

**Package leaflet: Information for the patient. OBIZUR is for in hospital use only and is to be administered by healthcare provider only.**

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

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What OBIZUR is and what it is used for
2. What you need to know before you are given OBIZUR
3. How OBIZUR is given
4. Possible side effects
5. How OBIZUR is stored
6. Contents of the pack and other information

**1. What OBIZUR is and what it is used for**

OBIZUR contains the active substance susoctocog alfa, antihaemophilic factor VIII, porcine sequence. Factor VIII is necessary for the blood to form clots and stop bleedings.

In patients with acquired haemophilia, factor VIII is not working properly because the patient has developed antibodies to his own factor VIII which neutralise this blood clotting factor.

OBIZUR is used for the treatment of bleeding episodes in adults with acquired haemophilia (a bleeding disorder caused by lack of factor VIII activity due to antibody development). These antibodies have less neutralising effect against OBIZUR than against human factor VIII.

OBIZUR restores this missing factor VIII activity and helps blood to form clots at the site of bleeding.

**2. What you need to know before you are given OBIZUR**

The medicine is for in-patient administration only. It requires clinical supervision of the bleeding status of the patient.

**You must not be given OBIZUR:**

- if you are allergic to susoctocog alfa or any of the other ingredients of this medicine (listed in section 6);
- if you are allergic to hamster proteins (trace amounts may be present in OBIZUR arising from the manufacturing process);
- if you have congenital haemophilia A with inhibitors (CHAWI).

If you are not sure, talk to your doctor before you are given this medicine.

## **Warnings and precautions**

Talk to your doctor before you are given OBIZUR.

### Hypersensitivity

There is a rare chance that you may experience an allergic reaction to OBIZUR. You should be aware of the early signs of allergic reactions (see section 4 for signs and symptoms). If any of these symptoms occur, the injection should be stopped. Severe symptoms, including difficulty in breathing and (near) fainting, require emergency treatment in the hospital.

### Inhibitors

Your doctor may check if you have inhibitory antibodies to porcine factor VIII and for increases in these antibodies.

Your doctor will check your blood factor VIII to confirm that enough factor VIII is being given to you. Your doctor will also check if the bleeding is adequately controlled.

### Cardiovascular events

Talk to your doctor if you currently have, or have had cardiovascular disease in the past or if you have a known risk of thrombosis (diseases from blood clots in normal vasculature), because the possibility of developing thromboembolic diseases at high and sustained blood factor VIII levels cannot be excluded.

## **Children and adolescents**

There is no information on the use of OBIZUR in children and adolescents aged under 18 years of age.

## **Other medicines and OBIZUR**

Tell your doctor if you are using, have recently used or might use any other medicines. No interactions of OBIZUR with other medicines are known.

## **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

## **Driving and using machines**

OBIZUR has no influence on your ability to drive and use machines.

## **OBIZUR contains sodium**

This medicine contains 4.6 mg sodium (main component of cooking/table salt) per milliliter once it is made up. This is equivalent to 0.23% of the recommended maximum daily dietary intake of sodium for an adult. Multiple vials must be taken per dose.

Talk to your doctor if you are on a controlled sodium diet.

## **3. How OBIZUR is given**

Treatment with OBIZUR will be conducted by a doctor who is experienced in the care of patients with haemophilia (bleeding disorders).

Your doctor will calculate your dose of OBIZUR (in units or U) depending on your condition and body weight. The frequency and duration of administration will depend on how well OBIZUR is working for you. Usually, the replacement therapy with OBIZUR is a temporary treatment until bleeding is resolved or the antibodies against your own factor VIII are eradicated.

Your doctor will monitor you for antibodies to OBIZUR.

The recommended first dose is 200 U per kilogram bodyweight given by intravenous injection.

Your doctor will measure your factor VIII activity regularly to decide the subsequent dose and frequency of OBIZUR.

The bleeding will usually respond within the first 24 hours, your doctor will adjust the dose and duration of OBIZUR until the bleeding stops.

The total volume of reconstituted OBIZUR should be administered at a rate of 1 to 2 mL per minute.

