have the barcode applied in accordance with the relevant standard with the exception of the reusable cardboard shippers used by the Blood Service

- All units are able to be uniquely identifiable globally, which shall be achieved through the DIN for ISBT 128 DataMatrix and through product serialisation for **GS1 DataMatrix**

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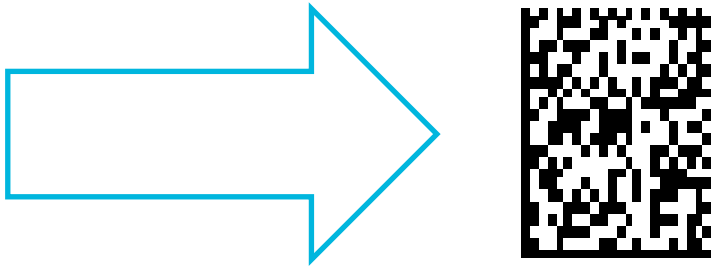
Barcodes with product serilisation

For products labelled using GS1 DataMatrix (or another GS1 barcode symbology for higher levels of packaging), the following minimum data elements must be contained in the DataMatrix, noting that suppliers may choose to include additional elements (Application Identifiers, AIs)

- GTIN – Global Trade Item Number
- AI (17) – Expiry Date
- AI (10) – Batch / Lot Number
- AI (21) – Serial Number



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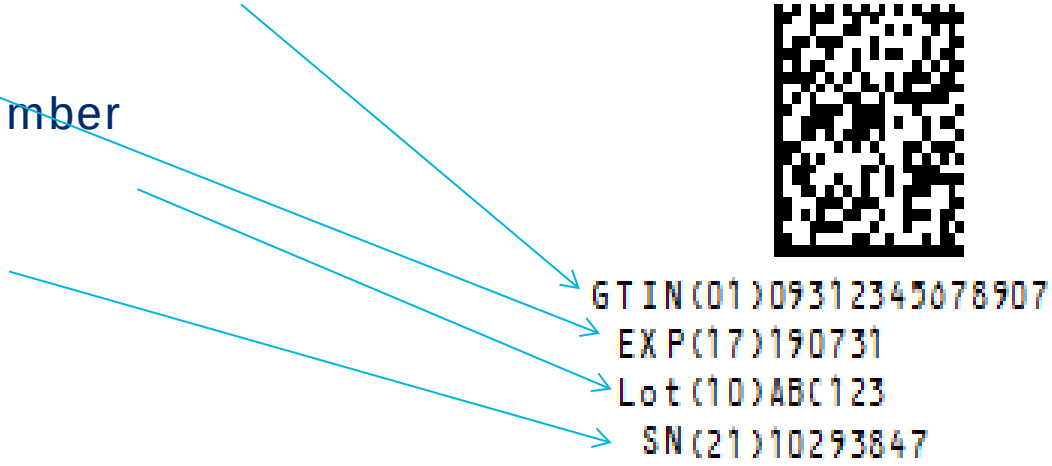

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GS1 DataMatrix is capable...

GS1 DataMatrix is the preferred two-dimensional (2D) matrix barcode symbology for use in Healthcare to efficiently meet the needs of our pharmaceutical and medical device members. Its use:

- Allows the encoding and marking of larger amounts of data within smaller spaces
- Allows printing of both static product identification (i.e. GTINs) and dynamic production information (i.e. AIs) in a barcode data carrier, at production & packaging rates
- Has inherent error detection and correction capabilities for increased robustness in use
- Well suited to and proven in healthcare applications
- **Also allows encodation of URLs for accessing trusted product data and use information... i.e. enabling "intelligent packaging" in Healthcare**

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Resources – creating a GS1 DataMatrix

Creating a GS1 DataMatrix requires barcode numbers (GTINs) and a technical understanding of specific GS1 online resources

- GS1 Membership for barcode number range (GTINs)
  - http://www.gs1au.org/membership/
- GS1 DataMatrix Guideline
  - http://www.gs1.org/docs/barcodes/GS1_DataMatrix_Guideline.pdf
- GS1 General Specifications
  - https://www.gs1au.org/assets/documents/info/GS1-General-Specifications-v15.pdf

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Barcode Scanners

Solution Providers Directory

- Area Image Scanners, not Linear Scanners
- Scanners which are 2D and linear barcode compliant will ensure cross-compatibility
  - Scans 1D / Linear, 2D Stacked & 2D Matrix symbols
- Camera based
- Growing installed base in industrial, commercial, healthcare

http://www.gs1au.org/membership/spd/

Scope

- GS1 website contains Solution Provider listings
- Solution Providers are reviewed by GS1 to ensure our standards and are supported
- Each organisation should each review and make their own decision on solutions required for their business

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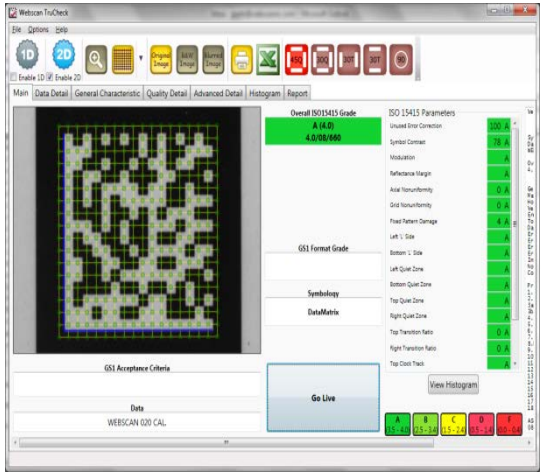
Barcode Quality Verifiers

Solution Providers Directory

- Bar Code Print Quality Verifiers are available for testing 2D Matrix symbols like GS1 DataMatrix

http://www.gs1au.org/membership/spd/



Scope

- Provides grade based on ISO/IEC 15415
- Solution Providers are reviewed by GS1 to ensure our standards and are supported
- Each organisation should each review and make their own decision on solutions required for their business

© GS1 Australia 2015

GS1 Barcode Quality Verification

GS1 offers Barcode Verification on a case-by-case basis

- GS1 are able to scan and provide feedback on individual GS1 DataMatrix codes
- Verification reports are available by e-mailing sample files to testing.sydney@gs1au.org

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What's in it for me?

- Hospitals can improve **patient safety**
  - Process quality improvement
  - Risk reduction

- Hospitals can increase **efficiency**
  - Simplification of logistics – improved process mapping and resulting process improvements
  - Automated documentation throughout its usage
  - Reduction of storage costs & minimisation of necessary sets

- Global standards ensure **interoperability** and **compatibility**
  - Various suppliers, networks, etc.

