5255401_v1.pdf 1 14/02/25 10:13 AM

BRAILLE EXPLANATIONS AND TRANSLATIONS

adynovate
#750

Item Number: 5255401	**Version:** 1	**Swatches**	
Profile: 0402418_1_UC_Drwg	**Technical Specification:** TO0402418	Varnish*	Twinlack/Security Pattern*
Artwork Dimensions/Size: 158.8 x 63.5 x 55.6 mm		C M Y K	
Graphics House: Perigord		**Visible / Not Printed***	
Date: 14FEB2025		Dieline	Technical Info
OPTIONAL: Artwork Approver outside the Takeda Management System:			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
8.0 pt	NA	NA	01010101010104
	Pharmacode	**Code 3 of 9**	**GTIN / EAN-13 Code**
	NA	5255401	NA

ADYNOVATE 750IU
powder and solvent for solution for injection
Rurioctocog alfa pegol

Note the date when the carton is removed from refrigeration and placed at room temperature storage, not to exceed 30°C (86°F):

Date: _____

Storage: Refrigeration temperature: 2°C to 8°C (36°F to 46°F). Do not freeze. Room temperature: up to 30°C (86°F) for 3 months, not to exceed the expiration date. Do not place the product back in the refrigerator once removed from refrigerated storage.
Do not exceed expiration date.

Administer within 3 hours of reconstitution
Components not made with natural rubber latex.

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ADYNOVATE 750IU
powder and solvent for solution for injection
Rurioctocog alfa pegol

Contents: Rurioctocog alfa pegol [Antihemophilic Factor (Recombinant), PEGylated] and 2 mL of Sterile Water for Injection preassembled in BAXJECT III system, one infusion set, one syringe, two sterile alcohol swabs, one package insert and two adhesive bandages.

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ADYNOVATE 750IU
powder and solvent for solution for injection
Rurioctocog alfa pegol

Single use only

For Intravenous Administration After Reconstitution Only

Lyophilized powder for reconstitution

ADYNOVATE and diluent preassembled in BAXJECT III system

Rx Only

Controlled medicine/Ubat terkawal
MAL21056012AZ
Keep medicine out of reach of children.
Jauhi dari kanak-kanak
Scan for Package Insert

Takeda

ADYNOVATE 750IU
powder and solvent for solution for injection
Rurioctocog alfa pegol

Contains no preservative. Reconstituted product contains the following excipients: tris, calcium chloride, mannitol, sodium chloride, trehalose, glutathione, histidine, and polysorbate 80.

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powder and solvent for solution for injection
Rurioctocog alfa pegol

ADYNOVATE and BAXJECT III system products of U.S.; Sterile Water for Injection, USP, product of Germany; Infusion set product of Belgium.

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Product Registration Holder:
Takeda Malaysia Sdn Bhd (Company No: 868989-K),
Unit TB-L 13-1, Level 13, Tower B, Plaza 33, No.1,
Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya
Malaysia

Manufacturer:
Baxalta Manufacturing Sàrl, Route de Pierre-à-Bot 111,
CH-2000 Neuchâtel, Switzerland
Labeling, secondary packaging & batch release site:
Baxalta US Inc, 1700 Rancho Conejo Boulevard,
Thousand Oaks CA 91320, United States

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