0752231_V4.pdf 1 14.10.21 09:40

Techn. Check PDD OK
20.10.2021
Heinz Klampfer

Item Number: 0752231	**Version:** 4	
Profile: 0402054_4_UC_Drwg	**Technical Specification:** 0402054	
Artwork Dimensions/Size: 145 x 30 x 200 mm		
Graphics House: 105923836 / 402509218 / SGK München		
Date: 14Oct2021		
OPTIONAL: Artwork Approver outside the Shire Management System:		
Role:	**Name:**	**Signature:**

Swatches	
PANTONE 287 C	Cyan
Magenta	Yellow
Black	Varnish
Visible / Not Printed*	
Dieline	Technical Info
Date:	Takeda Confidential Property of Takeda

* Color not present in printed material.

Body Text Size: 8 pt

Code ITF 2/5: 752231	Datamatrix Code: NA	RSS / GS1-128 Code: (01)05413765590795
Pharmacode: NA	Code 3 of 9: NA	GTIN / EAN-13 Code: NA

0752231

Artiss 10 ml
Solutions for Sealant
Deep frozen

(01)05413765590795

Baxter

10 ml

10 ml

Contents:
1 prefilled double-chamber syringe with two deep-frozen solutions for epileseonal use.
1 set of sterile accessory devices (2 joining pieces and 4 application cannulas
For epilesional (topical) use
Do not inject intravascularly.
Read package leaflet before use.
Keep out of the reach and sight of children.
Contain trace amount of Heparin Sodium
derived from animal origin (porcine).
Store and transport frozen (at ≤ -20°C). Keep the syringe in the outer carton in order to protect from light.
Any unused product or waste material should be disposed of in accordance with local requirements.
Subject to medical prescription. ARTISS is intended for Hospital Use Only by suitably experienced physicians or surgeons.
Use the thawed solutions within 14 days. Do not refreeze or refrigerate after thawing.

10 ml

Active Substances:
Human Fibrinogen, Human Thrombin, Aprotinin, Calcium Chloride
ARTISS contains Human Factor XIII co-purified with Human Fibrinogen in a range of 0.6 – 5 IU/ml.
One chamber contains:
Component 1 – Sealer Protein Solution 5 ml
Human Fibrinogen (as clottable protein) 91 mg/ml
Synthetic Aprotinin 3000 KIU/ml
Excipients: Human Albumin, L-Histidine, Nicotinamide, Polysorbate 80, Sodium Citrate Dihydrate and Water for Injections
One chamber contains:
Component 2 – Thrombin Solution 5 ml
Active Substances:
Human Thrombin 4 IU/ml
Calcium Chloride 40 µmol/ml
Excipients: Human Albumin, Sodium Chloride and Water for Injections

10 ml

Baxter

Artiss 10 ml
Solutions for Sealant
Deep frozen, with Prefilled PRIMA syringe
Ready to use after thawing

Baxter

10 ml

Artiss 10 ml
Solutions for Sealant
Deep frozen

Baxter

Artiss 10 ml
Solutions for Sealant
Deep frozen, with Prefilled PRIMA syringe
Ready to use after thawing

10 ml

MAL15055038AZ
Controlled medicine
Jauhi dari kanak-kanak

Product Registration Holder:
Baxter Healthcare (M) Sdn Bhd, B-21-3A, LEVEL 21,
THE ASCENT, PARADIGM,
NO.1, JALAN SS7/26A,
KELANA JAYA,
47301 PETALING JAYA
MALAYSIA

SIN14719P

Takeda Manufacturing Austria AG
Industriestrasse 67
A-1221, Vienna, Austria

Lot:
MFG.:
EXP.:

Artiss 10 ml
Solutions for Sealant
Deep frozen

10 ml