Package leaflet: Information for the patient

Vyloy 100 mg powder for concentrate for solution for infusion
Vyloy 300 mg powder for concentrate for solution for infusion
zolbetuximab

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

What is in this leaflet

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

1. What Vyloy is and what it is used for

Vyloy contains the active substance zolbetuximab, which is a monoclonal antibody that can recognise and attach to certain cancer cells. By attaching to these cancer cells, the medicine is intended to kill them.

Vyloy is used to treat adults with stomach (gastric) or gastro-oesophageal junction cancer. The gastro-oesophageal junction is the place where the oesophagus (gullet) joins the stomach.

This medicine is given to patients whose tumours are positive for the "Claudin18.2 (CLDN18.2)", and negative for the "Human epidermal growth factor receptor 2 (HER2)" proteins. It is given to patients whose gastric or gastro-oesophageal junction cancer cannot be removed by surgery or has spread to other parts of the body.

This medicine is given in combination with other anti-cancer medicines. It is important that you also read the package leaflets for these other medicines. If you have any questions about these medicines, ask your doctor.

2. What you need to know before you are given Vyloy

You must not be given Vyloy
- if you are allergic to zolbetuximab or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor before you are given Vyloy as it may cause:

- **Allergic (hypersensitivity) reactions**, **including anaphylaxis.** Serious allergic reactions can happen during or after you receive your infusion. Tell your doctor or get medical help right away if you have any of the following symptoms of a serious allergic reaction: itchy, swollen pink or red areas of the skin (hives), coughing that doesn't go away, breathing problems such as wheezing, or throat tightness/change in voice.

- **Infusion related reaction.** Severe infusion reactions can happen during or after you receive your infusion. Tell your doctor or get medical help right away if you have any of the following symptoms of an infusion related reaction: nausea, vomiting, stomach pain, increased saliva (salivary hypersecretion), fever, chest discomfort, chills or shaking, back pain, cough, or high blood pressure (hypertension).

- **Nausea and vomiting.** Before you start this medicine, tell your doctor if you are currently experiencing nausea and/or vomiting. Nausea (feeling sick) and vomiting (being sick) could be common during treatment and can sometimes be severe. Your doctor may give you medicine before each infusion to help relieve nausea and vomiting.

Tell your doctor immediately if you have any of these signs or symptoms or if they get worse. Your doctor may:
- give you other medicines in order to prevent complications and reduce your symptoms
- slow the rate of your Vyloy infusion or
- stop your treatment for a period of time (temporarily) or completely.

Children and adolescents
This medicine should not be used in children and adolescents below 18 years of age.

Other medicines and Vyloy
Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Pregnancy
- Vyloy should not be used if you are pregnant unless your doctor specifically recommends it.
- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
- It is not known if Vyloy will harm your unborn baby.

Breastfeeding
- Breastfeeding is not recommended during treatment with Vyloy.
- Tell your doctor if you are breastfeeding or plan to breastfeed.
- It is not known if Vyloy passes into your breast milk.

Driving and using machines
Vyloy can cause side effects that may affect your ability to drive or use machines. Use caution when deciding to drive or use machines after you have been given Vyloy if you are feeling unwell.

Vyloy contains polysorbate 80
This medicine contains 1.05 mg and 3.15 mg of polysorbate 80 in each 100 mg and 300 mg dose of Vyloy, respectively. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How Vyloy is given

You will receive Vyloy in a hospital or clinic under the supervision of a doctor experienced in cancer treatment.

How much Vyloy you will receive
Your doctor will decide how much of this medicine you will receive. You will usually receive Vyloy every 2 or 3 weeks based on the other anti-cancer medicines chosen by your doctor. Your doctor will decide how many treatments you need.

How you will receive Vyloy
Vyloy will be given to you by intravenous infusion into your vein over at least 2 hours.

If you miss a dose of Vyloy
It is very important that you do not miss a dose of this medicine. If you miss an appointment, call your doctor to reschedule your appointment as soon as possible.

If you stop treatment with Vyloy
Do not stop treatment with Vyloy unless you have discussed this with your doctor. Stopping your treatment may stop the effect of the medicine.

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.

Some possible side effects may be serious:

- **Hypersensitivity (allergic) reactions (including hypersensitivity and anaphylactic reaction).** Tell your doctor or get medical help right away if you have any of these symptoms of a serious allergic reaction: itchy, swollen pink or red areas of the skin (hives), coughing that doesn't go away, breathing problems such as wheezing, or throat tightness/change in voice (may affect up to 1 in 10 people).

- **Infusion related reaction.** Tell your doctor or get medical help right away if you have any of these symptoms of an infusion related reaction: nausea, vomiting, stomach pain, increased saliva (salivary hypersecretion), fever, chest discomfort, chills or shaking, back pain, cough, or high blood pressure (hypertension) (may affect up to 1 in 10 people).

- **Nausea and vomiting.** Tell your doctor if these symptoms do not go away or become worse (may affect more than 1 in 10 people).

Other possible side effects:

If these side effects become severe, tell your doctor.

