**VEYVONDI® ▼ (vonicog alfa) 650 IU and 1300 IU 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:** Each vial contains nominally 650 IU and 1300 IU vonicog alfa powder. After reconstitution with 5 mL or 10 mL, respectively, of solvent provided, VEYVONDI contains approximately 130 IU/mL of vonicog alfa. **Indication:** VEYVONDI is indicated in adults (age 18 and older) with von Willebrand disease (VWD), when desmopressin (DDAVP) treatment alone is ineffective or not indicated, for the treatment of haemorrhage and surgical bleeding and prevention of surgical bleeding. VEYVONDI should not be used in the treatment of Haemophilia A. **Dosage and administration:** Treatment of VWD should be supervised by a physician experienced in the treatment of haemostatic disorders. Dosage and frequency of administration must be individualised according to clinical judgement and based on the patient´s weight, type and severity of the bleeding episodes/surgical intervention and based on monitoring of appropriate clinical and laboratory measures. Dose based on body weight may require adjustment in underweight or overweight patients (refer to the SmPC for dosing calculations). Generally, 1 IU/kg of VEYVONDI raises the plasma VWF:RCo by 0.02 IU/mL (2%). If the patient's baseline plasma FVIII:C level is <40% or is unknown and in all situations where a rapid correction of haemostasis should be achieved, it is necessary to administer a recombinant factor VIII (rFVIII) product with the first infusion of VEYVONDI, in order to achieve a haemostatic plasma level of FVIII:C. However, if an immediate rise in FVIII:C is not necessary, or if the baseline FVIII:C level is sufficient to ensure haemostasis, the physician may decide to omit the co-administration of rFVIII at the first infusion with VEYVONDI. In case of major bleeding events or major surgeries requiring repeated, frequent infusions, monitoring of FVIII:C levels is recommended, to decide if rFVIII is required for subsequent infusions to avoid excessive rise of FVIII:C. For guidance on the treatment of bleeding episodes (on-demand treatment) and prevention of bleeding / haemorrhage and treatment in case of elective surgery, please refer to the SmPC. VEYVONDI should be administered via the intravenous route up to a maximum rate of 4 mL/min. If any reaction, such as tachycardia, occurs that might be related to the administration of the product, the rate of infusion should be reduced or stopped as required by the clinical condition of the patient. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Known allergic reaction to mouse or hamster proteins. **Warnings and precautions:** In actively bleeding patients it is recommended to co-administer a FVIII product with VEYVONDI as a first line treatment and depending on the FVIII activity levels. Traceability: Name and the batch number of the administered product should be clearly recorded. Hypersensitivity reactions: Hypersensitivity reactions (including anaphylaxis) have occurred. Patients should be closely monitored and carefully observed for any symptoms throughout the infusion period. If signs and symptoms occur, patients should immediately discontinue use of VEYVONDI and be provided with appropriate supportive care. VEYVONDI contains traces of mouse immunoglobulin and hamster proteins, and rFVIII. Thrombosis and embolism: There is a risk of occurrence of thrombotic events, particularly in patients with known clinical or laboratory risk factors for thrombosis including low ADAMTS13 levels. Therefore, patients at risk have to be monitored for early signs of thrombosis, and prophylaxis measures against thromboembolism should be instituted according to current recommendations and standard of care. In patients requiring frequent doses of VEYVONDI in combination with rFVIII, FVIII:C activity should be monitored to avoid sustained excessive FVIII:C plasma levels, which may increase the risk of thrombotic events. Any FVIII that would be administered along with VEYVONDI should be a pure FVIII product. A combination with a FVIII product containing von Willebrand factor (VWF) would pose an additional risk of thrombotic events. Inhibitors: Patients with VWD, especially type 3, may develop neutralising antibodies (inhibitors) to VWF. If the expected plasma levels of VWF:RCo are not attained, or if bleeding is not controlled with an appropriate dose, an appropriate assay should be performed to determine if a VWF inhibitor is present. In patients with high levels of anti-VWF antibodies, von Willebrand factor therapy may not be effective and other therapeutic options should be considered. Patients who have high-titre binding antibodies (due to previous treatment with plasma-derived VWF) may require a higher dose to overcome the binding antibody effect and such patients could be managed clinically by administration of higher doses of VEYVONDI based on the PK data for each individual patient. Excipient-related considerations: VEYVONDI contains 5.2 mg sodium in each 650 IU vial or 10.4 mg sodium in each 1300 IU vial. To be taken into consideration by patients on a controlled sodium diet. **Interactions:** None known. **Fertility, pregnancy and lactation:** Pregnancy: Experience in the treatment of pregnant or breast-feeding women is not available. VEYVONDI should be administered to pregnant women only if clearly indicated, taking into consideration that delivery confers an increased risk of haemorrhagic events in these patients. Breast-feeding: It is unknown whether VEYVONDI is excreted in human milk. VEYVONDI should be administered to lactating VWF-deficient women only if clearly indicated. Healthcare professionals should balance the potential risks and only prescribe VEYVONDI if needed. Fertility: The effects of VEYVONDI on fertility have not been established. **Undesirable effects:** *Common* (≥1/100 to <1/10): Dizziness, vertigo, dysgeusia, tremor, tachycardia, deep venous thrombosis (*serious*), hypertension, hot flush, vomiting, nausea, pruritus generalised, chest discomfort, infusion site paraesthesia, electrocardiogram T wave inversion and heart rate increased. *Other serious undesirable effects* (unknown frequency): Anaphylactic reaction, infusion-related reaction (including tachycardia, flushing, rash, dyspnoea, blurred vision). **Refer to the SmPC for details on full side effect profile and interactions**. **Legal classification:** POM. **UK basic NHS price:** 92p per IU. **Marketing authorisation numbers:** 650 IU: PLGB 34078/0031; 1300 IU: PLGB 34078/0032. **Business Responsible for Sale and Supply:** Takeda UK

