

HYQVIA- immune globulin infusion 10% (human) with recombinant human hyaluronidase
Bamboo US BidCo LLC

These highlights do not include all the information needed to use HYQVIA safely and effectively. See full prescribing information for HYQVIA.

HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] Solution, for subcutaneous administration
Initial U.S. Approval: 2014

PRINCIPAL DISPLAY PANEL - 2.5 g/25 mL Vial Label

Immune Globulin Infusion 10% (Human)

Component of HYQVIA

Single-Use Vial

Rx Only

Takeda Pharmaceuticals U.S.A., Inc.
Lexington, MA 02421
U.S. License No. 1898

Infuse 2nd

2.5 g/
25 mL

IG

LE-07-54397

Takeda



PRINCIPAL DISPLAY PANEL - 1.25 mL Vial Label

Recombinant Human Hyaluronidase

Component of HYQVIA

Single-Use Vial

Rx Only

Takeda Pharmaceuticals U.S.A., Inc.
Lexington, MA 02421

Infuse 1st

HY

1.25 mL
160 units per mL

Takeda



PRINCIPAL DISPLAY PANEL - 2.5 g/25 mL Kit Carton

Immune Globulin Infusion 10% (Human)
with Recombinant Human Hyaluronidase
HYQVIA

For Subcutaneous Administration Only.

Single-use dual vial unit

Directions for use:
Read the enclosed Package Insert.

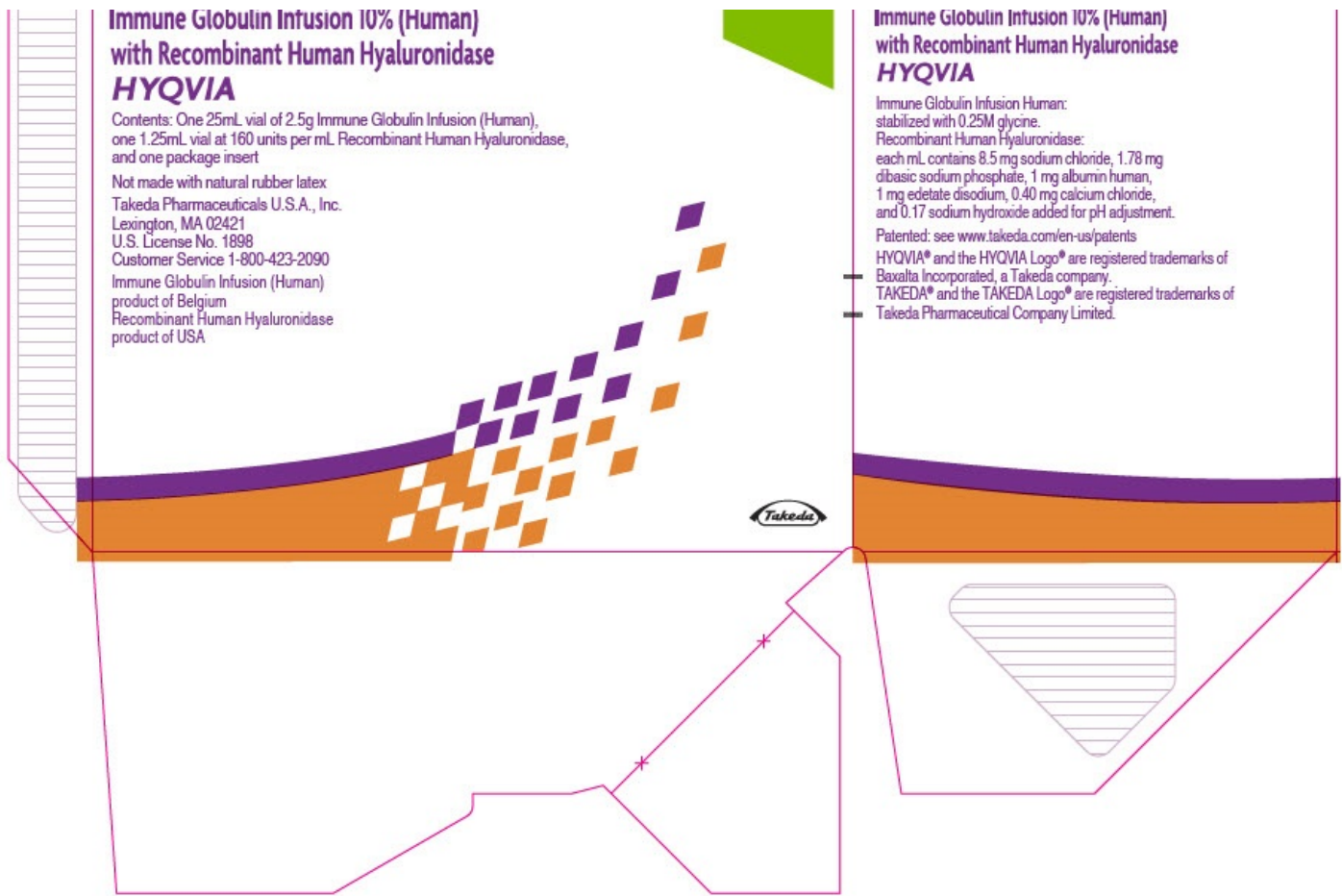
No preservative

Rx Only

2.5 g/
25 mL

Takeda





PRINCIPAL DISPLAY PANEL - 5 g/50 mL Vial Label

Immune Globulin Infusion 10% (Human)

Component of HYQVIA

Single-Use Vial

Rx Only

Takeda Pharmaceuticals U.S.A., Inc.