If you have any further questions on the use of this medicine, ask your doctor.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If severe and sudden allergic reactions occur, the injection must be stopped immediately. You must contact your doctor immediately if you have any of the following early symptoms:

- Swelling of lips and tongue;
- Burning and stinging at the injection site;
- Chills, flushing;
- Hives, generalised itching;
- Headache, low blood pressure;
- Lethargy, sickness, restlessness;
- Rapid beating of the heart, tightness of the chest;
- Tingling, vomiting;
- Wheezing.

#### **Very common side effects (may affect more than 1 in 10 people)**

Development of antibodies and increases in pre-existing antibodies against the medicine, which may result in lack of efficacy with continued bleeding.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website:

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

#### **5. How OBIZUR is stored**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, on the vial and on the pre-filled syringe after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).

Do not freeze.

Use the reconstituted solution immediately but no longer than 3 hours once the powder is completely dissolved.

After reconstitution the solution should be clear and colourless.

Do not administer if particulate matter or discoloration is found.

Since this medicine is used during hospitalisation, the hospital staff are responsible for the correct storage of this medicine before and during its use, as well as for correct disposal.

Name and batch number

It is strongly recommended that every time that OBIZUR is used, the name and batch number of the medicine are recorded by the medical professional to maintain a link between your treatment and the batch of the medicine.

## **6. Contents of the pack and other information**

### **What OBIZUR contains**

- The active substance is susoctocog alfa (antihaemophilic factor VIII, porcine sequence produced by recombinant DNA technology). Each powder vial contains 500 U of susoctocog alfa.
- The other ingredients in the powder are polysorbate 80, sodium chloride (see also section 2), calcium chloride dihydrate, sucrose, trometamol, trometamol hydrochloride, sodium citrate.
- The solvent is 1 ml sterilised water for injections.

### **What OBIZUR looks like and contents of the pack**

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

- glass vial of OBIZUR 500 U white, friable powder with a butyl rubber stopper coated with FluroTec® and a flip-off seal;
- pre-filled glass syringe with a stopper of bromobutyl rubber coated with FluroTec® foil on the contact side of 1 ml sterilised water for injections with a bromobutyl rubber tip cap and a Luer lock adapter;
- fluid transfer device with an integral plastic spike.

### **Marketing Authorisation Holder**

Baxalta Innovations GmbH  
Industriestrasse 67  
1221 Vienna  
Austria  
Tel: +44 (0)3333 000181  
[medinfoemea@takeda.com](mailto:medinfoemea@takeda.com)

### **Manufacturers**

Takeda Manufacturing Austria AG  
Industriestrasse 67  
1221 Vienna  
Austria

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

### **This leaflet was last revised in May 2023.**

This medicine has been authorised under ‘exceptional circumstances’. This means that because of the rarity of this disease it has been impossible to get complete information on this medicine. The Medicines and Healthcare products Regulatory Agency (MHRA) will review any new information on this medicine every year and this leaflet will be updated as necessary.

---

The following information is intended for healthcare professionals only:

## INSTRUCTIONS FOR PREPARATION AND ADMINISTRATION

### Preparation

Before starting reconstitution, you will need the following:

- Calculated number of powder vials;
- Same number of 1 mL solvent syringes and sterile vial adapters;
- Alcohol swabs;
- Large sterile syringe to contain the final volume of reconstituted product.

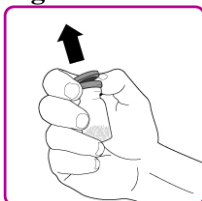
The procedures below are provided as general guidelines for the preparation and reconstitution of OBIZUR. Repeat following reconstitution instructions for each powder vial to be reconstituted.

### Reconstitution

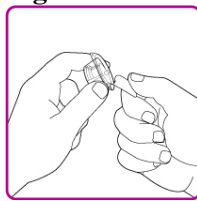
Use aseptic technique during the reconstitution procedure.

