ADYNOVI® ▼ (rurioctocog alfa pegol) powder and solvent for solution for injection

PRESCRIBING INFORMATION FOR GREAT BRITAIN (ENGLAND, SCOTLAND, WALES)

Refer to the Summary of Product Characteristics (SmPC) before prescribing

Presentation: ADYNOVI vials contain human coagulation factor VIII (rDNA), rurioctocog alfa pegol powder and solvent (2 or 5 ml sterilised water for injection). After reconstitution, nominally 250 IU/2 ml, 500 IU/2 ml, 1000 IU/2 ml, and 2000 IU/5 ml per vial.

Indication: Treatment and prophylaxis of bleeding in patients 12 years and above with haemophilia A (congenital factor VIII deficiency).

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 SmPC. Should be administered via the intravenous route at a maximum rate of 10 ml/min.

Contraindications: Hypersensitivity to the active substance, to the parent molecule octocog alfa or to any of the excipients. Known allergic reaction to mouse or hamster protein. **Warnings and precautions:** Traceability: Name and the batch number of the administered product should be clearly recorded. Hypersensitivity: Allergic type hypersensitivity reactions are possible with ADYNOVI. If symptoms occur, patients should be advised to discontinue use of the medicinal product immediately and contact their physician. In case of shock, standard medical treatment for shock should be implemented. Inhibitors: Development of neutralising antibodies (inhibitors) may occur in patients with haemophilia A treated with FVIII, including with ADYNOVI. If such inhibitors occur, the condition will manifest itself as an insufficient clinical response. In such cases, management of such patients should be directed by physicians with experience in the care of haemophilia and FVIII inhibitors. All patients should be monitored for the development of inhibitors especially following any product switch, if plasma levels are not attained or if bleeding is not controlled with an appropriate dose. Immune tolerance induction (ITI): No clinical data for use of ADYNOVI in ITI are available. Cardiovascular events: In patients with existing cardiovascular risk factors, substitution therapy with FVIII may increase the cardiovascular risk. Catheter-related complications: If a central venous access device (CVAD) is required, risk of CVAD-related complications including local infections, bacteraemia and catheter site thrombosis should be considered. Excipient-related considerations: ADYNOVI contains up to 12.42 mg sodium per vial, equivalent to 0.62% of the World Health Organisation (WHO) recommended maximum daily intake of 2 g sodium for an adult. Depending on the body weight and posology, the patient could receive more than one vial. This should be taken into consideration by patients on a controlled sodium diet. It is strongly recommended that every time that ADYNOVI is administered to a patient, the name and batch number of ADYNOVI is recorded in order to maintain a link between the patient and the batch of ADYNOVI. Paediatric population: The listed warnings and precautions apply both to adults and children (12 to 18 years of age).

Interactions: None reported.

Fertility, pregnancy and lactation: Based on the rare occurrence of haemophilia A in women, experience regarding the use of FVIII during pregnancy and breastfeeding is not available. Therefore, FVIII should be used during pregnancy and lactation only if clearly indicated.

Undesirable effects: Very common (≥1/10): Headache. Common (≥1/100 to <1/10): dizziness, diarrhoea, nausea, rash and urticaria. Uncommon (≥1/1000 to <1/100): FVIII inhibition (in previously treated patients), hypersensitivity, ocular hyperaemia, flushing, rash pruritic, eosinophil count increased and infusion related reaction. **Refer to the SmPC for details on full side effect profile and interactions**. **Legal classification:** POM.

Marketing authorisation (MA) numbers: 250 IU/2ml: PLGB 34078/0020; 500 IU/2ml: PLGB 34078/0022; 1000 IU/2ml: PLGB 34078/0017; 2000 IU/5ml: PLGB 34078/0019.

UK basic NHS price: 85p per IU.

Business responsible for sale and supply: Takeda UK Ltd, 1 Kingdom Street, London, W2 6BD, United Kingdom.

PI approval code: pi-02305.