Lexington, MA 02421

U.S. License No. 1898

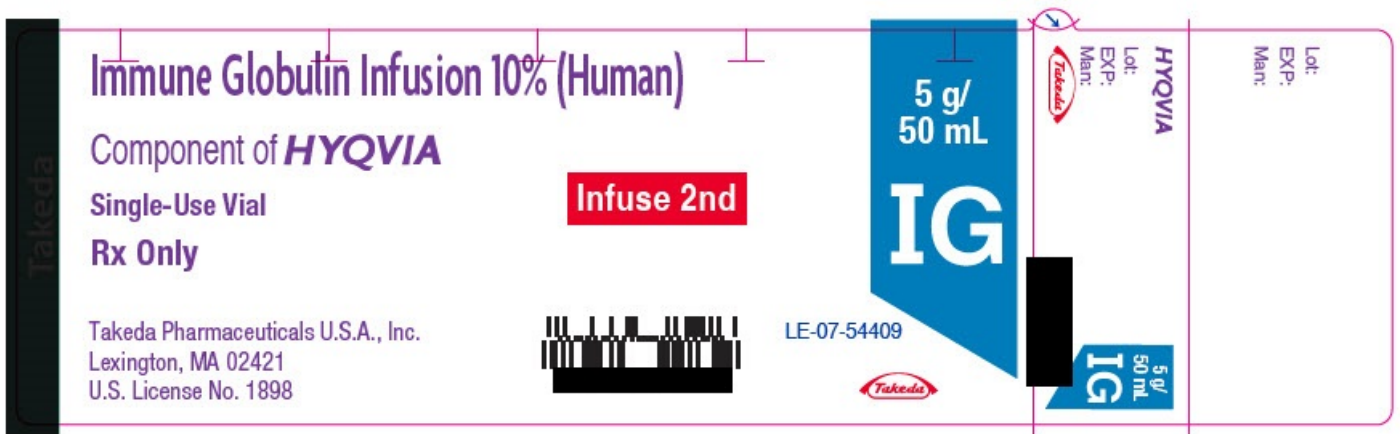
Infuse 2nd

5 g/
50 mL

IG

LE-07-54409

Takeda



PRINCIPAL DISPLAY PANEL - 2.5 mL Vial Label

Recombinant Human Hyaluronidase

Component of HYQVIA

Single-Use Vial

Rx Only

Takeda Pharmaceuticals U.S.A., Inc.
Lexington, MA 02421

Infuse 1st

HY

2.5 mL
160 units per mL

Takeda



PRINCIPAL DISPLAY PANEL - 5 g/50 mL Kit Carton

Immune Globulin Infusion 10% (Human)
with Recombinant Human Hyaluronidase
HYQVIA

For Subcutaneous Administration Only.

