OBIZUR®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using OBIZUR?

OBIZUR contains the active ingredient susoctocog alfa. OBIZUR is used to treat bleeding episodes in adults with acquired haemophilia A (a bleeding disorder caused by lack of Factor VIII activity due to antibody development against Factor VIII).

For more information, see Section 1. Why am I using OBIZUR? in the full CMI.

2. What should I know before I use OBIZUR?

Do not use if you have ever had an allergic reaction to OBIZUR, or you are allergic to hamster proteins or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use OBIZUR? in the full CMI.

3. What if I am taking other medicines?

There are no known interactions of OBIZUR with other medicines.

For more information, see Section 3. What if I am taking other medicines? in the full CMI.

4. How will I be given OBIZUR?

- OBIZUR injection will be prepared and administered by a qualified healthcare professional who is experienced in the care of patients with haemophilia.
- Your doctor will calculate your dose of OBIZUR depending on your condition and body weight.
- OBIZUR is given slowly by injection directly into your vein.
- The frequency of infusions you receive, and the duration of treatment, will depend on how well OBIZUR is working for you.

More instructions can be found in Section 4. How do I use OBIZUR? in the full CMI.

5. What should I know while using OBIZUR?

Things you should do	• Tell your doctor or healthcare professional straight away if you notice: • any sudden signs and symptoms of a severe allergic response, e.g. shortness of breath, wheezing, difficulty breathing; chest pain or discomfort; light headedness, dizziness or fainting; puffiness or swelling of your face, lips, or any other parts of the body; rash, itching or hives on the skin. • your bleeding is not controlled or worsens.
Driving or using machines	• OBIZUR is not expected to have an influence on your ability to drive or use machines.
Looking after your medicine	• OBIZUR is to be stored at 2°C to 8°C in the refrigerator. Do not freeze. • The staff at the hospital and/or Haemophilia Treatment Centre will be responsible for the correct storage of OBIZUR before and during its use.

For more information, see Section 5. What should I know while using OBIZUR? in the full CMI.

6. Are there any side effects?

Development of new antibodies and/or increases in pre-existing inhibitory antibodies against the medicine may occur, and this may result in lack of efficacy with continued bleeding.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

OBIZUR

Active ingredient(s): *susoctocog alfa*

Consumer Medicine Information (CMI)

This leaflet provides important information about using OBIZUR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using OBIZUR.**

Where to find information in this leaflet:

1. Why am I using OBIZUR?

OBIZUR contains the active ingredient susoctocog alfa.

OBIZUR is a recombinant DNA derived, anti-haemophilic Factor VIII.

OBIZUR is used to treat bleeding episodes in adult patients with Acquired Haemophilia A (a bleeding disorder caused by lack of Factor VIII due to antibody development against Factor VIII).

Factor VIII is necessary for the blood to form clots and stop bleedings. In patients with acquired haemophilia A, Factor VIII is not working properly because the patient has developed antibodies to the human body's Factor VIII which neutralise this blood clotting Factor and prevent blood from clotting.

OBIZUR works by temporarily replacing the missing Factor VIII activity so that blood can form clots at the site of bleeding.

2. What should I know before I use OBIZUR?

Warnings

Do not use OBIZUR if:

- you are allergic to susoctocog alfa, or any of the ingredients listed at the end of this leaflet.
- you are allergic to hamster proteins or if you have a known allergy to medicines of hamster origin.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have or have had any other medical conditions especially heart problems.
- have had a history of blood clots or are at risk of developing blood clots.
- are on a controlled sodium diet.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. It is not known if OBIZUR may harm your unborn baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if OBIZUR passes into your milk and if it can harm your baby.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with each other and affect how they work.

There are no known interactions of OBIZUR with other medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect OBIZUR.

4. How will I be given OBIZUR?

OBIZUR will be given to you in a hospital or Haemophilia Treatment Centre and under the care of your doctor who is experienced in the care of patients with haemophilia.