Date of preparation: May 2023.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Adverse events should be reported. Reporting forms and information can be found at: www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Takeda at: AE.GBR-IRL@takeda.com

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PRESCRIBING INFORMATION FOR NORTHERN IRELAND

Refer to the Summary of Product Characteristics (SmPC) before prescribing

Presentation: ADYNOVI vials contain human coagulation factor VIII (rDNA), rurioctocog alfa pegol powder and solvent (2 or 5 ml sterilised water for injection). After reconstitution, nominally 250 IU/2ml, 500 IU/2ml, 1000 IU/2ml, and 2000 IU/5ml per vial.

Indication: Treatment and prophylaxis of bleeding in patients 12 years and above with haemophilia A (congenital factor VIII deficiency).

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 SmPC. Should be administered via the intravenous route at a maximum rate of 10 ml/min.

Contraindications: Hypersensitivity to the active substance, to the parent molecule octocog alfa or to any of the excipients. Known allergic reaction to mouse or hamster protein.

Warnings and precautions: Traceability: Name and the batch number of the administered product should be clearly recorded. Hypersensitivity: Allergic type hypersensitivity reactions are possible with ADYNOVI. If symptoms occur, patients should be advised to discontinue use of the medicinal product immediately and contact their physician. In case of shock, standard medical treatment for shock should be implemented. Inhibitors: Development of neutralising antibodies (inhibitors) may occur in patients with haemophilia A treated with FVIII, including with ADYNOVI. If such inhibitors occur, the condition will manifest itself as an insufficient clinical response. In such cases, it is recommended that a specialised haemophilia centre be contacted. All patients should be monitored for the development of inhibitors especially following any product switch, if plasma levels are not attained or if bleeding is not controlled with an appropriate dose. Immune tolerance induction (ITI): No clinical data for use of ADYNOVI in ITI are available. Cardiovascular events: In patients with existing cardiovascular risk factors, substitution therapy with FVIII may increase the cardiovascular risk. Catheter- related complications: If a central venous access device (CVAD) is required, risk of CVAD-related complications including local infections, bacteraemia and catheter site thrombosis should be considered. Excipient-related considerations: ADYNOVI contains up to 12.42 mg sodium per vial, equivalent to 0.62% of the World Health Organisation (WHO) recommended maximum daily intake of 2 g sodium for an adult. Depending on the body weight and posology, the patient could receive more than one vial. This should be taken into consideration by patients on a controlled sodium diet. It is strongly recommended that every time that ADYNOVI is administered to a patient, the name and batch number of ADYNOVI is recorded in order to maintain a link between the patient and the batch of ADYNOVI. Paediatric population: The listed warnings and precautions apply both to adults and children (12 to 18 years of age).

Interactions: None reported.

Fertility, pregnancy and lactation: Based on the rare occurrence of haemophilia A in women, experience regarding the use of FVIII during pregnancy and breastfeeding is not available. Therefore, FVIII should be used during pregnancy and lactation only if clearly indicated.

Undesirable effects: *Very common* (≥1/10): Headache. *Common* (≥1/100 to <1/10): dizziness, diarrhoea, nausea, rash and urticaria. *Uncommon* (≥1/1000 to <1/100): FVIII inhibition (in previously treated patients), hypersensitivity, ocular hyperaemia, flushing, rash pruritic, eosinophil count increased and infusion related reaction.

Refer to the SmPC for details on full side effect profile and interactions.

Legal classification: POM.

Marketing authorisation numbers: 250 IU/2ml: EU/1/17/1247/002; 500 IU/2ml: EU/1/17/1247/006; 1000 IU/2ml: EU/1/17/1247/010; 2000 IU/5ml: EU/1/17/1247/014.

UK basic NHS price: 85p per IU.

Business responsible for sale and supply: Takeda UK Limited, 1 Kingdom Street, London, W2 6BD, United Kingdom.

PI approval code: pi-02205

Date of preparation: November 2022

▼ This medicinal product is subject to additional monitoring.

Adverse events should be reported. Reporting forms and information can be found at: www.mhra.gov.uk/yellowcard.

Adverse events should also be reported to Takeda at: AE.GBR-IRL@takeda.com