1. Bring the OBIZUR powder vial and pre-filled diluent solvent syringe to room temperature.
2. Remove the plastic cap from the OBIZUR powder vial (**figure A**).
3. Wipe the rubber stopper with an alcohol swab (not supplied) and allow it to dry prior to use.
4. Peel back the cover of the vial adapter package (**figure B**). Do not touch the Luer lock (tip) in the centre of the vial adapter. Do not remove the vial adapter from the package.
5. Place the vial adapter package on a clean surface with the Luer lock pointing up.
6. Snap off the tamper resistant cap of the pre-filled solvent syringe (**figure C**).
7. While firmly holding the vial adapter package connect the pre-filled solvent syringe to the vial adapter by pushing the syringe tip down onto the Luer lock in the centre of the vial adapter, and turning it clockwise until the syringe is secured. Do not over tighten (**figure D**).
8. Remove the plastic package (**figure E**).
9. Place the OBIZUR powder vial on a clean, flat, hard surface. Place the vial adapter over the OBIZUR powder vial and firmly push the filter spike of the vial adapter through the centre of the OBIZUR powder vial's rubber circle until the clear plastic cap snaps onto the vial (**figure F**).
10. Push the plunger down to slowly inject all of the diluent from the syringe into the OBIZUR powder vial.
11. Gently swirl (in a circular motion) the OBIZUR powder vial without removing the syringe until all of the powder is fully dissolved /reconstituted (**figure G**). The reconstituted solution should be inspected visually for particulate matter before administration. Do not use if particulate matter or discoloration is observed.
12. With one hand hold the powder vial and vial adapter, and with the other hand firmly grasp the barrel of the pre-filled solvent syringe and in a counterclockwise motion unscrew the syringe from the vial adapter (**figure H**).
13. Use OBIZUR immediately and within 3 hours after reconstitution when stored at room temperature.

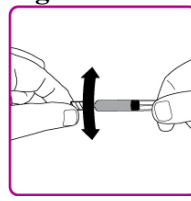
**Figure A**



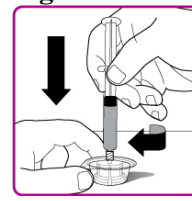
**Figure B**

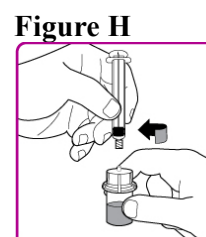
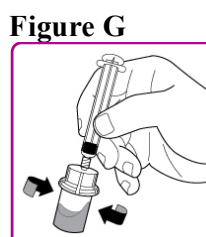
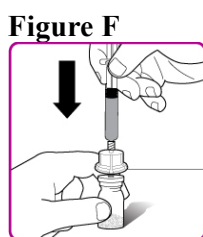
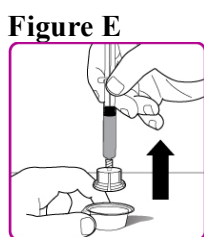


**Figure C**



**Figure D**





*Administration*

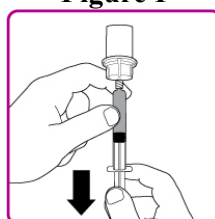
**For intravenous injection only.**

- Inspect the reconstituted OBIZUR solution for particulate matter and discoloration prior to administration. The solution should be clear and colourless in appearance. Do not administer if particulate matter or discoloration is observed.
- Do not administer OBIZUR in the same tubing or container with other medicinal products for injection.

Using aseptic technique, administer using the following procedure:

1. Once all vials have been reconstituted, connect a large syringe to the vial adapter by gently pushing the syringe tip down onto the Luer lock in the centre of the vial adapter, and turning clockwise until the syringe is secured.
2. Invert the vial; push the air in the syringe into the vial and withdraw the reconstituted OBIZUR into the syringe (**figure I**).
3. Unscrew the large syringe counterclockwise from the vial adapter, and repeat this process for all reconstituted vials of OBIZUR until the total volume to be administered is reached.
4. Administer the reconstituted OBIZUR intravenously at a rate of 1 to 2 mL per minute.

**Figure I**



The required initial dose of Obizur for a patient is calculated using the following formula:

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

e.g. for a 70 kg patient the number of vials for an initial dose will be calculated as follows:

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

*Dosing*

The recommended initial dose is 200 U per kilogram bodyweight, given by injection.

Type of bleeding	Target factor VIII trough activity (units per dL or % 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	Dose every 4 to 12 hours, frequency may be adjusted based on clinical response and measured

Major moderate to severe intramuscular, retroperitoneal, gastrointestinal, intracranial bleeding	>80%		target factor VIII trough activity	factor VIII activity
--	------	--	------------------------------------	----------------------