0756142_V1.pdf 1 15.12.21 07:58

BRAILLE EXPLANATIONS AND TRANSLATIONS

immunine
#600

Item Number: 0756142	**Version:** 1		**Swatches**
Profile: 0402338_2_UC_Drwg **Technical Specification:** 0402338 **Artwork Dimensions/Size:** 135 x 40.5 x 71 mm			Black / PANTONE Orange 021 C PANTONE 7688 C / PANTONE 185 C Varnish*
Graphics House: 106451043 / 402659497 / SGK München **Date:** 15Dec2021			**Visible / Not Printed***
OPTIONAL: Artwork Approver outside the Shire Management System:			Dieline / Technical Info Braille
Role:	**Name:**	**Signature:**	**Date:**

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* Color not present in printed material.

Body Text Size	Code ITF 2/5	Datamatrix Code	RSS / GS1-128 Code
7 pt	756142	NA	NA
	Pharmacode NA	**Code 3 of 9** NA	**GTIN / EAN-13 Code** NA

Lot:
Mfg:
EXP:

0756142

IMMUNINE 600 IU

Human Coagulation Factor IX
1 vial with powder for solution for injection contains 600 IU human coagulation factor IX.
1 ml of solution contains approximately 120 IU human coagulation factor IX, when reconstituted with 5 ml of water for injections.
Excipients:
Powder: Sodium chloride, Sodium citrate
Solvent: Sterilised Water for Injections

Slow **(max. 2 ml/min)** intravenous injection.
Intravenous use. For single use only. Use reconstituted solution immediately (within 3 hours). Stored between 2 – 8°C. Do not freeze. Keep the powder vial in the outer carton in order to protect from light. Product may be stored at room temperature (up to 25 °C) for a period of 3 months. Discard residues.
Keep out of the reach and sight of children.

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MAL20061477AZ
Jauhi dari kanak-kanak
Controlled medicine/ubat terkawal

Product registration holder:
Takeda Malaysia Sdn. Bhd.
Unit TB-L13-1, Level 13,
Tower B, Plaza 33, No.1,
Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya,
Selangor Malaysia

Read the package leaflet before use.

Manufacturer:
Takeda Manufacturing Austria AG,
Industriestrasse 67
1221 Vienna

IMMUNINE 600 IU

Powder and solvent for solution for injection or infusion

Human Coagulation Factor IX
1 vial with powder for solution for injection contains 600 IU human coagulation factor IX.
1 ml of solution contains approximately 120 IU human coagulation factor IX, when reconstituted with 5 ml of water for injections.
Excipients:
Powder: Sodium chloride, Sodium citrate
Solvent: Sterilised Water for Injections

Taken out of refrigerator on: .....

Slow **(max. 2 ml/min)** intravenous injection.
Intravenous use. For single use only. Use reconstituted solution immediately (within 3 hours). Stored between 2 – 8°C. Do not freeze. Keep the powder vial in the outer carton in order to protect from light. Product may be stored at room temperature (up to 25 °C) for a period of 3 months. Discard residues.
Keep out of the reach and sight of children.

End of 3 months room temperature storage at/or below up to 25°C: .....

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Contents:
1 vial of IMMUNINE 600 IU
1 vial of 5 ml Sterilised Water for Injections
1 transfer needle
1 aeration needle
1 filter needle
1 disposable needle
1 disposable syringe (5 ml)
1 winged infusion set