Single-use dual vial unit

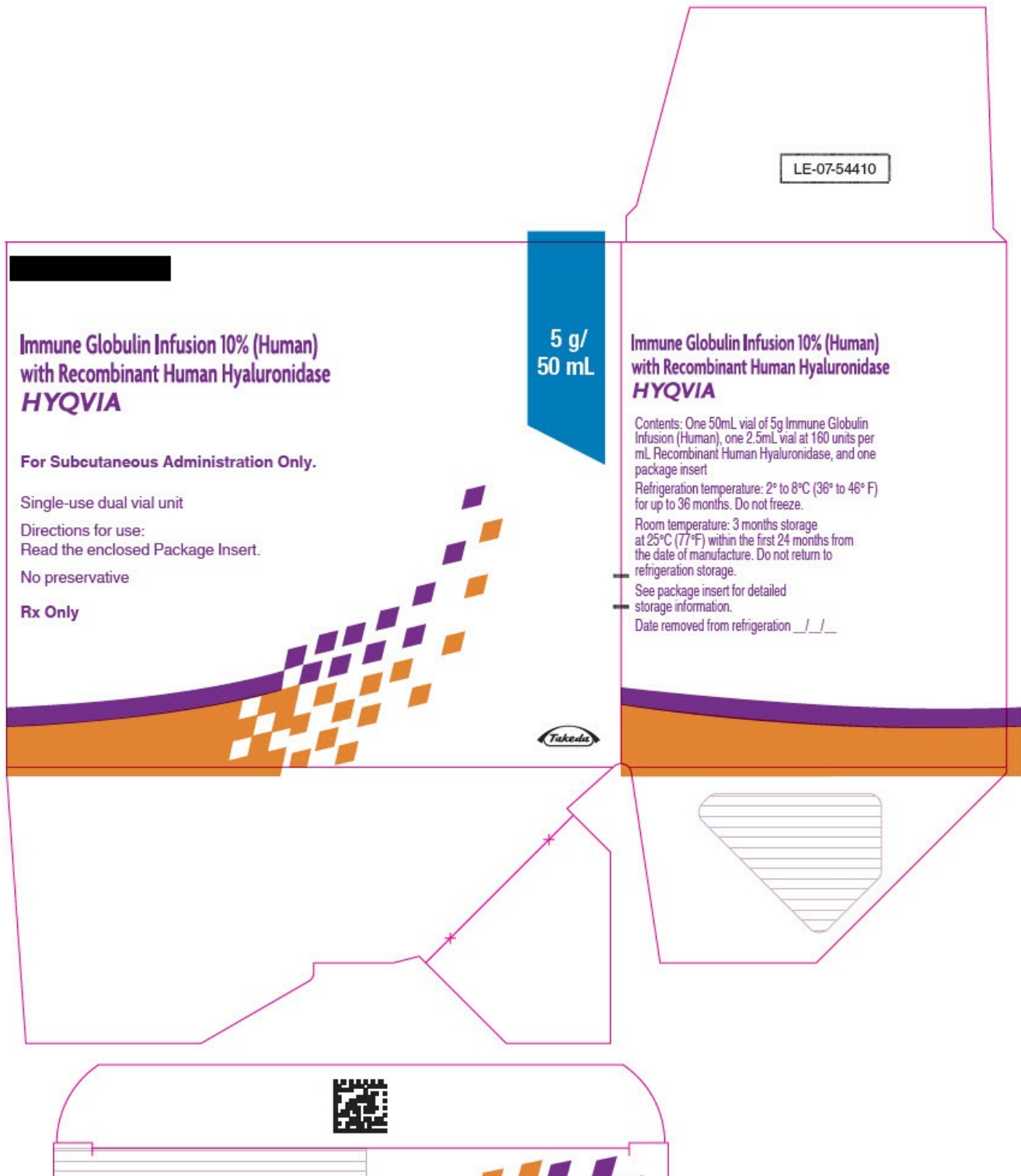
Directions for use:
Read the enclosed Package Insert.