© GS1 Australia 2015

GS1 contact

E-mail: HealthcareTeam@gs1au.org

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NovoSeven® RT (recombinant factor VIIa)

Implementation of the NBA barcoding project in Australia 2016-2017

Rowan O'Brien,
Regulatory Affairs and QA Manager,
Novo Nordisk Pharmaceuticals P/L,
Australia and NZ

NovoSeven® RT
eptacog alfa (activated) (bhk)

novo nordisk®

Agenda

1. Scope
2. Proposed labelling changes
3. Timing of implementation – transition labelling versus full serialisation

NovoSeven®RT
eptacog alfa (activated) (bhk)

novo nordisk®

1. Scope

- NovoSeven® RT is supplied in 4 presentations : 1 mg, 2 mg, 5 mg and 8 mg vial sizes

- Each carton of an individual unit contains:
  - single vial of NovoSeven® RT powder
  - prefilled solvent syringe
  - vial adaptor

- Project scope includes ONLY:
  - label of the powder vial component
  - unit carton

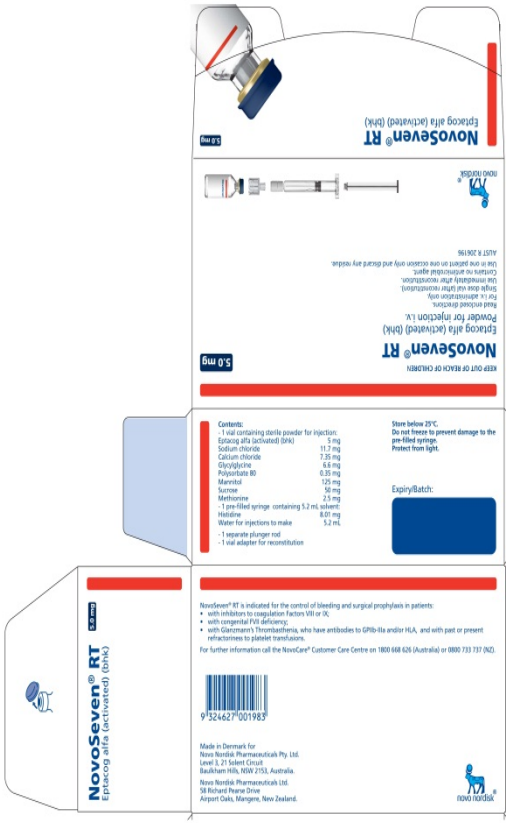
NovoSeven®RT
eptacog alfa (activated) (bhk)

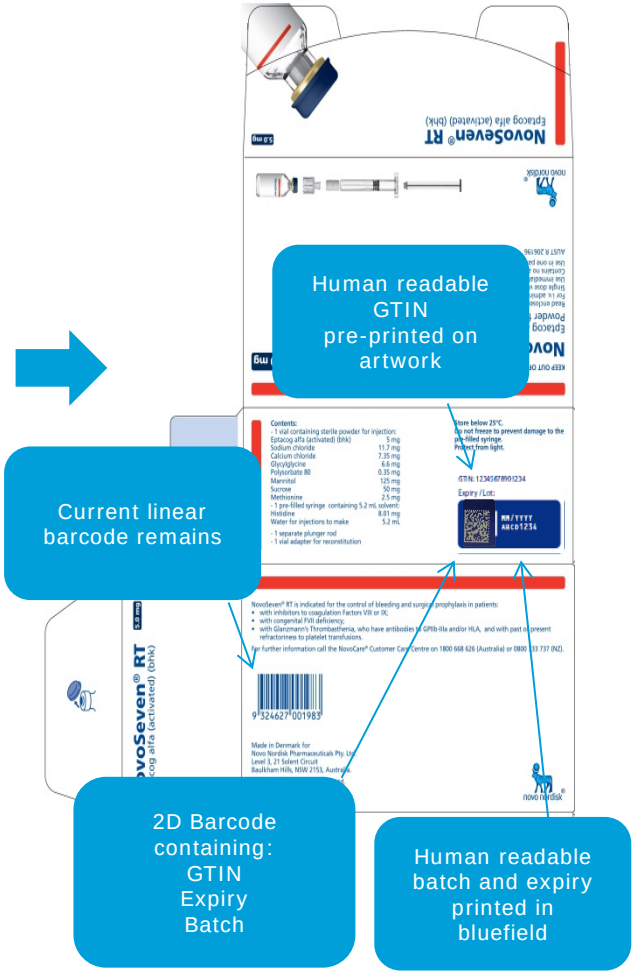
novo nordisk®

2. Proposed labelling changes

Three stage implementation:

- **Stage 1 – transition labelling (addition of 2d-matrix barcodes)**
  - Addition of 2d-matrix barcode to **carton** to supplement current linear barcode
  - GTIN, expiry, batch details ONLY



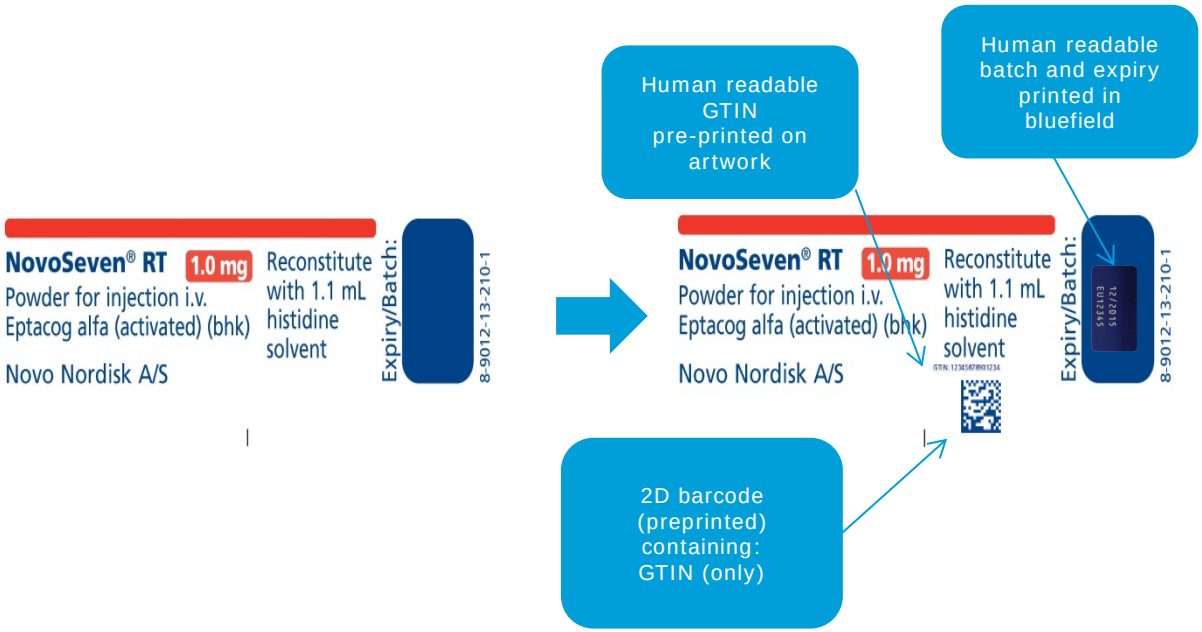


NovoSeven®RT
eptacog alfa (activated) (bhk)

