

## **Package leaflet: Information for the patient**

### **Korjunny 10 micrograms concentrate for solution for infusion Korjunny 50 micrograms concentrate for solution for infusion catumaxomab**

▼ 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 or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

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

#### **1. What Korjunny is and what it is used for**

Korjunny contains the active substance catumaxomab. Catumaxomab is a monoclonal antibody, a type of protein that binds to a target on the surface of cancer cells. This target is called epithelial cell adhesion molecule (EpCAM), and it is found on the surface of different types of cancer cells. It is also present on cancer cells in ascites fluid. Malignant ascites is the build-up of fluid containing cancer cells in the abdomen of cancer patients.

Catumaxomab activates cells of the immune system (part of the body's natural defences) to destroy the cancer cells.

Korjunny is used to treat malignant ascites in adults, when standard treatment of the cancer is no longer feasible.

#### **2. What you need to know before you are given Korjunny**

##### **Do not use Korjunny if you are**

- allergic to catumaxomab or any of the other ingredients of this medicine (listed in section 6)
- allergic to rat and/or mouse proteins

##### **Warnings and precautions**

Talk to your doctor or nurse before you are given Korjunny or during treatment if you have:

- signs of a condition known as cytokine release syndrome. This is a serious immune reaction with symptoms such as fever, low blood pressure, chills, difficulty breathing, fatigue, headache, fast heartbeat and increased level of liver enzymes in the blood. Please consider the instructions provided in your patient card, such as when you should seek medical attention. Before each infusion of Korjunny, you may be given medicines, which help reduce possible side effects of cytokine release syndrome.

- signs of the so-called systemic inflammatory response syndrome. Possible signs are fever, increased heartbeat, faster breathing and abnormal white blood cell counts. Contact your doctor immediately if you have any of these signs and consider the instructions provided in your patient card.
- an infection or signs of an infection such as feeling warm, fever, chills or shivering, sore throat or mouth ulcers. The infection will be treated before you are given Korjuno.
- low blood volume with symptoms such as cold hands and feet, light headedness, difficulty passing urine, increased heart rate or weakness
- symptoms of low levels of blood proteins such as weakness, shortness of breath or fluid retention
- low blood pressure with symptoms such as feeling dizzy, faint or weakness
- liver problems, including a blood clot or obstruction in the portal vein (a blood vessel that carries blood to the liver from the intestines, spleen, pancreas and gallbladder)
- kidney problems

#### Tests and checks

- Before you are given Korjuno, your doctor will check conditions that may affect your blood flow. This will include tests of your blood volume, level of blood proteins, blood pressure, pulse and kidney function.
- You may experience infusion-related reactions during or after the infusion of Korjuno. These can sometimes be severe with symptoms such as fever, low blood pressure, chills, headache, nausea, vomiting, muscle and joint pain, very fast heartbeat and shortness of breath. It is recommended that your doctor keep you under observation for at least 24 hours after the first infusion and at least 6 hours after each subsequent infusion.
- Your doctor may also conduct tests to check your liver function during treatment with Korjuno.

#### Children and adolescents

Korjuno is not recommended in children and adolescents under 18 years, as it has not been studied in this age group.

#### Other medicines and Korjuno

Tell your doctor if you are using, have recently used or might use any other medicines.

#### Pregnancy and breast-feeding

Korjuno is not recommended during pregnancy, breast-feeding and in women of childbearing potential not using contraception.

The effects of Korjuno on the developing foetus are unknown and a risk to a newborn/infant cannot be excluded.

If you could become pregnant, you must use effective contraception during treatment with Korjuno. Inform your doctor immediately if you become pregnant while being treated with this medicine.

It is not known if catumaxomab passes into breast milk. There may be a risk to breastfed newborns/infants. Ask your doctor for advice if you are breast-feeding.

#### Driving and using machines

Do not drive or use machines if you have side effects such as dizziness or infusion-related side effects during or after administration.