Ltd, 1 Kingdom Street, London, W2 6BD, United Kingdom**.** **PI approval code:** pi-01806. **Date of preparation:** December 2021.

▼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

**VEYVONDI® ▼ (vonicog alfa) 650 IU and 1300 IU powder and solvent for solution for injection**
**PRESCRIBING INFORMATION FOR NORTHERN IRELAND**
**Refer to the Summary of Product Characteristics (SmPC) before prescribing**

**Presentation:** Each vial contains nominally 650 IU and 1300 IU vonicog alfa powder. After reconstitution with 5 mL or 10 mL, respectively, of solvent provided, VEYVONDI contains approximately 130 IU/mL of vonicog alfa. **Indication:** VEYVONDI is indicated in adults (age 18 and older) with von Willebrand disease (VWD), when desmopressin (DDAVP) treatment alone is ineffective or not indicated, for the treatment of haemorrhage and surgical bleeding and prevention of surgical bleeding. VEYVONDI should not be used in the treatment of Haemophilia A. **Dosage and administration:** Treatment of VWD should be supervised by a physician experienced in the treatment of haemostatic disorders. Dosage and frequency of administration must be individualised according to clinical judgement and based on the patient´s weight, type and severity of the bleeding episodes/surgical intervention and based on monitoring of appropriate clinical and laboratory measures. Dose based on body weight may require adjustment in underweight or overweight patients (refer to the SmPC for dosing calculations). Generally, 1 IU/kg of VEYVONDI raises the plasma VWF:RCo by 0.02 IU/mL (2%). If the patient's baseline plasma FVIII:C level is <40% or is unknown and in all situations where a rapid correction of haemostasis should be achieved, it is necessary to administer a recombinant factor VIII (rFVIII) product with the first infusion of VEYVONDI, in order to achieve a haemostatic plasma level of FVIII:C. However, if an immediate rise in FVIII:C is not necessary, or if the baseline FVIII:C level is sufficient to ensure haemostasis, the physician may decide to omit the co-administration of rFVIII at the first infusion with VEYVONDI. In case of major bleeding events or major surgeries requiring repeated, frequent infusions, monitoring of FVIII:C levels is recommended, to decide if rFVIII is required for subsequent infusions to avoid excessive rise of FVIII:C. For guidance on the treatment of bleeding episodes (on-demand treatment) and prevention of bleeding / haemorrhage and treatment in case of elective surgery, please refer to the SmPC. VEYVONDI should be administered via the intravenous route up to a maximum rate of 4 mL/min. If any reaction, such as tachycardia, occurs that might be related to the administration of the product, the rate of infusion should be reduced or stopped as required by the clinical condition of the patient. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Known allergic reaction to mouse or hamster proteins. **Warnings and precautions:** In actively bleeding patients it is recommended to co-administer a FVIII product with VEYVONDI as a first line treatment and depending on the FVIII activity levels. Traceability: Name and the batch number of the administered product should be clearly recorded. Hypersensitivity reactions: Hypersensitivity reactions (including anaphylaxis) have occurred. Patients should be closely monitored and carefully observed for any symptoms throughout the infusion period. If signs and symptoms occur, patients should immediately discontinue use of VEYVONDI and be provided with appropriate supportive care. VEYVONDI contains traces