OBIZUR®

Susoctocog alfa (recombinant coagulation factor VIII, porcine sequence)

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before you start using OBIZUR.

This leaflet answers some common questions about OBIZUR. It does not contain all of the available information.

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

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.

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

Keep this leaflet with your medicine.

You may need to read it again.

What OBIZUR is used for

OBIZUR is a recombinant DNA derived, anti-haemophilic factor used for the treatment of bleeding episodes in adults with acquired haemophilia A.

It is possible that your doctor may give you OBIZUR for another reason.

Ask your doctor if you have any questions about why you are being given OBIZUR.

How does OBIZUR work

Under normal physiological conditions, factor VIII is essential for blood clotting and therefore the control of bleeding.

Acquired haemophilia is a bleeding disorder that is not present at birth but develops suddenly at some point in life due to an abnormality in the immune system. In patients with acquired haemophilia A, factor VIII is not working properly because the patient has developed antibodies which neutralise this blood clotting factor, and this prevents blood from clotting.

OBIZUR belongs to a group of medicines called anti-haemophilic agents.

OBIZUR is a man-made clotting factor. It is similar to the naturally occurring protein in the body.

OBIZUR works by temporarily replacing the inhibited human clotting factor VIII, so that blood can clot normally.

Before you are given OBIZUR

When you must not be given OBIZUR

OBIZUR should not be given to you if you are:

- allergic to any products of porcine or hamster origin;.
- allergic to any ingredients in this product which are listed at the end of the leaflet.

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

If you are not sure, talk to your doctor before using OBIZUR.

Do not use this medicine in children.

The safety and effectiveness in children have not been established.

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

Before you are given OBIZUR

You should tell your doctor if you:

- have or have had any medical problems;
- have any allergies, including allergies to products that are of porcine or hamster origin;
- have had heart problems or blood clot in the past or you have any other conditions that make you at risk of developing blood clots;
- are on a controlled sodium diet;
- are breast feeding (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).

If you are breast feeding or if you are pregnant or planning to have a baby, ask your doctor for advice before using OBIZUR.

Taking other medicines

Tell your doctor or pharmacist if you are using any other medicines

including any that you obtained without a prescription from your pharmacy, supermarket or health food shop.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while being given OBIZUR.

How OBIZUR is given

How much is given

Your doctor will decide the dose of OBIZUR you will receive. Each individual will receive a different amount, which may vary between treatments.

The dose you receive will be based on:

- body weight;
- your condition, e.g. in which sites the bleeding occurs (knees, muscle, etc.).

As a general guide, an initial first dose of 200 U per kilogram (U/kg) bodyweight is recommended.

The frequency and duration of treatment will depend on how well OBIZUR is working for you. Your doctor will adjust the dose and frequency of OBIZUR injections until the bleeding stopped.

How OBIZUR is given

OBIZUR is usually given in a hospital so that you are under the care of a healthcare professional.

OBIZUR is given by a slow injection directly into your vein.

Use aseptic technique to prepare OBIZUR for injection.

Use only the water for injections supplied with the pack to prepare OBIZUR for injection.

Do not mix OBIZUR with any other medicines or solvent.

Always inspect the solution after it is prepared for use and before injection.

The solution should be clear and colourless.

Do not inject if the solution is discoloured or cloudy or contains particles.

Use the solution straight away or within 3 hours after it is prepared.

Do not refrigerate the solution after it is prepared.

Use a new syringe and needle for each injection.

Do not mix OBIZUR with other medicines.

If you are given too much (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.

Immediately telephone your doctor or the National Poisons Information (telephone 131 126), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have been given too much OBIZUR.

Do this even if there are no signs of discomfort or poisoning.

While you are using OBIZUR

Things you must do

You will have your blood tested after the initial OBIZUR injection and also regularly after subsequent injections to see how your treatment is working. This is to check your blood level of factor VIII to confirm that you have received adequate treatment. Your doctor will also check if the bleeding is adequately controlled.

Your doctor may do additional blood tests to check if you have developed antibodies to OBIZUR treatment.

Monitor your bleeding and tell your doctor or nurse if your bleeding gets worse.

Tell your doctor or pharmacist immediately if you experience any of the following during the OBIZUR injection:

- shortness of breath; wheezing; difficulty breathing; chest pain or discomfort;
- changes in facial skin colour, puffiness or swelling of your face, lips, tongue, or other parts of the body, rash or hives.

The above list includes signs and symptoms of a severe allergic response to the medicine. The use of OBIZUR should be stopped immediately if any of the above occurs during injection.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after using OBIZUR.

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

You may need medical attention if you get some of these side effects.

Do not be alarmed by this list of possible side effects, you may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

The following list includes the common side effects for OBIZUR:

- antibodies against OBIZUR detected in blood test results.

A rapid increased production of antibodies in response to subsequent treatment with OBIZUR have also been reported.

Tell your doctor or pharmacist of any suspected undesirable effect that is not mentioned in this leaflet.

Other side effects not listed above may occur in some patients.

After using OBIZUR

Storage

Keep out of the reach and sight of children.

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

Keep OBIZUR in the pack until it is time to use it.

This will protect the vials from light. If the vials are not stored in the pack, the product may not keep well.

Do not store the solution in the fridge after the powder is mixed with the diluent.

Disposal

OBIZUR is for single use in single patient only.

Discard any unused solution left in the vial at the end of your infusion.

Dispose the used vials and all materials in an appropriate container.

Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.

If your doctor tells you to stop using OBIZUR or the expiry date has passed, ask your pharmacist or your Haemophilia Treatment Centre what to do with any medicine that is left over.

Ask your doctor, pharmacist or Haemophilia Treatment Centre if you have any questions about how to dispose OBIZUR.

Product Description

What OBIZUR looks like

OBIZUR is a white powder supplied in a glass vial with a diluent prefilled syringe for reconstitution.

After reconstitution, the solution is clear, colourless and free from foreign particles.

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 (used as the diluent to dissolve the OBIZUR powder);
- 1 vial adapter (to help with transferring the diluent to prepare the solution for injection).

Not all pack sizes may be marketed.

Ingredients

Active ingredient:

- susoctocog alfa.

Inactive ingredients:

- sodium chloride;
- sucrose;
- sodium citrate dihydrate;
- calcium chloride dihydrate;
- trometamol;
- water for injections (diluent).

Sponsor

OBIZUR is supplied in Australia by:

Takeda Pharmaceuticals Australia Pty Ltd

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225 George Street

Sydney NSW 2000

Australia

Telephone: 1800 012 612

www.takeda.com/en-au

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