#### Korjuno contains polysorbate 80 and sodium

This medicine contains 21.6 micrograms polysorbate 80 in each pre-filled syringe Korjuno 10 micrograms and 108 micrograms of polysorbate 80 in each pre-filled syringe Korjuno 50 micrograms. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’. The amount of sodium administered per infusion is higher than that contained in the medicinal product due to the dilution of the concentrate with sodium chloride 9 mg/ml (0.9%) solution. An additional 500 ml of sodium chloride 9 mg/ml (0.9%) solution for injection is given before each Korjony administration and 250 ml of sodium chloride 9 mg/ml (0.9%) solution for injection is given in parallel with each Korjony administration.

### 3. How to use Korjony

You will be given Korjony under supervision of a doctor experienced in the treatment of cancer.

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

Korjony is given as an infusion into the abdominal cavity over a period of at least 3 and a maximum of 6 hours.

You will be given 4 infusions that follow an increasing dose schedule: 10, 20, 50 and 150 micrograms. The infusions are separated by at least 2 infusion-free calendar days. For example, you will receive an infusion on day 0, 3, 7 and 10. However, your doctor may decide to extend the time between infusions in order to reduce the risk of side effects. The overall treatment period should not exceed a total of 21 days.

A catheter is placed in your abdominal cavity for the whole treatment period, until the day after your last infusion.

After the first Korjony infusion your doctor will observe you for at least 24 hours for infusion-related reactions and at least 6 hours after each subsequent infusion.

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.

**Inform your doctor immediately** if you have any of the following **serious side effects**:

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

- **infusion-related side effects**

During and after infusion with Korjony patients may experience infusion-related side effects. These include symptoms such as fever, low blood pressure, chills, headache, nausea, vomiting, muscle and joint pain. It can also cause rapid heartbeat, shortness of breath, skin symptoms and fatigue. These symptoms occur mainly within 24 hours after infusion and can become life-threatening. These side effects require immediate treatment.

Your doctor may consider reducing the infusion rate of Korjony or giving you additional treatment to reduce serious symptoms.

Other side effects may occur with the following frequencies:

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

- inflammatory response syndrome called cytokine release syndrome – see section 2, “Warnings and precautions”
- nausea, vomiting, diarrhoea
- abdominal pain
- fever, chills, fatigue, pain
- increased blood levels of C-reactive protein (a marker of inflammation)

**Common** (may affect up to 1 in 10 people)

- infection
- reduced number of red blood cells
- increased number of white blood cells, or specific white blood cells called neutrophils
- lack of certain white blood cells called lymphocytes
- systemic inflammatory response syndrome – see section 2, “Warnings and precautions”
- hypersensitivity
- decreased appetite
- dehydration
- low blood level of sodium, potassium or calcium
- increased blood sugar level
- decrease blood level of protein, like albumin
- anxiety
- dizziness
- accelerated heartbeat
- low or high blood pressure
- flushing, hot flush
- abdominal discomfort, wind
- heartburn
- upper abdominal pain
- partial bowel obstruction
- increased blood level of bilirubin, a yellow breakdown substance of the blood pigment
- inflammation of the bile duct
- allergic skin inflammation
- rash, skin reddening, itching
- excessive sweating
- back pain, muscle pain, joint pain
- blood in the urine, excess of protein in the urine
- weakness
- chest pain
- inflammation
- tissue swelling caused by excess fluid
- influenza-like illness
- feeling unwell
- accumulation of fluid in arms and/or legs
- insufficient oxygen supply of the whole body or a region of the body
- breathing difficulties, fluid in the thorax
- increased levels of liver enzymes, such as alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase, gamma-glutamyltransferase
- increased body temperature
- increased blood levels of urea, procalcitonin, amylase, creatinine phosphatase, the breakdown product from muscle tissue called creatinine
- decreased red blood cell pigment level
- increased number of blood platelets
- decreased total protein
- decreased weight

**Uncommon** (may affect up to 1 in 100 people)

- thrush
- skin infection
- inflammation of the fatty tissue under the skin with skin nodules on the calves
- herpes simplex infection, localised infection, urinary tract infection
- lung inflammation
- reduced number of blood platelets, reduced blood clotting
- lack of white blood cells, such as neutrophils

