OBIZUR ▼ (susoctocog alfa) 500 U 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: 500 U of B domain deleted antihaemophilic factor VIII (rDNA), porcine sequence, susoctocog alfa powder in a vial and solvent in pre-filled syringe (1 ml water for injection).
Indication: Treatment of bleeding episodes in patients with acquired haemophilia caused by antibodies to factor VIII. OBIZUR is indicated in adults.
Dosage and administration: Treatment with OBIZUR should be under the supervision of a physician experienced in the treatment of haemophilia. Treatment monitoring: The product is for in-patient administration only. Requires clinical supervision of the bleeding status of the patient. Dose based on bodyweight may require adjustment in underweight or overweight patients. In the case of major surgical interventions in particular, precise monitoring of the substitution therapy by means of coagulation analysis (plasma factor VIII activity) is indispensable. When using aPTT-based one-stage clotting assay results can be significantly affected by both the type of aPTT reagent and the reference standard. Also, there can be significant discrepancies between assay results obtained by aPTT-based one stage clotting assay and the chromogenic assay according to Ph. Eur. Posology: The dose, frequency, and duration of the therapy with OBIZUR depend on the location, extent and severity of the bleeding episode, target factor FVIII (FVIII) activity, and on the patient´s clinical condition. The recommended initial dose is 200 U/kg body weight, given by intravenous injection - titrate subsequent doses based on clinical response and to maintain target FVIII trough activity. Monitor FVIII activity and clinical condition 30 minutes after the first injection and 3 hours after administering OBIZUR. Monitor FVIII activity immediately prior to and 30 minutes after subsequent doses. Refer to the SmPC guide for dosing and frequency of administration. The total volume of reconstituted OBIZUR should be administered via the intravenous route at a rate of 1 to 2 mL per minute.
Contraindications: Hypersensitivity to the active substance, hamster protein, or to any of the excipients.
Warnings and precautions: Dosing: Initial dosing below the recommended 200 U/kg has been associated with lack of efficacy. Traceability: Name and the batch number of the administered medicinal product should be clearly recorded. Hypersensitivity: Allergic-type hypersensitivity reactions are possible with OBIZUR. The medicinal product contains trace amounts of hamster proteins. Cease treatment and seek medical attention if such reactions occur. Inhibitors: It is recommended to test for anti-rpFVIII antibodies prior to initiation of treatment. Treatment may be started at physician's discretion prior to receiving the result of this test. Treatment decisions can be further supported by monitoring FVIII levels. Inhibitory antibodies against porcine FVIII were detected before and after exposure to OBIZUR. Inhibitor titres of up to 29 Bethesda units were recorded at baseline yet patients responded positively to OBIZUR. Lack of efficacy could be due to inhibitory antibodies to OBIZUR. It is recommended that treatment should be based on clinical judgement and not based on detection of inhibitory antibodies by the Bethesda assay. Anamnestic reactions with rise in human FVIII and/or porcine FVIII inhibitors have also been reported. These anamnestic rises may result in lack of efficacy. There is a lack of clinical information on the development of inhibitory antibodies to OBIZUR following repeated administration. Therefore, OBIZUR must only be administered when considered clinically necessary. Cardiovascular events: In patients with existing cardiovascular risk factors, substitution therapy with FVIII may increase the cardiovascular risk. Thromboembolic Events: High and sustained FVIII activity in blood may predispose to thromboembolic events. Those with pre-existing cardiovascular disease and the elderly are at particular risk. Treatment Monitoring: FVIII activity determined by the chromogenic assay is generally lower than FVIII activity determined by the one stage clotting assay. Measurement of FVIII activity must always be carried out using the same assay methodology on any one patient. The one stage assay is recommended. Sodium content: OBIZUR contains 4.6 mg sodium in 1 mL of reconstituted solution in each vial. Multiple vials must be taken per dose.
Interactions: None reported.
Fertility, pregnancy and lactation: No clinical experience in pregnant or lactating women, therefore OBIZUR should only be used during pregnancy and lactation, if clearly indicated.
Undesirable effects: *Very common* (≥1/10): Anamnestic reaction; *Common* (≥1/100 to <1/10): Positive test for inhibitory antibodies against porcine FVIII. *Other serious undesirable effects:* Hypersensitivity or allergic reactions (which may include angioedema, burning and stinging at the injection site, chills, flushing, generalised urticaria, headache, hives, hypotension, lethargy, nausea, restlessness, tachycardia, tightness of the chest, tingling, vomiting, wheezing) are possible and may progress to severe anaphylaxis (including shock).
Refer to the SmPC for details on full side effect profile and interactions. Basic UK NHS Cost: £2.29 per IU. **Legal Category:** POM. **Marketing Authorisation (MA) Number:** PLGB 34078/0025.
Name and Address of MA Holder: Takeda UK Ltd, 1 Kingdom Street, London, W2 6BD, United Kingdom. **PI approval code:** pi-01602. **Date of preparation:** July 2021.

▼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 UK Ltd. at: AE.GBR-IRL@takeda.com