2. Proposed labelling changes (continued)

Three stage implementation:

- **Stage 1 – transition labelling (addition of 2d-matrix barcodes)**
  - Addition of 2d-matrix barcode to **powder vial label**
  - GTIN ONLY



NovoSeven®RT
eptacog alfa (activated) (bhk)

novo nordisk®

2. Proposed labelling changes (continued)

Three stage implementation:

- **Stage 2 – serialisation added to 2d-matrix barcodes**
  - Addition of serial number element to 2d-matrix barcode to carton ONLY
  - No change to powder vial label

NovoSeven®RT
eptacog alfa (activated) (bhk)

novo nordisk®

2. Proposed labelling changes (continued)

Three stage implementation:

- **Stage 3 – deletion of current linear barcode from NovoSeven® RT cartons**
  - Leaving only the serialised 2d-matrix barcode on the cartons and powder vial labels

3. Timing of implementation

Three stage implementation:

- **Stage 1 – transition labelling (addition of 2d-matrix barcodes)**
  - First batches expected to be sent to AU customers during 1H 2016
- **Stage 2 – serialised barcodes**
  - First batches expected to be sent to AU customers no later than Q4 2017
- **Stage 3 – deletion of linear barcodes**
  - First batches expected to be sent to AU customers no later than 2020

NovoSeven®RT
eptacog alfa (activated) (bhk)