- low blood sugar level
- low blood level of magnesium
- fluid retention
- restlessness, depression
- abnormal sensation such as prickling, tingling and itchiness
- sensory disorders in hands or feet caused by nerve damage
- nerve disorder effecting many nerves in the arms and/or legs simultaneously
- fainting, lethargy
- uncontrollable shaking, fit
- taste disturbance
- blurred vision
- feeling of increased heartbeat, irregular heartbeat
- heart weakness
- blockage of a lung artery
- breathing distress, cramp of bronchial muscles
- cough, hiccup
- migration of inflammatory cells or tumour cells in the lung tissue, lung failure
- pain in the throat and larynx
- faster breathing, wheezing
- abnormal cramps
- dry mouth
- loss of bowel movement
- reduced stomach emptying
- lower abdominal pain
- abdominal stiffness
- accumulation of fluid in the abdominal cavity
- backflow of bile from the first section of the small bowel into the stomach
- stomach disorder
- reduced stomach and bowel movement
- inflammation of the membrane which lines the abdomen cavity and covers the abdominal organs
- retching
- small bowel obstruction
- stomach discomfort
- vomiting blood
- inflammation of the inner lining of the mouth
- liver inflammation with destruction of cells, medicine-induced liver inflammation
- liver failure
- reduced bile flow
- abnormal liver function
- yellowing of the skin or whites of the eyes caused by liver problems
- night sweats
- redness of the palm, nettle-rash and other skin reactions
- bone pain, flank pain
- pain affecting muscles and skeleton, pain in arms and legs
- painful and difficult urination, decreased output of urine
- increased number of white blood cells in the urine
- kidney failure, kidney pain
- inflammation at application site
- pain at the catheter site, leakage of a fluid
- feeling full after eating very little food
- feeling cold or hot
- injection site reaction
- inflammation of mucous-secreting lining

- thirst
- skin reddening at the catheter site
- general health deterioration
- pelvic pain
- abnormal liver function tests, elevated liver enzymes
- increased level of the liver enzymes transaminases
- decreased oxygen saturation in the blood
- increased blood levels of conjugated bilirubin, uric acid, fibrinogen, lactate dehydrogenase, lipase
- decreased blood levels of iron, chloride
- decreased body temperature
- decreased percentage of blood cells on the blood volume
- urobilin in urine
- cells in urine, including white blood cells
- prolonged activated thromboplastin time – a test to control blood coagulation
- increased international normalised ratio, which shows that the blood is clotting too slowly
- problems during administration: pain, divergence of adjacent wound edges, anastomotic complication (e.g. bleeding or leakage at connections between vessels or hollow organs)

### **Reporting of side effects**

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [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 to store Korjunny**

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 and 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. Store in the original package in order to protect from light.

The prepared infusion solution should be used immediately.

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

### **What Korjunny contains**

- The active substance is catumaxomab.F  
One pre-filled syringe Korjunny 10 micrograms contains 10 micrograms of catumaxomab in 0.1 ml concentrate, corresponding to 0.1 mg/ml.  
One pre-filled syringe Korjunny 50 micrograms contains 50 micrograms of catumaxomab in 0.5 ml concentrate, corresponding to 0.1 mg/ml.
- The other ingredients are sodium citrate (E331), citric acid monohydrate (E330), polysorbate 80 (E433) and water for injections. See section 2, “Korjunny contains polysorbate 80 and sodium”.

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

Korjunny is a clear and colourless concentrate for solution for infusion (sterile concentrate) in pre-filled glass syringes with tip caps.

Pack sizes:

- Korjunny 10 micrograms: 3 pre-filled syringes and 5 cannulas in a carton with a blue colour code

- Korjuny 50 micrograms: 4 pre-filled syringes and 5 cannulas in a carton with a red colour code

#### **Marketing Authorisation Holder**

Atnahs Pharma UK Limited  
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#### **Manufacturer**

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**The following information is intended for healthcare professionals only:**

#### **Material and equipment required for dilution and administration of Korjuny**

- sodium chloride 9 mg/ml (0.9%) solution for injection
- 50 ml polypropylene syringes
- cap for 50 ml polypropylene syringes
- polyethylene perfusion tubing with an inner diameter of 1 mm and a length of 150 cm
- polycarbonate infusion valves / Y connections
- polyurethane silicon-coated catheters
- precision perfusion pump

#### **Dilution prior to administration**

Korjuny should be prepared by a healthcare professional using appropriate aseptic technique.  
The outer surface of the pre-filled syringe is not sterile.

