



11 November 2015  
EMA/770206/2015

## Educational brochure and video to be given to healthcare professionals to ensure Obizur is used correctly

Measures will help avoid medication errors

All healthcare professionals who are expected to prescribe and dispense Obizur (susoctocog alfa) will be provided with an educational package to ensure that the medicine is dispensed correctly.

Obizur is a medicine used for the treatment of bleeding episodes in adults with acquired haemophilia, a bleeding disorder caused by the spontaneous development of antibodies that inactivate factor VIII. Factor VIII is one of the proteins needed for normal clotting of the blood.

Obizur is available in vials containing a powder and solvent to make a solution for injection into a vein. It is for hospital use only.

The dose, and how often and for how long it is given, is adjusted depending on the patient's condition and requirements, and the degree of danger posed by the bleeding. During treatment with Obizur, the activity of factor VIII will be monitored and subsequent doses will be calculated on the basis of the clinical response and factor VIII activity. Injections may need to be repeated several times, until the bleeding has resolved.

The unusually high number of vials of Obizur that are needed for one injection may lead to confusion and errors during preparation. This could lead to the patient receiving either too much (overdose) or too little (underdose) of the medicine. Under-dosing may result in insufficient bleeding control.

### Information for healthcare professionals

- When prescribing and preparing Obizur, healthcare professionals should follow the instructions provided in the summary of product characteristics and the educational material for Obizur (brochure and on-line video).
- Obizur is available in vials containing 500 units (U) of susoctocog alfa and the recommended initial dose is 200 U/kg. To calculate how many vials are needed to make up one injection, healthcare professionals should use the following formula:

$$\text{Initial dose (U/kg)} \div \text{Product strength (U/vial)} \times \text{Body weight (kg)} = \text{Number of vials}$$



Example: for a 70 kg subject the number of vials for the recommended initial dose of 200 U/kg is calculated as follows:

$$200 \text{ U/kg} \div 500 \text{ U/vial} \times 70 \text{ kg} = 28 \text{ vials}$$

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

- 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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### More about the medicine

Obizur is a medicine used for the treatment of bleeding episodes in adults with acquired haemophilia, a bleeding disorder caused by the spontaneous development of antibodies that inactivate factor VIII. Factor VIII is one of the proteins needed for normal clotting of the blood.

Obizur contains the active substance susoctocog alfa.

More information on Obizur can be found on the Agency's website: [ema.europa.eu/Find\\_medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports).