

## 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.

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 (U/kg) x Body weight (kg) = Recommended initial dose (U)

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

➤ Recommended initial dose (U) ÷ Product strength (U/vial) = number of vials

#### 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.

▼ 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. See section 4.8 for how to report adverse reactions.

**Allergic type hypersensitivity reactions are possible with OBIZUR. Please refer to the SmPC for further safety information.**

**Please see OBIZUR full accompanying Summary of Product Characteristics for more information.**

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## NATURE AND CONTENTS OF CONTAINER<sup>1</sup>

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

## POSOLGY

- The activity of factor VIII and the clinical condition of the patient should be monitored 30 minutes after the first injection, and three hours after administering OBIZUR
- 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

**Allergic type hypersensitivity reactions are possible with OBIZUR. Please refer to the SmPC for further safety information.**

**Please see OBIZUR full accompanying Summary of Product Characteristics for more information.**

**Reference: 1.** Obizur [Summary of Product Characteristics]. Vienna, Austria: Baxalta Innovations GmbH. Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via: HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +3531 6764971; Fax: +3531 6762517. Website: [www.hpra.ie](http://www.hpra.ie). Adverse events should also be reported to Baxalta Pharmacovigilance on +44 (0) 203 6552430, or by email to [pvuknordic@baxalta.com](mailto:pvuknordic@baxalta.com)