OBIZUR

Susoctocog alfa (recombinant porcine coagulation factor VIII) 500U/mL

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about OBIZUR. It does not contain all of the available information. All medicines have risks and benefits. Your doctor has weighed the risks of using your medicine against the benefit that it will have for you.

It does not take the place of talking to your doctor or pharmacist.

If you have any concerns about having this medicine, ask your doctor or pharmacist.

Please read this leaflet carefully before using your medicine as it contains information about your medicine.

Keep this leaflet with your medicine.
You may need to read it again.

What OBIZUR is used for

OBIZUR, antihaemophilic factor (recombinant), porcine sequence is a recombinant DNA derived, antihaemophilic factor indicated for the treatment and prevention of bleeding episodes in adults with acquired haemophilia A (AHA).

This medicine belongs to a group of medicines called antihaemophilic agent.

OBIZUR is a man-made clotting factor. It is similar to the naturally occurring protein in the body. OBIZUR works by increasing the amount of clotting factor VIII in the blood, which helps the blood to clot normally.

OBIZUR should only be used in adults.

Before you use OBIZUR

To make sure that your medicine is suitable for you, it is important to tell your healthcare professional if any of the points below apply to you. If there is anything you do not understand, ask your healthcare professional to explain.

When you must not use OBIZUR

Do not use OBIZUR if you:

- are allergic to hamster proteins.
- are allergic to any ingredients in OBIZUR (see "What is in OBIZUR?").

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

What should I tell my doctor before using OBIZUR?

You should tell your doctor if you:

- have or have had any medical problems.
- take any medicines, including prescription and non-prescription medicines, such as over-the-counter medicines, supplements or herbal remedies.
- have any allergies, including allergies to hamster proteins.
- are breastfeeding. It is not known if OBIZUR passes into your milk and if it can harm your baby.
- are pregnant or planning to become pregnant. It is not known if OBIZUR may harm your unborn baby.

Do not use this medicine in children.
The safety and effectiveness in children have not been established.

Do not use this medicine after the expiry date printed on the pack or if the packaging shows sign of tampering.

How OBIZUR is given

OBIZUR is usually administered in a hospital. It is administered by intravenous injection.

- Your medicine contains no additives that would prevent the growth of bacteria once the powder is dissolved with sterile water. For this reason, each syringe of OBIZUR is for single use only, in one patient only. Discard any residue.
- Your healthcare professional will conduct blood tests to be sure that your blood has adequate factor VIII levels, clotting factor.

Only the materials provided in the box for dissolving the OBIZUR powder should be used.

OBIZUR must be injected immediately or within 3 hours after dissolving the powder.

OBIZUR must not be mixed with other injectable medicines.

Overdose

As OBIZUR will be given to you by a doctor/nurse, it is unlikely that you will be given an overdose.

Your healthcare professional will regularly monitor your condition and test your blood to prevent overdose. Your healthcare professional has information on how to treat an overdose. Ask your doctor if you have any concerns.

While you are using OBIZUR

Things you must do

- See your doctor immediately if your bleeding does not stop as expected
- Tell all the doctors, dentists and pharmacists who are treating you that you are using OBIZUR
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using OBIZUR
- If you become pregnant while you are using your medicine, tell your doctor.

Keep all your doctor's appointments so that your progress can be checked.

Side effects

Allergic reactions may occur with your medicine.

Call your doctor or get emergency treatment right away if you get a rash or hives, itching, tightness of the throat, chest pain or tightness, difficulty breathing, lightheadedness, dizziness, nausea or fainting.

Tell your doctor or pharmacist about any side effects that bother you or do not go away.

These are not all the possible side effects with OBIZUR. You can ask your doctor or pharmacist for information that is written for healthcare professionals.

Storage

OBIZUR is a protein preparation; therefore it should be stored at 2°C - 8°C in a refrigerator for the duration of its shelf life. Store product in the original container. Protect from light. Do not freeze.

OBIZUR contains no preservatives. Reconstituted product (what you get after dissolving the powder with the sterile water) must be used within 3 hours and cannot be stored or refrigerated.

Discard any medicine left in the vial at the end of the infusion.

Keep out of the reach and sight of children.

Do not use OBIZUR after the expiry date which is printed on the label after the word 'EXP'.
The expiry date refers to the last day of that month.

Dispose of all materials, including any leftover reconstituted medicine, in an appropriate container.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What OBIZUR looks like?

OBIZUR comes as a white powder in a glass vial.

Each vial of your medicine is accompanied by a glass vial containing sterile water for dissolving the powder.

What is in OBIZUR?

The active substance in OBIZUR is susoctocog alfa.

other ingredients: sodium chloride, sucrose, sodium citrate, calcium chloride, polysorbate 80 and trometamol.

Name and address of sponsor

Baxalta Australia Pty Limited
1 Baxter Drive,
Old Toongabbie NSW 2146

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