Rurioctocog Alfa Pegol (PEGylated Recombinant Human FVIII) -250 IU, 500 IU, 750 IU, 1000 IU, 1500 IU & 2000 IU.

Adynovate® Lyophilized Powder for Solution for Injection

ABBREVIATED PRESCRIBING INFORMATION

Before prescribing and for complete details please refer to the India Package Insert. **Presentation:** Adynovate® vials contain Human Coagulation Factor VIII (rDNA), Rurioctocog Alfa Pegol (PEGylated Recombinant Human FVIII) powder and solvent (2 or 5 ml sterilized water for injection). After reconstitution, nominally 250 IU/2 ml, 500 IU/2 ml, 750 IU/ 2ml, 1000 IU/2 ml, 1500 IU/ 2 ml and 2000 IU/5 ml per vial. **Indication:** Adynovate® is a human antihemophilic factor indicated in children and adults with Hemophilia A (congenital factor VIII deficiency) for: • On-demand treatment and control of bleeding episodes • Perioperative management • Routine prophylaxis to reduce the frequency of bleeding episodes **Limitation of Use:** Adynovate® is not indicated for the treatment of von Willebrand disease. **Dosage and Administration:** Treatment should be under the supervision of a physician experienced in the treatment of Haemophilia. The dose and duration of the substitution therapy depend on the severity of the factor VIII (FVIII) deficiency, on the location and extent of the bleeding and on the patient's clinical condition. For guidance on prophylactic and on demand treatment dosing, please refer to the Summary of Product Characteristics (SmPC). After reconstitution, it should be administered via the intravenous route at a maximum rate of 10 ml/min. **Contraindications:** Adynovate® is contraindicated in patients who have had prior anaphylactic reaction to Adynovate®, to the parent molecule (Advate), mouse or hamster protein, or excipients of Adynovate® (e.g. Tris, Mannitol, Trehalose, Glutathione, and/or Polysorbate 80). **Special warnings and precautions for use: Hypersensitivity Reactions:** Hypersensitivity reactions are possible with Adynovate®. Allergic-type hypersensitivity reactions, including anaphylaxis, have been reported with other recombinant antihemophilic factor VIII products, including the parent molecule, Advate. **Hypervolemia/Hemodilution:** Formation of neutralizing antibodies (inhibitors) to factor VIII can occur following administration of Adynovate®. Monitor patients regularly for the development of factor VIII inhibitors by appropriate clinical observations and laboratory tests. **Interactions:** No interactions of Adynovate® product with other medicinal products have been reported. **Fertility, Pregnancy and Lactation:** There are no data with Adynovate® use in pregnant women to inform a drug-associated risk. There is no information regarding the presence of Adynovate® in human milk, the effect on the breastfed infant, or the effects on milk production. **Undesirable Effects:** Very common (≥1/10):Headache.

Common (≥1/100 to <1/10): Dizziness, Diarrhoea, Nausea and Rash. Uncommon (≥1/1000 to <1/100): FVIII Inhibition (in previously treated patients), hypersensitivity, ocular hyperaemia, flushing, drug eruption, eosinophil count increased and infusion related reaction.

Name and Address of Imported and Marketed by:
Takeda Biopharmaceuticals India Pvt. Ltd,
Khasra No. 1/24, 25, 3/1/1, Gala No. 1A-1F, 2A-2E,
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Suspected Adverse Reactions should be reported at: AE.India@takeda.com.
Consumer Care No: 00080 0050 4087

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