

BRaille EXPLANATIONS AND TRANSLATIONS

i m m u n a t e z z 2 5 0

immunate #250

Item Number: 0756136Version: 1

Profile: 0402340_2_UC_DrwgTechnical Specification: 0402340

Artwork Dimensions/Size: 147 x 51 x 84.5 mm

Graphics House: 106451373 / 402659607 / SGK München

Date: 16Dec2021

OPTIONAL: Artwork Approver outside the Shire Management System:

Role:Name:Signature:

Swatches

BlackPANTONE 7688 C

PANTONE 185 CVarnish*

Visible / Not Printed*

DielineTechnical Info

Braille

Date:

Takeda

Confidential Property of Takeda

Body Text Size

7 pt

Code ITF 2/5756136

Datamatrix CodeNA

PharmacodeNA

RSS / GS1-128 CodeNA

Code 3 of 9NA

GTIN / EAN-13 Code0642621070750

0756136

0 642621 070750

IMMUNATE

250 IU

Powder and solvent for solution for injection

Active Substance: Human Coagulation Factor VIII, VHSD (Vapour Heated and Solvent Detergent) treated
1 vial provides: 250 IU human coagulation factor VIII and 190 IU von Willebrand Factor activity (VWF:RCo);
appr. 50 IU FVIII/ml and 38 IU VWF/ml after reconstitution.
Human Albumin, Glycine, Sodium chloride, Sodium citrate, Lysine HCl, Calcium chloride
Store at 2°C – 8°C (in a refrigerator). Do not freeze. Store in the original package in order to protect from light. For single
use only. For intravenous use. Use the reconstituted solution immediately (within 3 hours). Slow (max. 2 ml/min) i. v.
injection. Discard residues.
Can be stored at room temperature (≤25°C) for a period not exceeding 6 months.
Taken out of refrigerator on:
End of 6 months room temperature storage:

Jauhi dari kanak-kanak
Controlled medicine/ubat terkawal

Read package leaflet before use.
Keep out of the reach and sight of
children.
Medicinal product subject to
medicinal prescription.
This product contains animal part(s)
(porcine/pig)

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

MAL20061559AZ

Manufactured by:
Takeda Manufacturing Austria AG
Industriestrasse 67
1221 Vienna, Austria

0756136

0 642621 070750

IMMUNATE

250 IU

Powder and solvent for solution for injection

Active Substance: Human Coagulation Factor VIII, VHSD (Vapour Heated and Solvent Detergent) treated
1 vial provides: 250 IU human coagulation factor VIII and 190 IU von Willebrand Factor activity (VWF:RCo);
appr. 50 IU FVIII/ml and 38 IU VWF/ml after reconstitution.
Human Albumin, Glycine, Sodium chloride, Sodium citrate, Lysine HCl, Calcium chloride
Store at 2°C – 8°C (in a refrigerator). Do not freeze. Store in the original package in order to protect from light. For single
use only. For intravenous use. Use the reconstituted solution immediately (within 3 hours). Slow (max. 2 ml/min) i. v.
injection. Discard residues.
Can be stored at room temperature (≤25°C) for a period not exceeding 6 months.
Taken out of refrigerator on:
End of 6 months room temperature storage:

Contents:
1 vial of IMMUNATE 250 IU
1 vial with Sterilised Water for
Injections (5 ml)
1 transfer/filter set
1 disposable syringe (5 ml)
1 disposable needle
1 winged infusion set