novo nordisk®

Baxalta

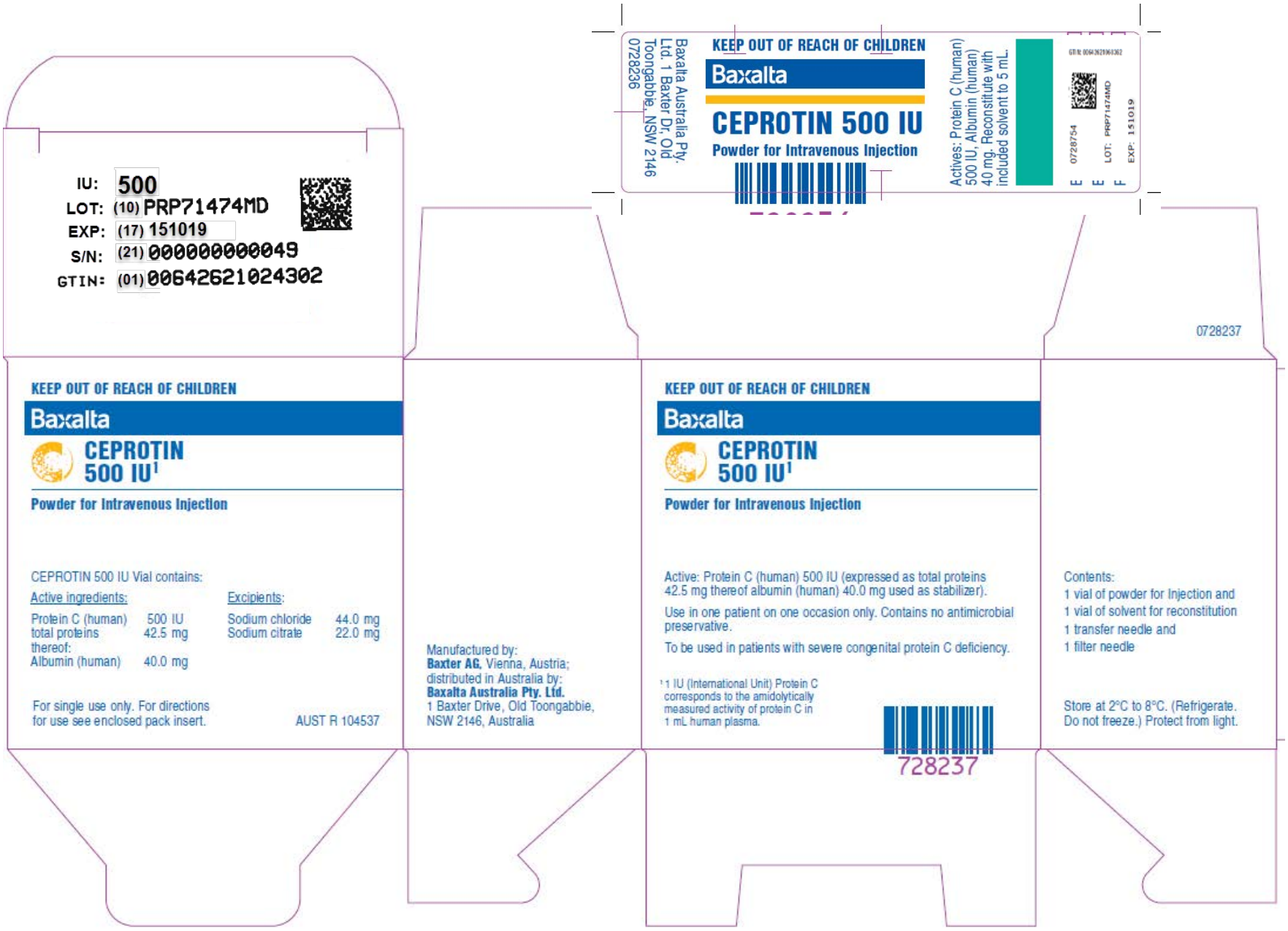
Barcoding Reform

21st October 2015

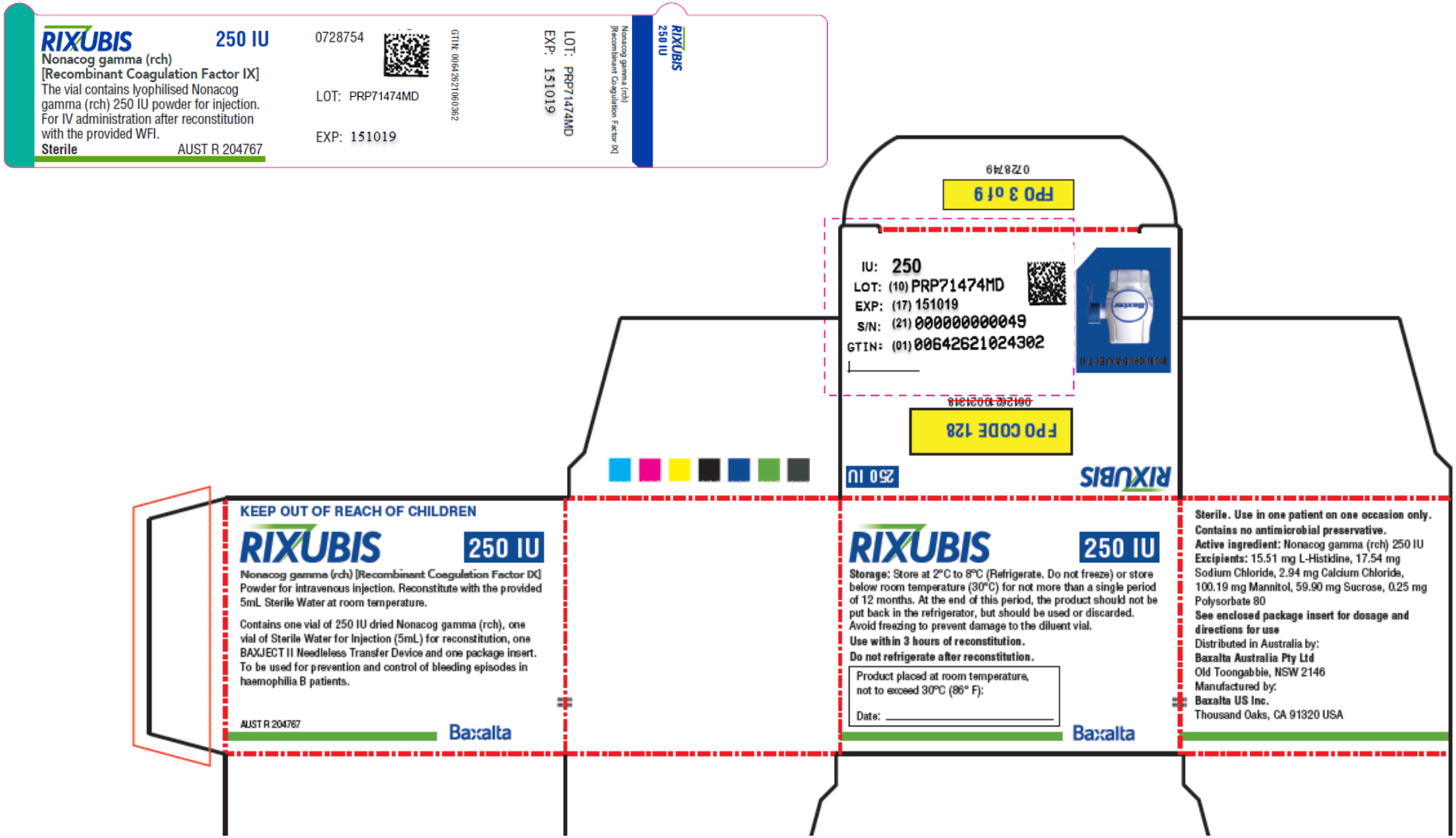
Cartons and Vials

Baxter
ADVATE 250 IU
LE-07-24835
Octocog alfa (rch) [Recombinant Anthaemophilic FVIII]
The vial contains lyophilised Octocog alfa (rch): 250 IU powder for injection. For IV administration after reconstitution with the provided WFI. For excipients composition see carton box.
Sterile
AUST R 100384
GTIN: 05413760494838
Batch No.:
Expiry date:
Octocog alfa (rch)
Advate 250 IU
[Recombinant Antihaemophilic FVIII]
Octocog alfa (rch)
Batch No.:
Expiry date:
Baxter Healthcare Corp.
Peel at arrow for patient records.
05413760259437
Product code: 150212
IU: 250
LOT: (10) PRP71474MD
EXP: (17) 151019
S/N: (21) 000000000049
GTIN: (01) 00642621024302
250 IU
ADVATE
LE-07-23691
KEEP OUT OF REACH OF CHILDREN
ADVATE
250 IU
Octocog alfa (rch) [Recombinant Antihaemophilic FVIII, Plasma / Albumin Free Method (rAHF-PFM)]
Powder for intravenous injection. Reconstitute with the provided sterilized water for injection (5mL) at room temperature.
To be used for control and prevention of bleeding episodes in haemophilia A patients.
Contents: One ADVATE vial contains nominally 250 IU Octocog alfa (rch), with excipients: trehalose (40mg), histidine (8,0 mg), trometamol (6,0 mg), sodium chloride (26,5 mg), calcium chloride (1,3 mg), glutathione [(reduced), 0,4 mg], polysorbate 80 (0,5 mg), and mannitol (160,0 mg).
For dosage and directions for use, see accompanying package insert.
Baxter
Store at 2°C-8°C (Refrigerate. Do not freeze) or store below 25°C for a single period of up to 6 months and then discard. Do not refrigerate after reconstitution.
Protect from light.
ADVATE is trade mark of Baxter International, Inc.
Distributed in Australia by:
Baxter Healthcare Pty, Ltd.
1 Baxter Drive, Old Toongabbie
NSW 2146
Manufactured by:
Baxter Healthcare Corporation
Westlake Village, CA 91362
KEEP OUT OF REACH OF CHILDREN
ADVATE
250 IU
Octocog alfa (rch) [Recombinant Antihaemophilic FVIII, Plasma / Albumin Free Method (rAHF-PFM)]
Powder for intravenous injection. Reconstitute with the provided sterilized water for injection (5mL) at room temperature.
To be used for control and prevention of bleeding episodes in haemophilia A patients.
One vial containing 5 mL of water for injection for reconstitution.
One BAXJECT II Needleless Transfer Device, Package Leaflets PI and CMI.
Use in one patient on one occasion only. Contains no anti-microbial preservative.
Sterile
Nonpyrogenic
AUST R 100384
Baxter

