

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Removab 10 microgram concentrate for solution for infusion catumaxomab

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Removab is and what it is used for
2. Before you use Removab
3. How to use Removab
4. Possible side effects
5. How to store Removab
6. Further information

1. WHAT REMOVAB IS AND WHAT IT IS USED FOR

Removab contains the active substance catumaxomab, a monoclonal antibody. It recognises a protein on the surface of cancer cells and recruits immune cells to destroy them.

Removab is used to treat malignant ascites, when standard treatment is not available or no longer feasible. Malignant ascites is an accumulation of fluid in the abdominal space (peritoneal cavity) resulting from certain types of cancer.

2. BEFORE YOU USE REMOVAB

Do not use Removab

- if you are allergic (hypersensitive) to catumaxomab or any of the other ingredients of Removab (see section 6)
- if you are allergic (hypersensitive) to murine proteins (from rat and / or mouse)

Take special care with Removab

It is important to tell your doctor if you have any of the following:

- undrained fluid in your abdominal cavity
- cold hands and feet, light headedness, difficulty passing urine, increased heart rate, and weakness (symptoms of low blood volume)
- weight gain, weakness, shortness of breath and fluid retention (symptoms of low blood protein levels)
- feeling dizzy and faint (symptoms of low blood pressure)
- problems with your heart and circulation
- kidney or liver problems
- an infection.

Removab should not be used in children and adolescents under 18 years of age.

Before you start using Removab your doctor will check your:

- Body Mass Index (BMI), which depends on your height and weight

- Karnofsky Index, a measure of your general performance status.
You are required to have a BMI above 17 (after drainage of the ascites fluid) and a Karnofsky Index above 60 to use this medicine.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including those obtained without a prescription.

Pregnancy and breast-feeding

You should not use Removab if you are pregnant unless clearly necessary. Talk to your doctor if you are, might be or are planning to become pregnant.

If you are breast-feeding, talk to your doctor before starting treatment.

Driving and using machines

There are no studies on the effects of Removab on the ability to drive and use machines. However, if you experience side effects such as dizziness or chills during or after administration, you should not drive or use machines until they disappear.

3. HOW TO USE REMOVAB

You will be given Removab under the supervision of a doctor experienced in treating cancer. After the Removab infusion you will be observed as decided by your doctor.

Before starting and during treatment, you will be given other medicines to reduce fever, pain or inflammation caused by Removab.

A catheter will be placed in your abdominal space (intraperitoneal) for the whole treatment period, until the day after your last infusion.

Removab is given as 4 intraperitoneal infusions with increasing dose (10, 20, 50 and 150 micrograms), separated at least by a 2-day break.

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

4. POSSIBLE SIDE EFFECTS

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

These side effects may occur with certain frequencies, which are defined as follows:

- very common: affects more than 1 user in 10
- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000
- not known: frequency cannot be estimated from the available data.

Serious side effects

Some of these side effects may be serious and require medical treatment. You should tell a doctor immediately if you experience any of these serious side effects.

Very common serious side effects:

- Abdominal pain
- Fever

Common serious side effects:

- Abdominal pain accompanied by difficulty passing stools
- Shortness of breath

Uncommon serious side effects:

- Very fast heart beat, fever, shortness of breath, feeling faint or light-headed within 24 hours of infusion.
- Blockage in the gut or bowel
- Bleeding in the stomach, shown by the vomiting of blood or the passage of red or black stools
- Inflammation and pain or burning and stinging in the area around the catheter
- Infection of the skin
- Fits
- Lung problems including blood clot in the lungs or accumulation of fluid around the lungs which cause chest pain and breathlessness
- Severe skin reactions such as flaking of the skin, rash and sensitive skin
- Severe kidney problems

Other side effects

Very common side effects:

- Feeling sick (nausea), vomiting and diarrhoea
- Tiredness, pain and chills
- Reduction in number of white blood cells

Common side effects:

- Increased number of white blood cells
- Increased clotting factors
- Reduction in red blood cells (anaemia)
- Decreased blood levels of calcium, potassium and sodium
- Decreased blood protein levels
- High blood sugar
- A very fast heart beat
- Spinning sensation
- Constipation, indigestion, stomach problems, heartburn, passing wind and mouth ulcers
- Flu-like symptoms
- Fluid retention
- Dizziness or headache
- Chest pain
- Increased sweating, feeling thirsty and weak
- Liver problems and yellowing of the skin (jaundice)
- Infections including bladder infections
- Lumps under the skin on the back of the legs that may become sores and leave scars
- Increased protein levels or white blood cells in urine
- Loss of appetite
- Dehydration
- Back pain, aching muscles and joints
- Feeling anxious and having difficulty sleeping.
- Passing small amounts of urine or finding blood in the urine
- Skin redness, itchy rash, hives, sensitive skin or a sudden widespread rash
- High or low blood pressure
- Flushing and hot flushes.

If any of the side effects become serious or if you notice any side effects not listed in this leaflet, tell your doctor or nurse.

5. HOW TO STORE REMOVAB

Keep out of the reach and sight of children.

Do not use Removab after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C). Do not freeze. Store in the original package in order to protect from light.

The prepared infusion solution should be used immediately.

6. FURTHER INFORMATION

What Removab contains

- The active substance is catumaxomab (10 microgram in 0.1 ml, corresponding to 0.1 mg/ml).
- The other ingredients are sodium citrate, citric acid monohydrate, polysorbate 80 and water for injections.

What Removab looks like and contents of the pack

Removab is presented as a clear and colourless concentrate for solution for infusion in a pre-filled syringe with a cannula. Pack size of 1.

Marketing Authorisation Holder and Manufacturer

Fresenius Biotech GmbH
Am Haag 6-7
82166 Graefelfing
Germany

For any information about this medicine, please contact the Marketing Authorisation Holder.

This leaflet was last approved in MM/YYYY.

Detailed information on this medicine is available on the European Medicines Agency (EMA) web site: <http://www.emea.europa.eu/>.

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The following information is intended for medical or healthcare professionals only:

For information on dilution and administration of Removab please refer to section 6.6 of the Summary of Product Characteristics (SPC) included in each package of Removab 10 microgram and Removab 50 microgram, respectively.

PACKAGE LEAFLET: INFORMATION FOR THE USER

Removab 50 microgram concentrate for solution for infusion catumaxomab

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- if you are allergic (hypersensitive) to murine proteins (from rat and / or mouse)

Take special care with Removab

It is important to tell your doctor if you have any of the following.

- undrained fluid in your abdominal cavity
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- weight gain, weakness, shortness of breath and fluid retention (symptoms of low blood protein levels)
- feeling dizzy and faint (symptoms of low blood pressure)
- problems with your heart and circulation.
- kidney or liver problems
- an infection.

Removab should not be used in children and adolescents under 18 years of age.

Before you start using Removab your doctor will check your:

- Body Mass Index (BMI), which depends on your height and weight

- Karnofsky Index, a measure of your general performance status.
You are required to have a BMI above 17 (after drainage of ascites fluid) and a Karnofsky Index above 60 to use this medicine.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including those obtained without a prescription.

Pregnancy and breast-feeding

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The prepared infusion solution should be used immediately.

6. FURTHER INFORMATION

What Removab contains

- The active substance is catumaxomab (50 microgram in 0.5 ml, corresponding to 0.1 mg/ml).
- The other ingredients are sodium citrate, citric acid monohydrate, polysorbate 80 and water for injections.

What Removab looks like and contents of the pack

Removab is presented as a clear and colourless concentrate for solution for infusion in a pre-filled syringe with a cannula. Pack size of 1.

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