

BRaille EXPLANATIONS AND TRANSLATIONS

ADYNOVATE
#1000

Item Number: 5255402		Version: 1		Swatches	
Profile: 0402418_1_UC_Drwg		Technical Specification: T00402418		Varnish* C M Y K	
Artwork Dimensions/Size: 158.8 x 63.5 x 55.6 mm				Visible / Not Printed*	
Graphics House: Perigord				Dieline	
Date: 14FEB2025				Technical Info	
OPTIONAL: Artwork Approver outside the Takeda Management System:				Braille	
Role:	Name:	Signature:	Date:		
Body text size		Code ITF 2/5	Datamatrix Code	RSS / GS1-128 Code	
8.0 pt		NA	NA	010101010104	
		Pharmacode	Code 3 of 9	GTIN / EAN-13 Code	
		NA	5255402	NA	

* Color not present in printed material.

5255402

**STERILE
NONPYROGENIC**

ADYNOVATE and diluent preassembled
in BAXJECT III system

Lot No: _____

Mfg Date: _____

Exp Date: _____

ADYNOVATE 1000IU
powder and solvent for solution for injection
Ruriotocog alfa pegol

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powder and solvent for solution for injection
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Single use only

ADYNOVATE 1000IU
powder and solvent for solution for injection
Ruriotocog 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.

Contents: Ruriotocog 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.

For Intravenous Administration After Reconstitution Only

Lyophilized powder for reconstitution.

ADYNOVATE and diluent preassembled in BAXJECT III system

Rx Only

Controlled medicine/Ubat terkawal
MAL21056013AZ

Keep medicine out of reach of children.
Jauhi dari kanak-kanak

Scan for Package Insert

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

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

010101010104

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