

**BRaille EXPLANATIONS AND TRANSLATIONS**

**adynovate  
#1500**

<b>Item Number:</b> 5255403		<b>Version:</b> 1		<b>Swatches</b>	
<b>Profile:</b> 0402418_1_UC_Drwg		<b>Technical Specification:</b> T00402418		Varnish* Twinlack/Security Pattern*	
<b>Artwork Dimensions/Size:</b> 158.8 x 63.5 x 55.6 mm				C M Y K	
<b>Graphics House:</b> Perigord					
<b>Date:</b> 14FEB2025				Visible / Not Printed*	
<b>OPTIONAL:</b> Artwork Approver outside the Takeda Management System:				Dieline Technical Info	
<b>Role:</b>	<b>Name:</b>	<b>Signature:</b>	<b>Date:</b>	Braille	
				Confidential Property of Takeda	
				Body text size	
				8.0 pt	
				Code ITF 2/5 NA	
				Datamatrix Code NA	
				RSS / GS1-128 Code 010101010104	
				Pharmacode NA	
				Code 3 of 9 5255403	
				GTIN / EAN-13 Code NA	

5255403

ADYNOVATE 1500IU  
powder and solvent for solution for injection  
Ruriotocog alfa pegol

**STERILE  
NONPYROGENIC**

ADYNOVATE and diluent preassembled  
in BAXJECT III system

Lot No:  
Mfg Date:  
Exp Date:

**ADYNOVATE 1500IU**  
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.

**ADYNOVATE 1500IU**  
powder and solvent for solution for injection  
Ruriotocog alfa pegol

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.

**ADYNOVATE 1500IU**  
powder and solvent for solution for injection  
Ruriotocog alfa pegol

**For Intravenous Administration After Reconstitution Only**

Lyophilized powder for reconstitution.

ADYNOVATE and diluent preassembled in BAXJECT III system

Rx Only

Controlled medicine/Ubat terkawal  
MAL21056014AZ  
Keep medicine out of reach of children.  
Jauhi dari kanak-kanak  
Scan for Package Insert

**ADYNOVATE 1500IU**  
powder and solvent for solution for injection  
Ruriotocog alfa pegol

Single use only

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

**ADYNOVATE 1500IU**  
powder and solvent for solution for injection  
Ruriotocog alfa pegol

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