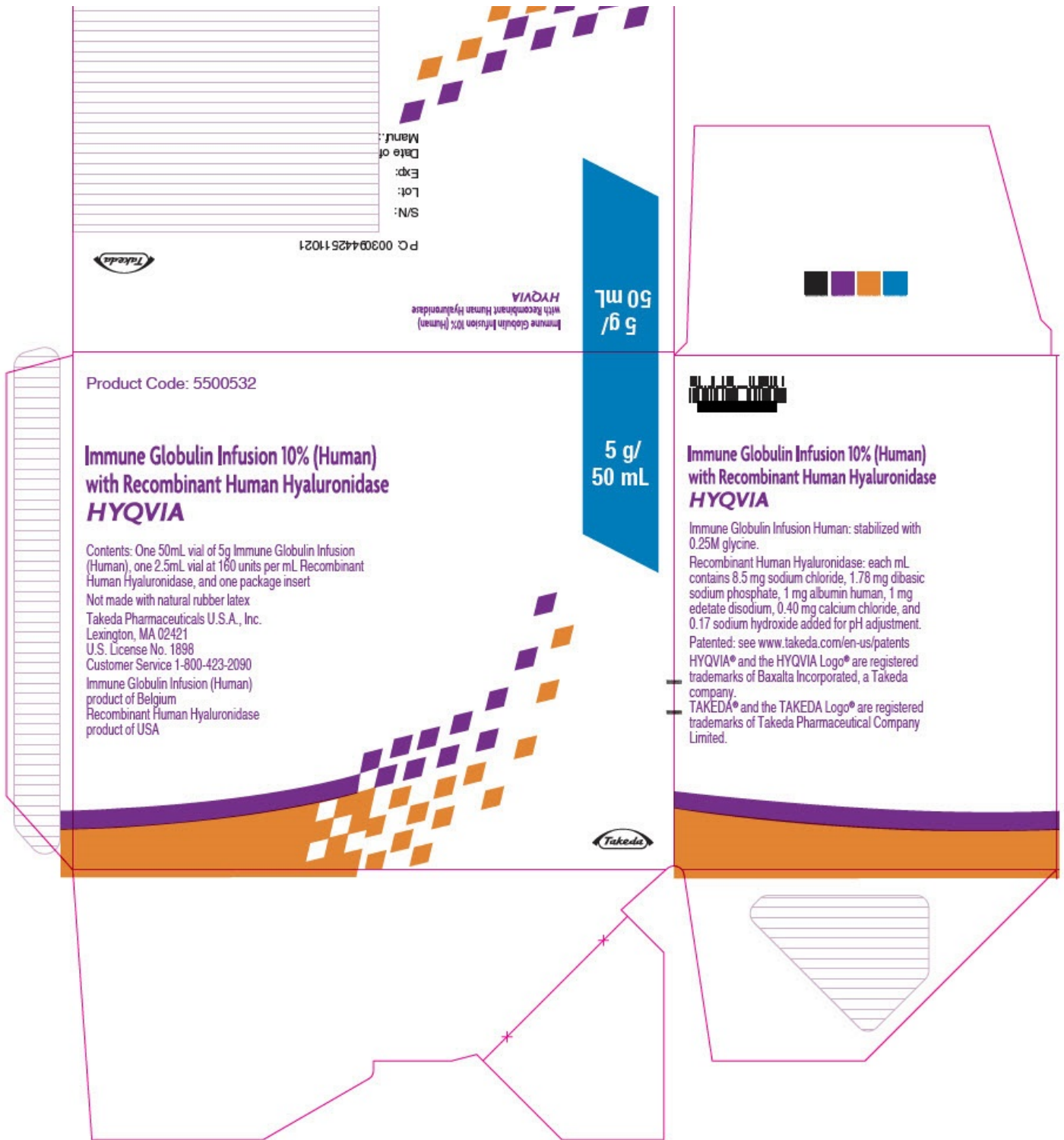
No preservative

Rx Only

5 g/
50 mL

Takeda





PRINCIPAL DISPLAY PANEL - 10 g/100 mL Vial Label

Immune Globulin Infusion 10% (Human)

Component of HYQVIA

Single-Use Vial

Rx Only

Takeda Pharmaceuticals U.S.A., Inc.

Lexington, MA 02421
U.S. License No. 1898

Infuse 2nd

10 g/
100 mL

IG

LE-07-54412

Takeda

Immune Globulin Infusion 10% (Human)
Component of **HYQVIA**
Single-Use Vial
Rx Only
Takeda Pharmaceuticals U.S.A., Inc.
Lexington, MA 02421
U.S. License No. 1898

Infuse 2nd

LE-07-54412

10 g/
100 mL
IG

Lot:
Expiry date:
Mfg date:

HYQVIA
Lot:
Expiry date:
Mfg date:
Takeda NDC [REDACTED]

HYQVIA
Lot:
Expiry date:
Mfg date:
Takeda NDC [REDACTED]

PRINCIPAL DISPLAY PANEL - 5 mL Vial Label

Recombinant Human Hyaluronidase

Component of HYQVIA

Single-Use Vial

Rx Only

Takeda Pharmaceuticals U.S.A., Inc.
Lexington, MA 02421

Infuse 1st

5 mL
160 units per mL

HY

Takeda



PRINCIPAL DISPLAY PANEL - 10 g/100 mL Kit Carton

Immune Globulin Infusion 10% (Human)
with Recombinant Human Hyaluronidase
HYQVIA

For Subcutaneous Administration Only.

Single-use dual vial unit

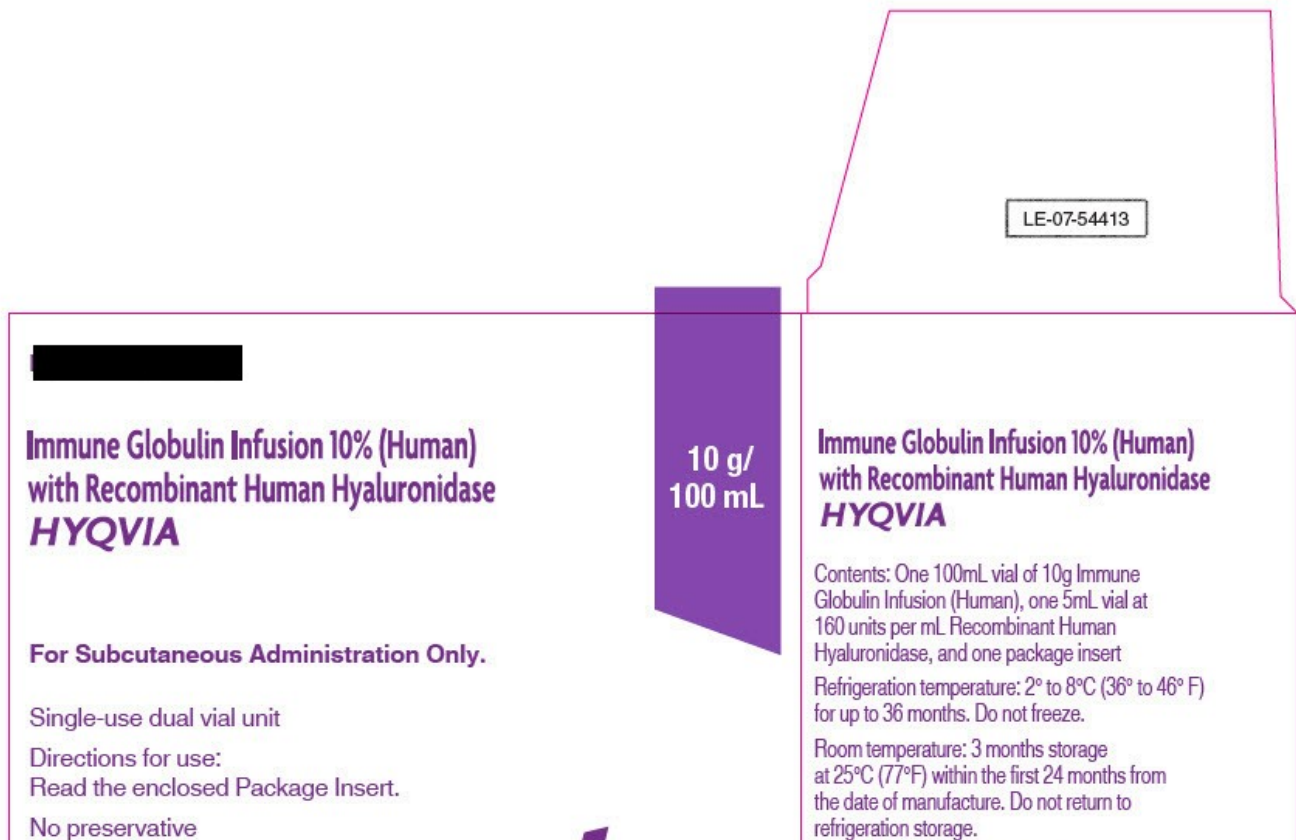
Directions for use:
Read the enclosed Package Insert.