Baxalta


IU: 500
LOT: (10) PRP71474MD
EXP: (17) 151019
S/N: (21) 000000000049
GTIN: (01) 00642621024302
Baxalta Australia Pty. Ltd. 1 Baxter Dr, Old Toongabbie, NSW 2146
0728236
KEEP OUT OF REACH OF CHILDREN
Baxalta
CEPROTIN 500 IU
Powder for Intravenous Injection
Actives: Protein C (human) 500 IU, Albumin (human) 40 mg. Reconstitute with included solvent to 5 mL.
0728754
LOT: PRP71474MD
EXP: 151019
0728237
KEEP OUT OF REACH OF CHILDREN
Baxalta
CEPROTIN 500 IU[1]
Powder for Intravenous Injection
CEPROTIN 500 IU Vial contains:
Active ingredients:
Protein C (human) 500 IU
total proteins 42.5 mg
thereof:
Albumin (human) 40.0 mg
Excipients:
Sodium chloride 44.0 mg
Sodium citrate 22.0 mg
For single use only. For directions for use see enclosed pack insert.
AUST R 104537
Manufactured by:
Baxter AG, Vienna, Austria;
distributed in Australia by:
Baxalta Australia Pty. Ltd.
1 Baxter Drive, Old Toongabbie, NSW 2146, Australia
KEEP OUT OF REACH OF CHILDREN
Baxalta
CEPROTIN 500 IU[1]
Powder for Intravenous Injection
Active: Protein C (human) 500 IU (expressed as total proteins 42.5 mg thereof albumin (human) 40.0 mg used as stabilizer).
Use in one patient on one occasion only. Contains no antimicrobial preservative.
To be used in patients with severe congenital protein C deficiency.
[1] 1 IU (International Unit) Protein C corresponds to the amidolytically measured activity of protein C in 1 mL human plasma.
728237
Contents:
1 vial of powder for Injection and
1 vial of solvent for reconstitution
1 transfer needle and
1 filter needle
Store at 2°C to 8°C. (Refrigerate. Do not freeze.) Protect from light.

U: 1000
LOT: (10) PRP71474MD
EXP: (17) 151019
S/N: (21) 000000000049
GTIN: (01) 00642621024302
KEEP OUT OF REACH OF CHILDREN
FEIBA NF 1000 U*
Factor VIII Inhibitor Bypassing Fraction
(human plasma derived protein)
AUST R 104911
Baxalta
Lyophilised powder for intravenous administration only. Reconstitute with the provided 20 mL of Sterilized Water for Injection at room temperature.
Storage: Store below 25°C. Avoid freezing to prevent damage to the diluent bottle. Protect from light.
During reconstitution, swirl the vial gently until all material is dissolved. Administer immediately after reconstitution by slow intravenous injection (do not exceed 2 units FEIBA/kg body weight per minute).
Do not refrigerate after reconstitution.
Contains no antimicrobial preservative. Use in one patient on one occasion only.
* A solution containing 1 Unit of Factor Eight Inhibitor Bypassing Activity (FEIBA) shortens the activated partial thromboplastin time (APTT) of a factor VIII inhibitor plasma to 50% of the buffer value (blank).
Reorder Number: 1502907
Manufactured by:
Baxter AG
Industriestrasse 67
A-1220 Vienna, Austria
Distributed by:
Baxalta Australia Pty. Ltd.
Old Toongabbie, NSW 2146
KEEP OUT OF REACH OF CHILDREN
FEIBA NF 1000 U*
Factor VIII Inhibitor Bypassing Fraction
(human plasma derived protein)
AUST R 104911
Baxalta
Powder for intravenous injection. Reconstitute with 20 mL of Sterilized Water for Injection at room temperature.
To be used for the treatment of haemophilia A patients with Factor VIII inhibitor and the treatment of haemophilia B patients with Factor IX inhibitor.
Active Ingredient: Human plasma proteins (400 – 1200 mg) thereof with a Factor Eight Inhibitor Bypassing Activity of 1000 FEIBA-Units*
Excipients: after reconstitution with 20 mL of Sterilized Water for Injection, FEIBA NF vial contains 160 mg Sodium Chloride, and 80 mg Sodium Citrate.
See the accompanying package insert with dosage, instructions for use and additional information.
728329
Baxalta
Content: one vial of 50 mL containing nominally lyophilised 1000 FEIBA-Units*, one vial with 20 mL Sterilized Water for Injection for reconstitution; 1 BAXJECT II Hi-Flow Needleless Transfer Device and package insert.
Baxalta and FEIBA are trademarks of Baxalta Incorporated
Baxter is a registered trademark of Baxter International Inc.
KEEP OUT OF REACH OF CHILDREN
FEIBA NF
1000 U*
Factor VIII Inhibitor Bypassing fraction (human plasma derived protein)
Powder for intravenous injection
Baxalta
AUST R 104911
* see carton label for detail
Active Ingredient: 1000 FEIBA (Factor Eight Inhibitor Bypassing Activity) Units, contained in human plasma proteins (400 – 1200 mg). Excipients: after reconstitution, FEIBA NF contains 160 mg Sodium Chloride, and 80 mg Sodium Citrate. Directions for use: see package insert. Store below 25°C. Avoid freezing to prevent damage to the diluent bottle. Protect from light. To be used for the treatment of haemophilia patients (see carton label and package insert for details). Contains no antimicrobial preservative. Use in one patient on one occasion only.
Sponsor:
Baxalta Australia Pty Ltd, 1 Baxter Drive, Old Toongabbie, NSW 2146
0728328
0728754
Bat
Exp
P
LOT: PRP71474MD
EXP: 151019
FEIBA NF 1000 U
Batch No:
FEIBA NF 1000 U
Batch No:


