Information On Dose Calculation

OBIZUR ▼

[antihaemophilic Factor VIII (recombinant), porcine sequence]
500 U powder and solvent for solution for injection
INN: susoctocog alfa

Therapeutic indications

Treatment of bleeding episodes in patients with acquired haemophilia caused by antibodies to Factor VIII.

OBIZUR is indicated in adults.

Antibody and Dosing Considerations:
It is recommended to test for anti-rpFVIII antibodies prior to initiation of treatment with OBIZUR. Treatment may be started at physician's discretion prior to receiving the result of this test. Treatment decisions can be further supported by monitoring factor VIII levels.

Initial dosing below the recommended 200U/kg has been associated with lack of efficacy.

Anamnestic reactions with rise in human factor VIII and/or porcine factor VIII inhibitors have been reported in patients treated with OBIZUR. These anamnestic rises may result in lack of efficacy.

The recommended initial dose is 200 U per kilogram (kg) body weight, given by intravenous injection. Follow the steps below to determine the required number of vials needed for the recommended initial dose of OBIZUR:

Step 1: Calculate recommended initial dose

➤ Initial dose (200 U/kg) x Body weight (kg)

Step 2: Calculate required number of vials needed to administer the dose per step 1

➤ Calculated initial dose (U) ÷ Product strength (500 U/vial)

Example:
For a 70 kg patient, the required number of vials for an initial dose is calculated as follows:

Step 1: 200 U/kg × 70 kg = 14000 U

Step 2: 14000 U ÷ 500 U/vial* = 28 vials

*OBIZUR 500 U powder and solvent for solution for injection susoctocog alfa.

Reporting of suspected adverse reactions.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions to HPRA Pharmacovigilance at www.hpra.ie. Alternatively, adverse events should be reported to Takeda Products Ireland Ltd on 1800 937 970 (freephone from Ireland only) or +44 (0)3333 000181 or via AE.GBR-IRL@takeda.com.

Allergic type reactions may occur. Anamnestic reactions may occur. Please see OBIZUR full accompanying Summary of Product Characteristics for more information.

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NATURE AND CONTENTS OF CONTAINER[1]

One pack of OBIZUR contains 1, 5 or 10 each of the following:

1. Powder vials (type I glass) with a stopper (butyl rubber) and a flip-off seal
2. Pre-filled (type I glass) syringes with a stopper (butyl rubber), a rubber tip cap and a Luer Lock
3. Fluid transfer device with an integral plastic spike

POSOLOGY

- It is recommended to test for anti-rpFVIII antibodies prior to initiation of treatment with OBIZUR. Treatment may be started at physician's discretion prior to receiving the result of this test. Treatment decisions can be further supported by monitoring factor VIII levels.
- The activity of factor VIII and the clinical condition of the patient should be monitored 30 minutes after the first injection, and after three hours
- The activity of factor VIII should be monitored immediately before and 30 minutes after each subsequent dose of OBIZUR
- Subsequent doses and frequency of OBIZUR administration should be based on results of factor VIII activity (to be maintained within recommended limits) and on the clinical response achieved

Type of Bleeding	Mild and Moderate Superficial muscle/ no neurovascular compromise, and joint bleeding	Major moderate to severe intramuscular, retroperitoneal, gastrointestinal, intracranial bleeding
Target Factor VIII Trough Activity (Units per dL or % of normal)	>50%	>80%
Initial Dose (Units per kg)	200	
Subsequent Dose	Titrate subsequent doses based on clinical response and to maintain target factor VIII trough activity	
Frequency and Duration of Subsequent Dosing	Dose every 4 to 12 hours, frequency may be adjusted based on clinical response and measured factor VIII activity	

- Once bleeding has responded to treatment, usually within the first 24 hours, treatment with OBIZUR should be continued with a dose that maintains the trough factor VIII activity at 30%-40% until bleeding is controlled. The maximum blood factor VIII activity must not exceed 200%
- The length of treatment depends on clinical judgement

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EXA/IE/OBI/0005
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This information is provided by Takeda Products Ireland Ltd, the local representative for the Marketing Authorisation Holder Baxalta Innovations GmbH.