No preservative

Rx Only

10 g/
100 mL

Takeda



Rx Only

See package insert for detailed storage information.

Date removed from refrigeration ___/___/___



SN:
Lot:
Exp:
Date of
Manuf.:

PC: 00309442512028



**Immune Globulin Infusion 10% (Human)
with Recombinant Human Hyaluronidase
HYQVIA**

10 g/
100 mL



Product Code: 5500533

Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase HYQVIA

Contents: One 100mL vial of 10g Immune Globulin Infusion (Human), one 5mL vial at 160 units per mL Recombinant Human Hyaluronidase, and one package insert

Not made with natural rubber latex

Takeda Pharmaceuticals U.S.A., Inc.
Lexington, MA 02421
U.S. License No. 1898
Customer Service 1-800-423-2090

Immune Globulin Infusion (Human)
product of Belgium
Recombinant Human Hyaluronidase
product of USA

10 g/
100 mL



Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase HYQVIA

Immune Globulin Infusion Human:
stabilized with 0.25M glycine.

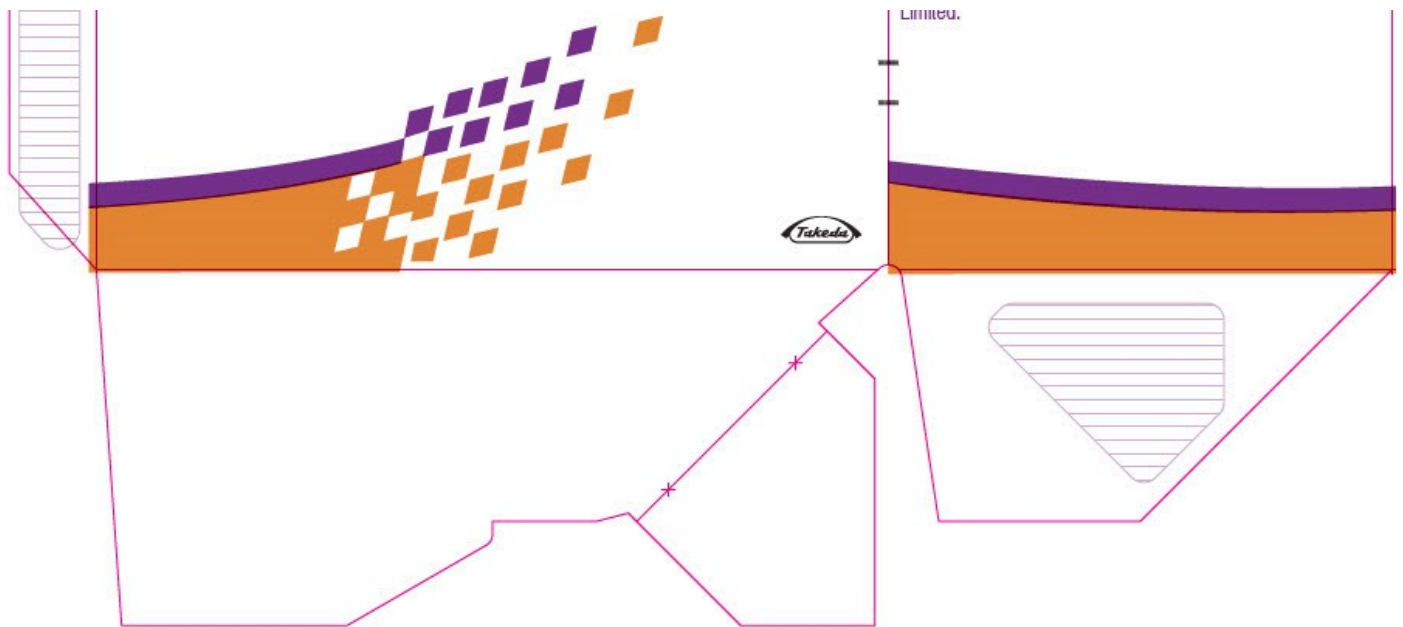
Recombinant Human Hyaluronidase:
each mL contains 8.5 mg sodium chloride, 1.78 mg dibasic sodium phosphate, 1 mg albumin human, 1 mg edetate disodium, 0.40 mg calcium chloride, and 0.17 sodium hydroxide added for pH adjustment.