RIXUBIS
250 IU
Nonacog gamma (rch)
[Recombinant Coagulation Factor IX]
The vial contains lyophilised Nonacog gamma (rch) 250 IU powder for injection. For IV administration after reconstitution with the provided WFI.
Sterile
AUST R 204767
0728754
GTIN: 00642621060362
LOT: PRP71474MD
EXP: 151019
LOT: PRP71474MD
EXP: 151019
Nonacog gamma (rch) [Recombinant Coagulation Factor IX]
RIXUBIS 250 IU
FPO 3 of 9
IU: 250
LOT: (10) PRP71474MD
EXP: (17) 151019
S/N: (21) 000000000049
GTIN: (01) 00642621024302
FPO CODE 128
250 IU
RIXUBIS
KEEP OUT OF REACH OF CHILDREN
RIXUBIS 250 IU
Nonacog gamma (rch) [Recombinant Coagulation Factor IX]
Powder for intravenous injection. Reconstitute with the provided 5mL Sterile Water at room temperature.
Contains one vial of 250 IU dried Nonacog gamma (rch), one vial of Sterile Water for Injection (5mL) for reconstitution, one BAXJECT II Needleless Transfer Device and one package insert. To be used for prevention and control of bleeding episodes in haemophilia B patients.
AUST R 204767
Baxalta
RIXUBIS 250 IU
Storage: Store at 2°C to 8°C (Refrigerate. Do not freeze) or store below room temperature (30°C) for not more than a single period of 12 months. At the end of this period, the product should not be put back in the refrigerator, but should be used or discarded.
Avoid freezing to prevent damage to the diluent vial.
Use within 3 hours of reconstitution.
Do not refrigerate after reconstitution.
Product placed at room temperature, not to exceed 30°C (86° F):
Date:
Baxalta
Sterile. Use in one patient on one occasion only.
Contains no antimicrobial preservative.
Active ingredient: Nonacog gamma (rch) 250 IU
Excipients: 15.51 mg L-Histidine, 17.54 mg Sodium Chloride, 2.94 mg Calcium Chloride, 100.19 mg Mannitol, 59.90 mg Sucrose, 0.25 mg Polysorbate 80
See enclosed package insert for dosage and directions for use
Distributed in Australia by:
Baxalta Australia Pty Ltd
Old Toongabbie, NSW 2146
Manufactured by:
Baxalta US Inc.
Thousand Oaks, CA 91320 USA

When we will see this in market?

In Market Timeline

- Work through:
  - In Country Reserve (ICR): 3 months
  - Stock on Hand: 2-3 months

May 2016

BeneFIX® nonacog alfa (rch) Recombinant Coagulation Factor IX

xyntha® dual chamber moroctocog alfa (rch) recombinant coagulation factor VIII

Barcoding Reform

Australia 21st October 2015

Louise Misso

SKU Transition Timetable

Dual barcode transition labelling from June 2016*

BeneFix® (nonacog alfa (rch))

EAN	Size	Dual Barcode Availability Date
9315850001802	250 IU	1st June 2016*
9315850001819	500 IU	1st June 2016*
9315850001826	1000 IU	1st June 2016*
9315850001833	2000 IU	1st June 2016*
9313212105922	3000 IU	1st June 2016*

XYNTHA® (moroctocog alfa (rch))

XYNTHA powder for injection plus diluent dual chamber syringe

EAN	Size	Dual Barcode Availability Date
9313212105403	250 IU	1st June 2016*
9313212105410	500 IU	1st June 2016*
9313212105427	1000 IU	1st June 2016*
9313212105434	2000 IU	1st June 2016*
9313212105441	3000 IU	1st June 2016*

*Please note that the timings above are indicative only and may change dependent on rates of demand for each SKU between now and indicated implementation date. Pfizer recommends that health providers, laboratories and distributors contact Pfizer directly for more precise implementation dates for each SKU as the implementation date approaches.

Barcoding Open Forum

HAA Adelaide – 21st October 2015

GRIFOLS | 75 ANNIVERSARY

Your health, our commitment

Flebogamma® DIF
Human Normal Immunoglobulin (IVIg)
50 mg/ml 100 mg/ml

- Grifols was founded in Barcelona, Spain in 1940
  - Today it employs more than 14,000 people and is present in over 100 countries
- The company has become one of the world's largest producers of plasma derived medicines
  - Largest network of plasma collection centres in the world
  - 150 plasma donation centres across the United States
  - Collects plasma from more than 25,000 donors daily
- All donors must meet stringent health and lifestyle criteria
  - Use qualified, repeat donors
  - All donations are rigorously tested in state-of-the-art plasma testing labs
  - Plasma collection to finished product takes between 9-12 months
- Grifols' pioneering spirit embodies innovation and a forward-looking approach to product development

Flebogamma® DIF

Human Normal Immunoglobulin (IVIg)

50 mg/ml **100** mg/ml

Flebogamma® DIF

Human Normal Immunoglobulin (IVIg)

50 mg/ml

20g 10g 5g 2.5g 0.5g

Flebogamma® DIF

Human Normal Immunoglobulin (IVIg)

100 mg/ml

20g 10g 5g

GRIFOLS 75 ANNIVERSARY

Flebogamma® DIF

Human Normal Immunoglobulin (IVIg)

50 mg/ml **100** mg/ml

Holographic seal

Vials laser etched with Lot and Expiry

Bottle hanger

Peel away label

GRIFOLS 75 ANNIVERSARY

Flebogamma® DIF Product Carton

Flebogamma® DIF
Human Normal Immunoglobulin (IVIg)
50 mg/ml 100 mg/ml

	Barcode	Eye-readable
	Linear & 2D Data Matrix barcode symbology will be available on all Flebogamma® DIF cartons from 1st November 2015	
	(01) - numeric	(01) - numeric
	(10) - alphanumeric	(10) - alphanumeric
	(17) - numeric	(17) - alphanumeric

Flebogamma® DIF

Human Normal Immunoglobulin (IVIg)

50 mg/ml | 100 mg/ml

GRIFOLS 75 ANNIVERSARY

Current situation

- All CSL products are currently barcoded
  - Codabar barcoding
  - Data matrix
  - GS1 128

- CSL Australia Toll products manufactured from Australian plasma currently use the Codabar system.

Codabar system

- Developed >25 years ago with ARCBS
- Information transferred via the Barcode number.
- Is a “lineal” barcode format.
- CNNNNPPBBBBC
  - C = Start/end code
  - N = Item/product Number
  - P = Product presentation
  - B = Batch number

3468 10 0863

GS1 Data Matrix

- Phased product transition to this system
- Privigen is the first CSL product with GS1 data matrix
- Data matrix is encoded with;
  - Global Trade Identification Number (GTIN)
  - Expiry date
  - Batch/Lot #