How much you will be given

- Your doctor will calculate your dose of OBIZUR depending on your condition and body weight.
- The frequency of infusions you receive, and the duration of treatment will depend on how well OBIZUR is working for you.
- The recommended first dose is 200 Units (U) per kilogram bodyweight. Your doctor will measure your Factor VIII activity regularly to see how well you are responding to OBIZUR and decide on how much OBIZUR to give you on your next dose. Your doctor will adjust the dose and duration of OBIZUR until your bleeding stopped.

How is OBIZUR given

- OBIZUR is given slowly by injection and your doctor or a qualified healthcare professional will inject OBIZUR directly into your vein.
- Before you receive your OBIZUR injection, your doctor or a qualified healthcare professional will mix the vial of OBIZUR powder with the water for injections, which is included in the pack, to form a clear solution.

If you forget to use OBIZUR

As OBIZUR is given to you by your doctor or a qualified healthcare professional, it is unlikely that you will have a missed dose.

If you use too much OBIZUR

As your dose is calculated by your doctor based on your condition and body weight, it is unlikely that you will be given too much OBIZUR.

However, if you think that you have used too much OBIZUR, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using OBIZUR?

Things you should do

You will have your blood tested before and after your first OBIZUR injection, and also regularly in between injections. This is so that your doctor and/or healthcare professional can monitor your blood level of Factor VIII to see how well OBIZUR is working for you. You will also have your bloods taken to check if you have developed any inhibitory antibodies to OBIZUR.

Tell your doctor and/or healthcare professional straight away if you notice:

- any sudden signs and symptoms of a severe allergic response, e.g.
  - shortness of breath, wheezing, difficulty breathing,
  - chest pain or discomfort
  - light headedness, dizziness, fainting
  - puffiness or swelling of your face, lips, tongue, or any parts of your body
  - rashes, itchiness, or hives on your skin.
- your bleeding is not controlled or worsens.

Things you should not do

- Do not stop receiving OBIZUR because you are feeling better, unless advised by your doctor or healthcare professional.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how OBIZUR affects you.

OBIZUR is not expected to have an influence on your ability to drive and use machines.

Looking after your medicine

- Store at 2°C to 8°C in a refrigerator. Do not freeze.

The staff at the hospital and/or Haemophilia Treatment Centre will be responsible for the correct storage of OBIZUR before and during its use. They will also take care of discarding any unused solution after you have received your injection.

Keep OBIZUR out of reach of children.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• Development of antibodies against OBIZUR detected in blood test results.	**Your doctor will discuss this with you and decide what to do.**

Serious side effects

Serious side effects	What to do
Rapid increase in existing inhibitory antibodies to OBIZUR may develop, which may result in lack of efficacy with continued bleeding. Signs and symptoms include: • bruises • bleeding of the mouth and gums • blood in urine or stool • frequent and hard-to-stop nosebleeds • swelling and pain or tightness in the joints, e.g. knees, elbows and ankles.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

What OBIZUR contains

Active ingredient (main ingredient)	susoctocog alfa
Other ingredients (inactive ingredients)	polysorbate 80 sodium chloride sucrose sodium citrate dihydrate calcium chloride dihydrate

	trometamol water for injections (diluent)
Potential allergens	OBIZUR does not contain gluten, dyes or preservatives.

Do not take this medicine if you are allergic to any of these ingredients.

What OBIZUR looks like

OBIZUR is supplied in a glass vial as a white powder, which requires mixing with the prefilled syringe of water for injections that is included in the pack. After the powder is fully mixed with the water for injections, a clear and colourless solution is formed.

OBIZUR is packed in cartons of 1, 5 and 10 single-packs. Each single pack contains:

- 1 vial of OBIZUR powder for injection
- 1 prefilled syringe of water for injections
- 1 vial adapter (a fluid transfer device)

Not all pack sizes may be marketed.

(AUST R 236475).

Who distributes OBIZUR

Takeda Pharmaceuticals Australia Pty Ltd

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www.takeda.com/en-au

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