- The volume of sodium chloride 9 mg/ml (0.9%) solution for injection listed in the table is extracted with a 50 ml syringe.
- An additional air buffer of at least 3 ml is included in the 50 ml syringe.
- The Korjuny pre-filled syringe(s) of the required strength listed in the table are visually inspected for any foreign particulates or discolouration.
- With the pre-filled syringe tip pointing up, the tip cap is gently removed. **Do not** twist off or rotate the cap.
- The enclosed cannula is attached to the pre-filled syringe and the cannula shield removed. A new cannula must be used for each syringe.
- The cannula is inserted through the 50 ml syringe opening so that the cannula is immersed in the sodium chloride 9 mg/ml (0.9%) solution for injection (figure).  
**Do not** administer the Korjuny pre-filled syringe directly to a patient.
- The entire content of the pre-filled syringe is injected into the sodium chloride 9 mg/ml (0.9%) solution for injection.  
The plunger rod **must not** be drawn back to rinse the pre-filled syringe, to avoid contamination and to ensure that the correct volume is ejected.
- Based on the table, the previous steps are repeated to inject the required number of pre-filled

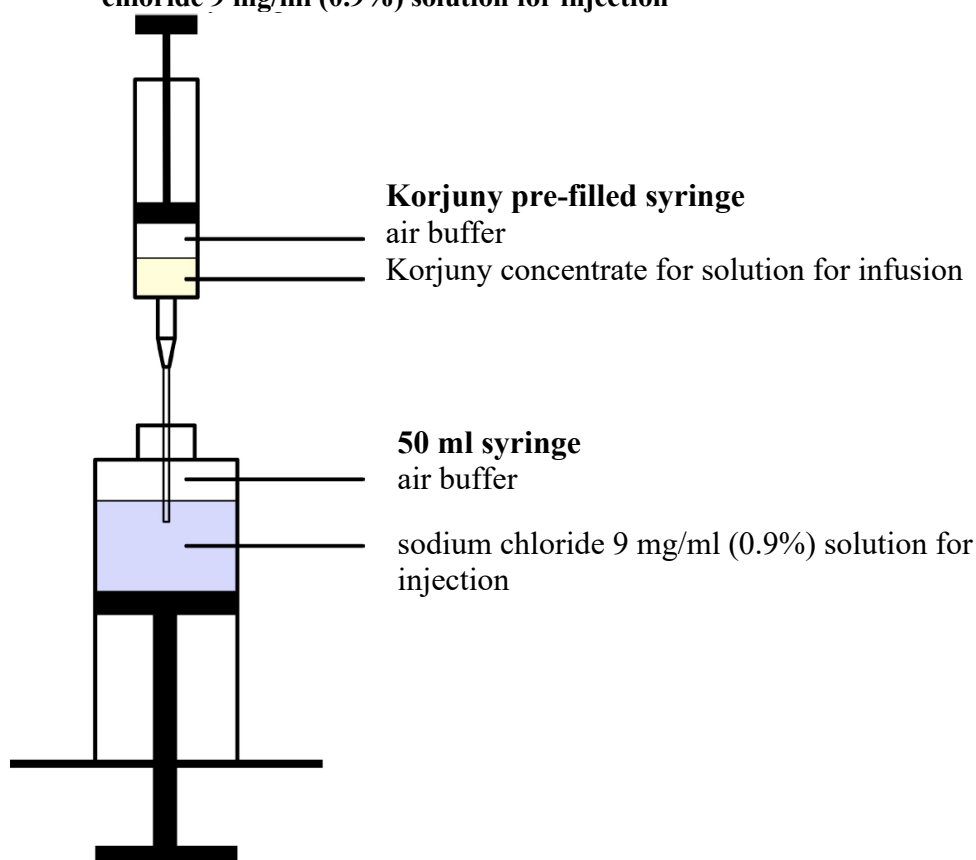
syringes into the 50 ml syringe.