GTIN

Expiry

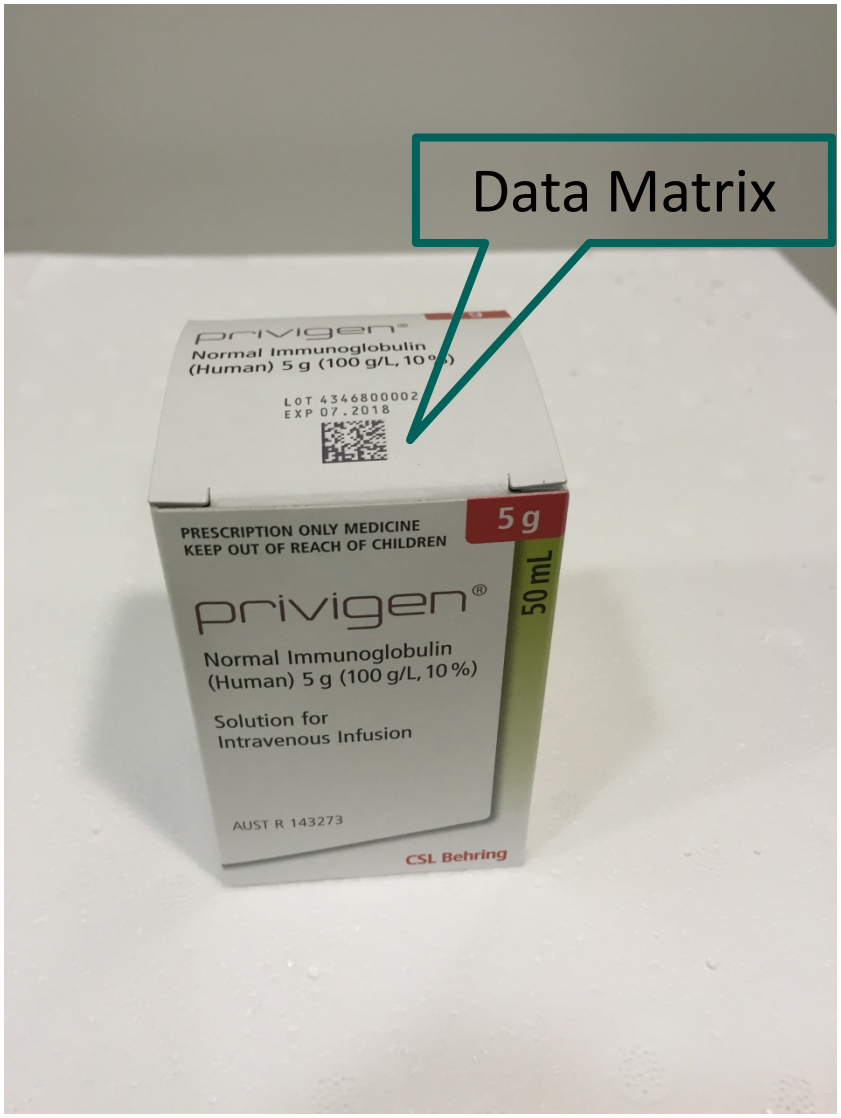
Batch/Lot#

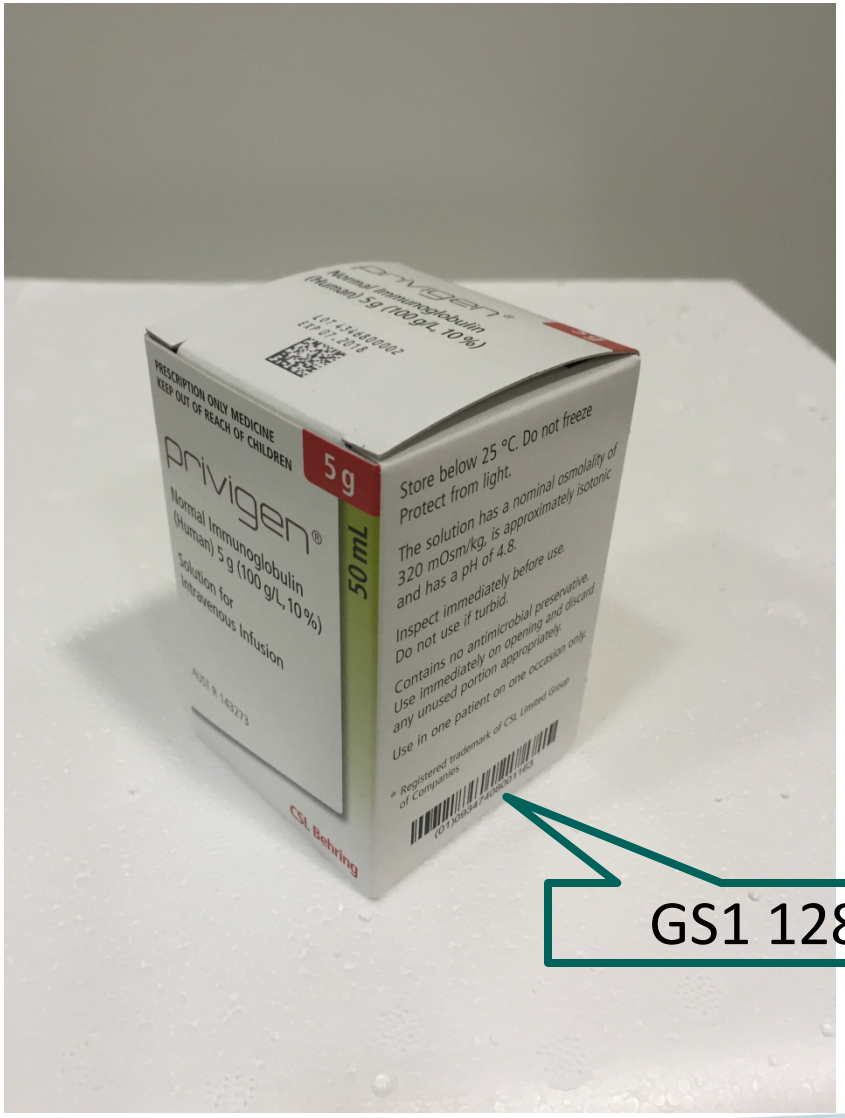
GS1 128 Barcode

- Is not an NBA requirement
- Currently printed on commercial products
  - Privigen & Hizentra
- Is encoded with GTIN only