Patented: see www.takeda.com/en-us/patents

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PRINCIPAL DISPLAY PANEL - 10 mL Vial Label

Recombinant Human Hyaluronidase

Component of HYQVIA

Single-Use Vial

Rx Only

Takeda Pharmaceuticals U.S.A., Inc.
Lexington, MA 02421

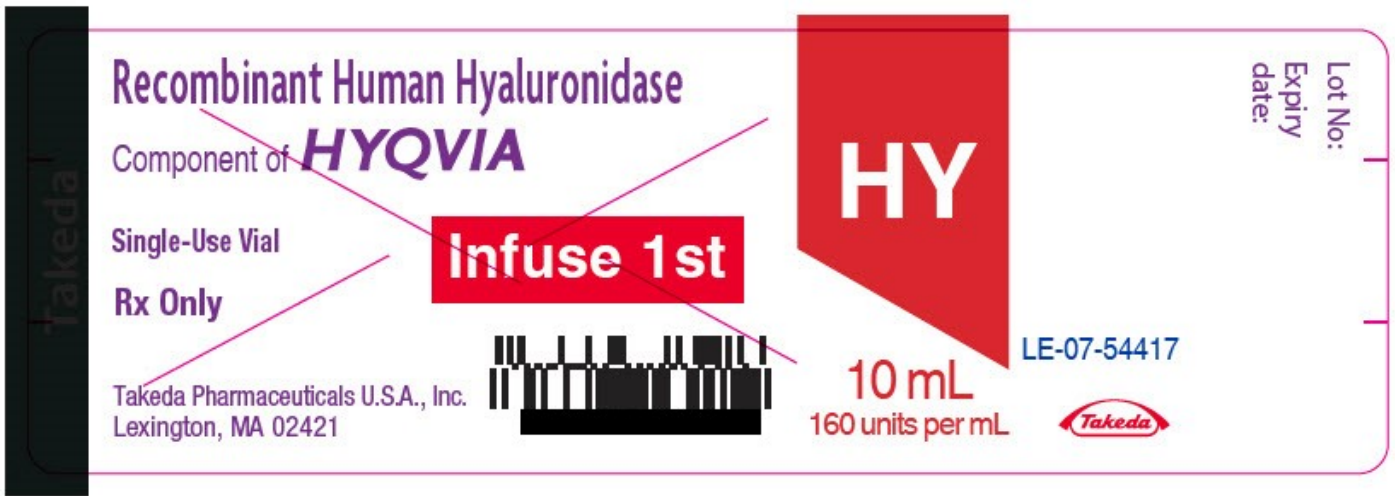
Infuse 1st

HY

10 mL
160 units per mL

LE-07-54417

Takeda



PRINCIPAL DISPLAY PANEL - 15 mL Vial Label

Recombinant Human Hyaluronidase

Component of HYQVIA

Single-Use Vial

Rx Only

Takeda Pharmaceuticals U.S.A., Inc.
Lexington, MA 02421

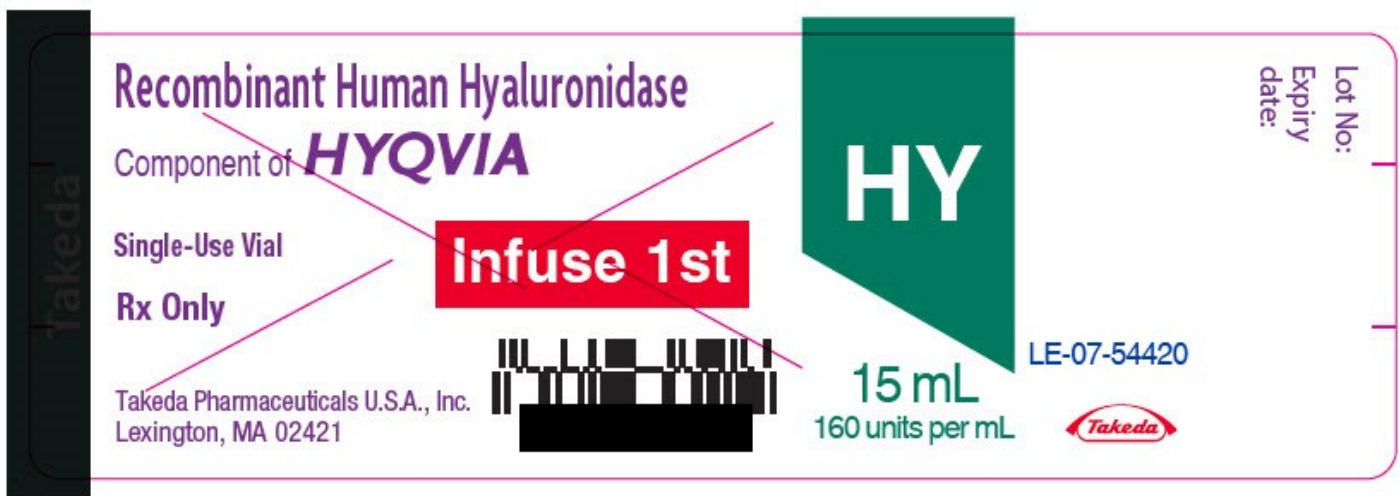
Infuse 1st

HY

15 mL
160 units per mL

LE-07-54420

Takeda



HYQVIA

immune globulin infusion 10% (human) with recombinant human hyaluronidase kit

Product Information

Product Type	PLASMA DERIVATIVE	Item Code (Source)	NDC:83703-038
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83703-038-02	1 in 1 CARTON; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 VIAL, GLASS	25 mL
Part 2	1 VIAL, GLASS	1.25 mL

Part 1 of 2

IMMUNE GLOBULIN INFUSION (HUMAN), 10%

human immunoglobulin g solution

Product Information

Item Code (Source)	NDC:0944-2715
Route of Administration	SUBCUTANEOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HUMAN IMMUNOGLOBULIN G (UNII: 66Y330CJHS) (HUMAN IMMUNOGLOBULIN G - UNII:66Y330CJHS)	HUMAN IMMUNOGLOBULIN G	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCINE (UNII: TE7660XO1C)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0944-	25 mL in 1 VIAL, GLASS; Type 9: Other Type of Part 3 Combination		

2715-25	Product (e.g., Drug/Device/Biological Product)		
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125402	09/12/2014	

Part 2 of 2

RECOMBINANT HUMAN HYALURONIDASE

hyaluronidase (human recombinant) solution

Product Information

Item Code (Source)	NDC:0944-2720
Route of Administration	SUBCUTANEOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYALURONIDASE (HUMAN RECOMBINANT) (UNII: 743QUY4VD8) (HYALURONIDASE (HUMAN RECOMBINANT) - UNII:743QUY4VD8)	HYALURONIDASE (HUMAN RECOMBINANT)	160 [USP'U] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
ALBUMIN HUMAN (UNII: ZIF514RVZR)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0944-2720-03	1.25 mL in 1 VIAL, GLASS; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125402	09/12/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125402	09/12/2014	

HYQVIA

immune globulin infusion 10% (human) with recombinant human hyaluronidase kit

Product Information

Product Type	PLASMA DERIVATIVE	Item Code (Source)	NDC:83703-039
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83703-039-02	1 in 1 CARTON; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 VIAL, GLASS	50 mL
Part 2	1 VIAL, GLASS	2.5 mL

Part 1 of 2

IMMUNE GLOBULIN INFUSION (HUMAN), 10%

human immunoglobulin g solution

Product Information

Item Code (Source)	NDC:0944-2716
Route of Administration	SUBCUTANEOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HUMAN IMMUNOGLOBULIN G (UNII: 66Y330CJHS) (HUMAN IMMUNOGLOBULIN G - UNII:66Y330CJHS)	HUMAN IMMUNOGLOBULIN G	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCINE (UNII: TE7660XO1C)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0944-2716-05	50 mL in 1 VIAL, GLASS; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125402	06/04/2012	

Part 2 of 2

RECOMBINANT HUMAN HYALURONIDASE

hyaluronidase (human recombinant) solution

Product Information

Item Code (Source)	NDC:0944-2721
Route of Administration	SUBCUTANEOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYALURONIDASE (HUMAN RECOMBINANT) (UNII: 743QUY4VD8) (HYALURONIDASE (HUMAN RECOMBINANT) - UNII:743QUY4VD8)	HYALURONIDASE (HUMAN RECOMBINANT)	160 [USP'U] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
ALBUMIN HUMAN (UNII: ZIF514RVZR)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:0944-2721-03	2.5 mL in 1 VIAL, GLASS; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125402	09/12/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125402	09/12/2014	

HYQVIA

immune globulin infusion 10% (human) with recombinant human hyaluronidase kit

Product Information

Product Type	PLASMA DERIVATIVE	Item Code (Source)	NDC:83703-040
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83703-040-02	1 in 1 CARTON; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 VIAL, GLASS	100 mL
Part 2	1 VIAL, GLASS	5 mL