- The 50 ml syringe is closed with a cap and shaken gently to mix the solution.
- After removing the cap, any air bubbles are eliminated from the 50 ml syringe.
- The red peelable sticker, which is provided inside the carton lid, displaying the text “Diluted Korjony. Intraperitoneal use only.” must be attached to the 50 ml syringe. This is a precautionary measure to ensure Korjony is intraperitoneally infused only.
- The 50 ml syringe is inserted in the infusion pump.

**Table      Number of pre-filled syringes and volumes required for preparation of Korjony solution for intraperitoneal infusion**

| Infusion/Dose                               | Number of 10 micrograms pre-filled syringes | Number of 50 micrograms pre-filled syringes | Total volume of Korjony concentrate for solution for infusion | Sodium chloride 9 mg/ml (0.9%) solution for injection | Final volume for administration |
|---------------------------------------------|---------------------------------------------|---------------------------------------------|---------------------------------------------------------------|-------------------------------------------------------|---------------------------------|
| 1 <sup>st</sup> infusion/<br>10 micrograms  | 1                                           | ---                                         | 0.1 ml                                                        | 10 ml                                                 | 10.1 ml                         |
| 2 <sup>nd</sup> infusion/<br>20 micrograms  | 2                                           | ---                                         | 0.2 ml                                                        | 20 ml                                                 | 20.2 ml                         |
| 3 <sup>rd</sup> infusion/<br>50 micrograms  | ---                                         | 1                                           | 0.5 ml                                                        | 49.5 ml                                               | 50 ml                           |
| 4 <sup>th</sup> infusion/<br>150 micrograms | ---                                         | 3                                           | 1.5 ml                                                        | 48.5 ml                                               | 50 ml                           |

**Figure      Transfer of Korjony from the pre-filled syringe to the 50 ml syringe containing sodium chloride 9 mg/ml (0.9%) solution for injection**



The prepared solution for infusion is physically and chemically stable for 48 hours at 2 °C to 8 °C and for 24 hours at a temperature not above 25 °C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 °C to 8 °C, unless dilution

has taken place in controlled and validated aseptic conditions.

### **Method of administration**

The catheter for intraperitoneal administration is placed under ultrasound guidance by a doctor experienced in intraperitoneal administration. The catheter is used for ascites drainage, and administration of diluted Korjunny solution for infusion and sodium chloride 9 mg/ml (0.9%) solution for injection. It is recommended that the catheter remains in the abdominal cavity during the entire treatment period. It can be removed based on the judgement of the treating doctor on the day after the last infusion.

Prior to each Korjunny administration, the ascites fluid must be drained until cessation of spontaneous flow or symptom relief (see section 4.4). Subsequently, prior to each Korjunny administration, 500 ml sodium chloride 9 mg/ml (0.9%) solution for injection shall be infused to support distribution of the antibody in the abdominal cavity.

Diluted Korjunny solution for infusion is intraperitoneally administered over an infusion time of at least 3 hours via a constant infusion pump system, as follows:

- The connected perfusion tubing equipment of the infusion pump is prefilled with the diluted Korjunny solution for infusion.
- The perfusion tubing is connected to the Y connection.
- Parallel to each Korjunny administration, 250 ml sodium chloride 9 mg/ml (0.9%) solution for injection is infused via an infusion valve / Y connection in the perfusion lead of the catheter.
- The pump speed is adjusted according to the volume to be administered and the scheduled infusion time of at least 3 hours.
- When the 50 ml syringe containing the diluted Korjunny solution for infusion is empty, it is replaced with a 50 ml syringe containing 20 ml sodium chloride 9 mg/ml (0.9%) solution for injection, to clear the dead volume in the perfusion lead (approximately 2 ml), under unchanged conditions. The remaining sodium chloride 9 mg/ml (0.9%) solution for injection can be discarded.
- The catheter is kept closed until the next infusion.
- The day after the last infusion, a drainage of ascites is performed until cessation of spontaneous flow. Subsequently, the catheter can be removed.

### **Disposal**

No special requirements.