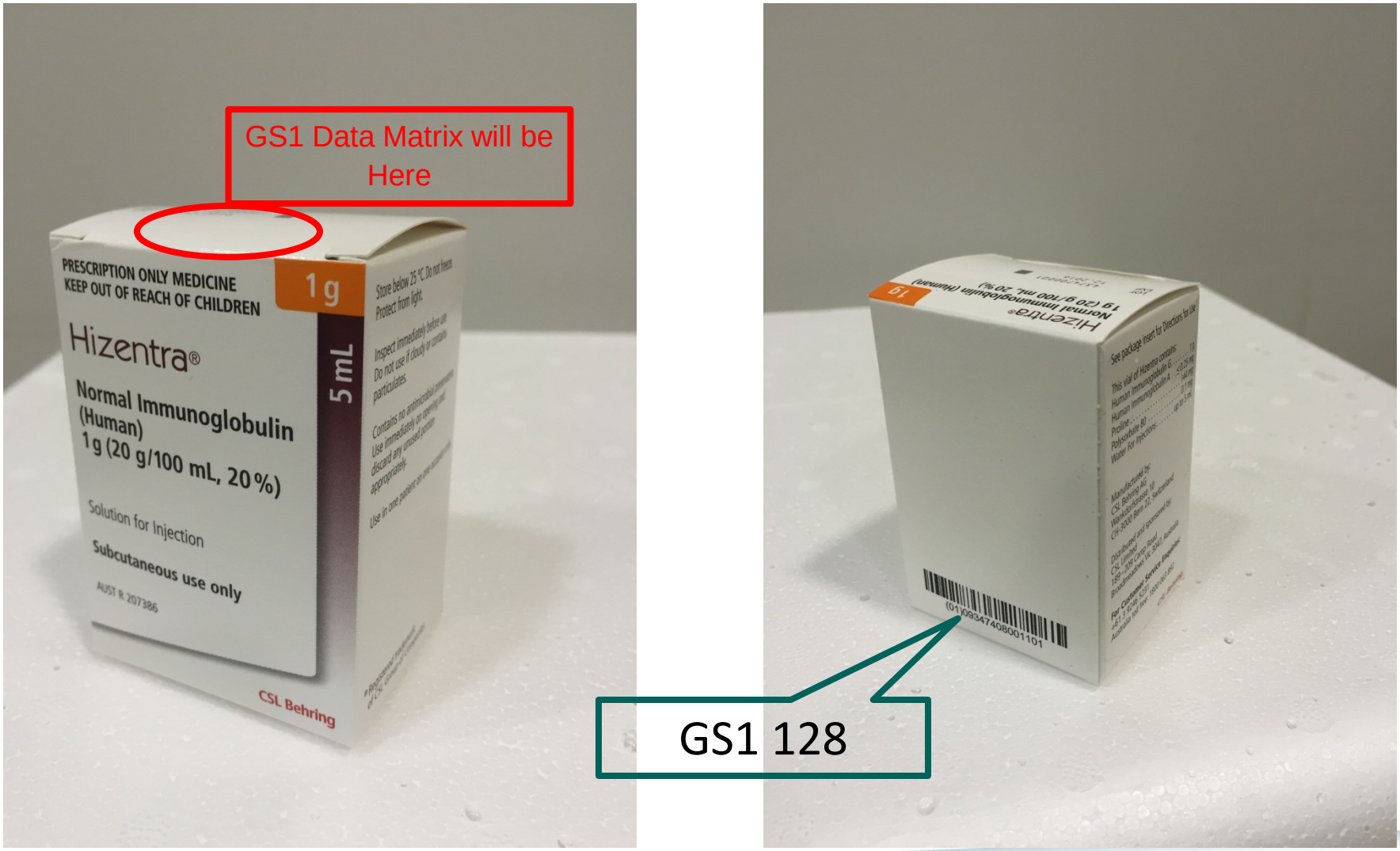
GTIN

CSL Behring – Barcoding Privigen

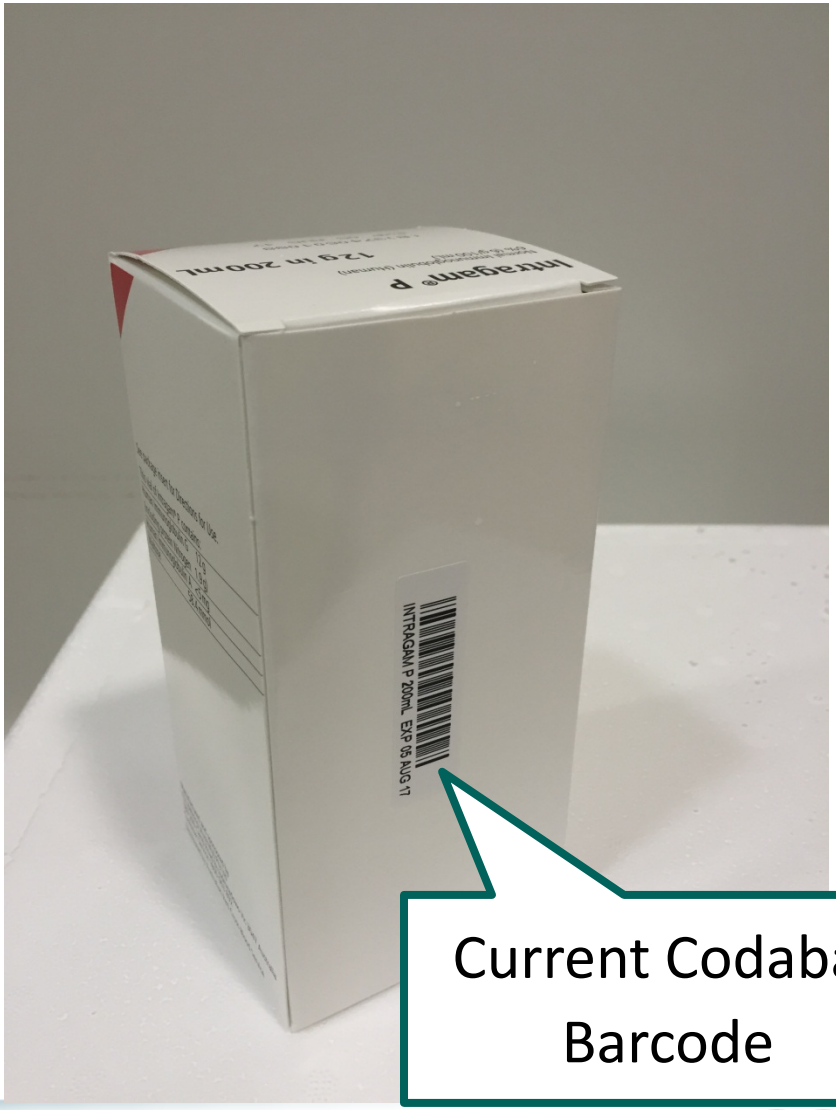




CSL Behring – Barcoding Hizentra



CSL Behring – Barcoding Intragam P



CSL Data Matrix and serialisation project

- Global project team supporting serialisation in US, Europe & Australia
  - Serialisation is a very complex & expensive project
  - Demanding on engineering, data & process solutions

- Local project team to address Australian requirements
  - NBA requirements
  - Project Scope
  - Equipment requirements / Production line upgrades
  - Packaging Artwork changes & barcode placement

CSL Toll products transition

- We will continue to mark all Toll product with the Codabar barcode.

- When Data matrix coding begins for Toll products, they will be Dual coded with both Data matrix and Codabar.

Questions