

Item Number: 0752226		Version: 1		Swatches	
Profile: 0402215_1_VL_Drwg		Technical Specification: 0402215_TSIE38		pms287li	pms544c
Artwork Dimensions/Size: 120 x 70 mm				pms361c	Colorshift
Graphics House: 104551696 / 402103872 / SGK München					
Date: 28Oct2020				Visible / Not Printed*	
OPTIONAL: Artwork Approver outside the Shire Management System:				Dieline	Technical Info
Role:	Name:	Signature:	Date:	 Confidential Property of Takeda	
			Body Text Size 6 pt	Code ITF 2/5 752226	Datamatrix Code NA
				Pharmacode NA	RSS / GS1-128 Code NA
					Code 3 of 9 NA
					GTIN / EAN-13 Code NA

* Color not present in printed material.

Baxter	
ARTISS	
2 ml	
Solutions for Sealant · Deep frozen · Ready-to-use after thawing	
For epilepsial use.	
● = <u>Component 1 = Sealer Protein Solution (1 ml)</u> Active substances: Human Fibrinogen (as clottable protein), 91 mg/ml; Aprotinin, 3000 KIU/ml.	
● = <u>Component 2 = Thrombin Solution (1 ml)</u> Active substances: Human Thrombin, 4 IU/ml; Calcium Chloride, 40 µmol/ml.	
Contain trace amount of Heparin Sodium derived from animal origin (porcine)	
ARTISS contains Human Factor XIII co-purified with Human Fibrinogen in a range of 0.6 – 5 IU/ml.	
For epilepsial (Topical) use.	
Do not inject intravascularly.	
1 ml of sealer protein solution, frozen, and 1 ml of Thrombin Solution, frozen, in a single-use double-chamber syringe with a tip-cap.	
Store and transport frozen (at ≤ -20°C). Keep the syringe in the outer carton in order to protect from light.	
Use the thawed solutions within 14 days. Do not refreeze or refrigerate after thawing.	
Contents were sterilized and packaged under aseptic conditions.	
0752226	
ARTISS 2 ml	
Baxter	

Item Number: 0752228		Version: 1		Swatches	
Profile: 0402215_1_VL_Drwg		Technical Specification: 0402215_TSIE38		pms287li	pms544c
Artwork Dimensions/Size: 120 x 70 mm				pms red032c	Colorshift
Graphics House: 104552021 / 402103905 / SGK München					
Date: 28Oct2020				Visible / Not Printed*	
OPTIONAL: Artwork Approver outside the Shire Management System:				Dieline	Technical Info
Role:	Name:	Signature:	Date:	 Confidential Property of Takeda	
			Body Text Size 6 pt	Code ITF 2/5 752228	Datamatrix Code NA
				Pharmacode NA	RSS / GS1-128 Code NA
					Code 3 of 9 NA
					GTIN / EAN-13 Code NA

* Color not present in printed material.

Baxter	
ARTISS	
4 ml	
Solutions for Sealant · Deep frozen · Ready-to-use after thawing	
For epilepsial use.	
● = <u>Component 1 = Sealer Protein Solution (2 ml)</u> Active substances: Human Fibrinogen (as clottable protein), 91 mg/ml; Aprotinin, 3000 KIU/ml.	
● = <u>Component 2 = Thrombin Solution (2 ml)</u> Active substances: Human Thrombin, 4 IU/ml; Calcium Chloride, 40 µmol/ml.	
Contain trace amount of Heparin Sodium derived from animal origin (porcine)	
ARTISS contains Human Factor XIII co-purified with Human Fibrinogen in a range of 0.6 – 5 IU/ml.	
For epilepsial (Topical) use.	
Do not inject intravascularly.	
2 ml of sealer protein solution, frozen, and 2 ml of Thrombin Solution, frozen, in a single-use double-chamber syringe with a tip-cap.	
Store and transport frozen (at ≤ -20°C). Keep the syringe in the outer carton in order to protect from light.	
Use the thawed solutions within 14 days. Do not refreeze or refrigerate after thawing.	
Contents were sterilized and packaged under aseptic conditions.	
0752228	
	ARTISS 4 ml
	Baxter

Item Number: 0752230		Version: 1		Swatches															
Profile: 0402215_1_VL_Drwg		Technical Specification: 0402215_TSIE38		pms287li	pms544c														
Artwork Dimensions/Size: 120 x 70 mm				pms313c	Colorshift														
Graphics House: 104551632 / 402103843 / SGK München																			
Date: 27Oct2020				Visible / Not Printed*															
OPTIONAL: Artwork Approver outside the Shire Management System:				Dieline	Technical Info														
Role:	Name:	Signature:	Date:	 Confidential Property of Takeda															
			<table border="1"> <tr> <td>Body Text Size</td> </tr> <tr> <td>6 pt</td> </tr> </table>	Body Text Size	6 pt	<table border="1"> <tr> <td>Code ITF 2/5</td> <td>Datamatrix Code</td> <td>RSS / GS1-128 Code</td> </tr> <tr> <td>752230</td> <td>NA</td> <td>NA</td> </tr> <tr> <td>Pharmacode</td> <td>Code 3 of 9</td> <td>GTIN / EAN-13 Code</td> </tr> <tr> <td>NA</td> <td>NA</td> <td>NA</td> </tr> </table>	Code ITF 2/5	Datamatrix Code	RSS / GS1-128 Code	752230	NA	NA	Pharmacode	Code 3 of 9	GTIN / EAN-13 Code	NA	NA	NA	
Body Text Size																			
6 pt																			
Code ITF 2/5	Datamatrix Code	RSS / GS1-128 Code																	
752230	NA	NA																	
Pharmacode	Code 3 of 9	GTIN / EAN-13 Code																	
NA	NA	NA																	

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Baxter	
ARTISS	10 ml
Solutions for Sealant · Deep frozen · Ready-to-use after thawing For epilepsial use.	
● = <u>Component 1 = Sealer Protein Solution (5 ml)</u> Active substances: Human Fibrinogen (as clottable protein), 91 mg/ml; Aprotinin, 3000 KIU/ml. ● = <u>Component 2 = Thrombin Solution (5 ml)</u> Active substances: Human Thrombin, 4 IU/ml; Calcium Chloride, 40 µmol/ml.	
Contain trace amount of Heparin Sodium derived from animal origin (porcine) ARTISS contains Human Factor XIII co-purified with Human Fibrinogen in a range of 0.6 – 5 IU/ml. For epilepsial (Topical) use. Do not inject intravascularly. 5 ml of sealer protein solution, frozen, and 5 ml of Thrombin Solution, frozen, in a single-use double-chamber syringe with a tip-cap. Store and transport frozen (at ≤ -20°C). Keep the syringe in the outer carton in order to protect from light. Use the thawed solutions within 14 days. Do not refreeze or refrigerate after thawing.	
Contents were sterilized and packaged under aseptic conditions.	Lot: Mfg.: EXP.: Lot: EXP.:
0752230	ARTISS 10 ml 