Part 1 of 2

IMMUNE GLOBULIN INFUSION (HUMAN), 10%

human immunoglobulin g solution

Product Information

Item Code (Source)	NDC:0944-2717
Route of Administration	SUBCUTANEOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HUMAN IMMUNOGLOBULIN G (UNII: 66Y330CJHS) (HUMAN IMMUNOGLOBULIN G - UNII:66Y330CJHS)	HUMAN IMMUNOGLOBULIN G	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCINE (UNII: TE7660XO1C)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0944-2717-10	100 mL in 1 VIAL, GLASS; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125402	06/04/2012	

Part 2 of 2**RECOMBINANT HUMAN HYALURONIDASE**

hyaluronidase (human recombinant) solution

Product Information

Item Code (Source)	NDC:0944-2722
Route of Administration	SUBCUTANEOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYALURONIDASE (HUMAN RECOMBINANT) (UNII: 743QUY4VD8) (HYALURONIDASE (HUMAN RECOMBINANT) - UNII:743QUY4VD8)	HYALURONIDASE (HUMAN RECOMBINANT)	160 [USP'U] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
ALBUMIN HUMAN (UNII: ZIF514RVZR)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

CALCIUM CHLORIDE (UNII: M4I0D6VV5M)

SODIUM HYDROXIDE (UNII: 55X04QC32I)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0944-2722-03	5 mL in 1 VIAL, GLASS; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125402	09/12/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125402	09/12/2014	

HYQVIA

immune globulin infusion 10% (human) with recombinant human hyaluronidase kit

Product Information

Product Type	PLAS MA DERIVATIVE	Item Code (Source)	NDC:83703-041
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83703-041-02	1 in 1 CARTON; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 VIAL, GLASS	200 mL
Part 2	1 VIAL, GLASS	10 mL

Part 1 of 2

IMMUNE GLOBULIN INFUSION (HUMAN), 10%

human immunoglobulin g solution

Product Information

Item Code (Source)	NDC:0944-2718
Route of Administration	SUBCUTANEOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HUMAN IMMUNOGLOBULIN G (UNII: 66Y330CJHS) (HUMAN IMMUNOGLOBULIN G - UNII:66Y330CJHS)	HUMAN IMMUNOGLOBULIN G	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCINE (UNII: TE7660XO1C)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0944-2718-20	200 mL in 1 VIAL, GLASS; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125402	06/04/2012	

Part 2 of 2

RECOMBINANT HUMAN HYALURONIDASE

hyaluronidase (human recombinant) solution

Product Information

Item Code (Source)	NDC:0944-2723
Route of Administration	SUBCUTANEOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYALURONIDASE (HUMAN RECOMBINANT) (UNII: 743QUY4VD8) (HYALURONIDASE (HUMAN RECOMBINANT) - UNII:743QUY4VD8)	HYALURONIDASE (HUMAN RECOMBINANT)	160 [USP'U] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
ALBUMIN HUMAN (UNII: ZIF514RVZR)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0944-2723-03	10 mL in 1 VIAL, GLASS; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125402	09/12/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125402	09/12/2014	

HYQVIA

immune globulin infusion 10% (human) with recombinant human hyaluronidase kit

Product Information

Product Type	PLASMA DERIVATIVE	Item Code (Source)	NDC:83703-042
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83703-042-02	1 in 1 CARTON; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
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Part 1	1 VIAL, GLASS	300 mL
Part 2	1 VIAL, GLASS	15 mL

Part 1 of 2

IMMUNE GLOBULIN INFUSION (HUMAN), 10%

human immunoglobulin g solution

Product Information

Item Code (Source)	NDC:0944-2719
Route of Administration	SUBCUTANEOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HUMAN IMMUNOGLOBULIN G (UNII: 66Y330CJHS) (HUMAN IMMUNOGLOBULIN G - UNII:66Y330CJHS)	HUMAN IMMUNOGLOBULIN G	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCINE (UNII: TE7660XO1C)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0944-2719-30	300 mL in 1 VIAL, GLASS; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125402	06/04/2012	

Part 2 of 2

RECOMBINANT HUMAN HYALURONIDASE

hyaluronidase (human recombinant) solution

Product Information

Item Code (Source)	NDC:0944-2724
Route of Administration	SUBCUTANEOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYALURONIDASE (HUMAN RECOMBINANT) (UNII: 743QUY4VD8) (HYALURONIDASE (HUMAN RECOMBINANT) - UNII:743QUY4VD8)	HYALURONIDASE (HUMAN RECOMBINANT)	160 [USP'U] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
ALBUMIN HUMAN (UNII: ZIF514RVZR)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0944-2724-03	15 mL in 1 VIAL, GLASS; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125402	09/12/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125402	09/12/2014	

Labeler - Bamboo US BidCo LLC (119087615)