of mouse immunoglobulin and hamster proteins, and rFVIII. Thrombosis and embolism: There is a risk of occurrence of thrombotic events, particularly in patients with known clinical or laboratory risk factors for thrombosis including low ADAMTS13 levels. Therefore, patients at risk have to be monitored for early signs of thrombosis, and prophylaxis measures against thromboembolism should be instituted according to current recommendations and standard of care. In patients requiring frequent doses of VEYVONDI in combination with rFVIII, FVIII:C activity should be monitored to avoid sustained excessive FVIII:C plasma levels, which may increase the risk of thrombotic events. Any FVIII that would be administered along with VEYVONDI should be a pure FVIII product. A combination with a FVIII product containing von Willebrand factor (VWF) would pose an additional risk of thrombotic events. Inhibitors: Patients with VWD, especially type 3, may develop neutralising antibodies (inhibitors) to VWF. If the expected plasma levels of VWF:RCo are not attained, or if bleeding is not controlled with an appropriate dose, an appropriate assay should be performed to determine if a VWF inhibitor is present. In patients with high levels of anti-VWF antibodies, von Willebrand factor therapy may not be effective and other therapeutic options should be considered. Patients who have high-titre binding antibodies (due to previous treatment with plasma-derived VWF) may require a higher dose to overcome the binding antibody effect and such patients could be managed clinically by administration of higher doses of VEYVONDI based on the PK data for each individual patient. Excipient-related considerations: VEYVONDI contains 5.2 mg sodium in each 650 IU vial or 10.4 mg sodium in each 1300 IU vial. To be taken into consideration by patients on a controlled sodium diet. **Interactions:** None known. **Fertility, pregnancy and lactation:** Pregnancy: Experience in the treatment of pregnant or breast-feeding women is not available. VEYVONDI should be administered to pregnant women only if clearly indicated, taking into consideration that delivery confers an increased risk of haemorrhagic events in these patients. Breast-feeding: It is unknown whether VEYVONDI is excreted in human milk. VEYVONDI should be administered to lactating VWF-deficient women only if clearly indicated. Healthcare professionals should balance the potential risks and only prescribe VEYVONDI if needed. Fertility: The effects of VEYVONDI on fertility have not been established. **Undesirable effects:** Very common (≥1/10): Headache. *Common* (≥1/100 to <1/10): Dizziness, vertigo, dysgeusia, tremor, tachycardia, deep venous thrombosis (*serious*), hypertension, hot flush, vomiting, nausea, pruritus generalised, chest discomfort, infusion site paraesthesia, electrocardiogram T wave inversion and heart rate increased. *Other serious undesirable effects* (unknown frequency): Anaphylactic reaction, infusion-related reaction (including tachycardia, flushing, rash, dyspnoea, blurred vision). **Refer to the SmPC for details on full side effect profile and interactions**. **Legal classification:** POM. **UK basic NHS price:** 92p per IU. **Marketing authorisation numbers:** 650 IU: EU/1/18/1298/001; 1300 IU: EU/1/18/1298/002. **Business Responsible for Sale and Supply:** Takeda UK Ltd, 1 Kingdom Street, London, W2 6BD, United Kingdom.
**PI approval code:** pi-02204
**Date of preparation:** January 2023

▼ 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

Job code: C-APROM/GB/Vey/0044
Date of preparation: February 2023