Very common *(may affect more than 1 in 10 people):*
- decreased appetite
- pain in the upper abdomen
- decreased weight
- low levels of albumin in the blood (hypoalbuminaemia)
- swelling of the lower legs or hands (oedema peripheral)

Common *(may affect up to 1 in 10 people):*
- increased saliva (salivary hypersecretion)
- generally feeling unwell

Uncommon *(may affect up to 1 in 100 people):*
- inflammation of the stomach lining (gastritis)

Other side effects that have been reported with frequency not known *(cannot be estimated from the available data):*
- loss of protein from the digestive tract (protein-losing gastroenteropathy)

Reporting of side effects
If you get any side effects, talk to your doctor. 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 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 Vyloy

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 vial label after EXP. The expiry date refers to the last day of that month.

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

Do not store any unused portion of the single-dose vials for reuse. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What Vyloy contains
- The active substance is zolbetuximab.
- One vial of 100 mg powder for concentrate for solution for infusion contains an extractable amount of 100 mg zolbetuximab.
- One vial of 300 mg powder for concentrate for solution for infusion contains an extractable amount of 300 mg zolbetuximab.
- After reconstitution, each ml of solution contains 20 mg of zolbetuximab.

The other ingredients are arginine, phosphoric acid, sucrose, and polysorbate 80 (see section 2 “Vyloy contains polysorbate 80”).

What Vyloy looks like and contents of the pack
Vyloy powder for concentrate for solution for infusion is a white to off-white lyophilised powder.

Vyloy is supplied in a carton containing 1 vial.

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The following information is intended for healthcare professionals only:

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Instructions for preparation and administration

Reconstitution in single-dose vial

1. Follow procedures for proper handling and disposal of anticancer drugs.
2. Use appropriate aseptic technique for reconstitution and preparation of dosing solutions.
3. Calculate the recommended dose based on the patient's body surface area to determine the number of vials needed.
4. Reconstitute each vial as follows. If possible, direct the stream of sterile water for injections (SWFI) along the walls of the vial and not directly onto the lyophilised powder:
   a. 100 mg vial: Slowly add 5.0 mL of SWFI, resulting in 20 mg/mL zolbetuximab.
   b. 300 mg vial: Slowly add 15.0 mL of SWFI, resulting in 20 mg/mL zolbetuximab.
5. Slowly swirl each vial until the contents are completely dissolved. Allow the reconstituted vial(s) to settle. Visually inspect the solution until the bubbles are gone. Do not shake the vial.
6. Visually inspect the solution for particulate matter and discolouration. The reconstituted solution should be clear to slightly opalescent, colourless to slight yellow and free of visible particles. Discard any vial with visible particles or discolouration.
7. Based upon the calculated dose amount, the reconstituted solution from the vial(s) should be added to the infusion bag immediately. This product does not contain a preservative.

Dilution in infusion bag

8. Withdraw the calculated dose amount of reconstituted solution from the vial(s) and transfer into an infusion bag.
9. Dilute zolbetuximab with 0.9% Sodium Chloride Injection. The infusion bag size should allow enough diluent to achieve a final concentration of 2 mg/mL zolbetuximab.

The diluted dosing solution of zolbetuximab is compatible with intravenous infusion bags composed of polyethylene (PE), polypropylene (PP), polyvinyl chloride (PVC) with either plasticiser [Di-(2-ethylhexyl) phthalate (DEHP) or Trioctyl trimellitate (TOTM)], ethylene propylene copolymer, ethylene-vinyl acetate (EVA) copolymer, polypropylene and styrene-ethylene-butylene-styrene copolymer, or glass (bottle for administration use), and infusion tubing composed of PE, polyurethane (PU), PVC with either plasticiser [DEHP, TOTM or Di-(2-ethylhexyl) terephthalate], polybutadiene (PB), or elastomer modified polypropylene with in-line filter membranes (pore size 0.2 μm) composed of polyethersulfone or polysulfone.

10. Mix diluted solution by gentle inversion. Do not shake the bag.
11. Visually inspect the infusion bag for any particulate matter prior to use. The diluted solution should be free of visible particles. Do not use the infusion bag if particulate matter is observed.
12. Discard any unused portion left in the single-dose vials.

Administration

13. Do not co-administer other medicinal products through the same infusion line.

14. Immediately administer the infusion over a minimum of 2 hours through an intravenous line. Do not administer as an IV push or bolus.

If not administered immediately, the prepared infusion bag should be stored:

- under refrigeration at 2°C to 8°C for no longer than 24 hours including infusion time from the end of the preparation of the infusion bag. Do not freeze.
- at room temperature (≤30°C) for no longer than 8 hours including infusion time from when the prepared infusion bag is removed from the refrigerator.

Do not expose to direct sunlight. Discard unused prepared infusion bags beyond the recommended storage time.

No incompatibilities have been observed with closed system transfer device composed of PP, PE, stainless steel, silicone (rubber/oil/resin), polyisoprene, PVC or with plasticiser [TOTM], acrylonitrile-butadiene-styrene (ABS) copolymer, methyl methacrylate-ABS copolymer, thermoplastic elastomer, polytetrafluoroethylene, polycarbonate, polyethersulfone, acrylic copolymer, polybutylene terephthalate, PB, or EVA copolymer.

No incompatibilities have been observed with central port composed of silicone rubber, titanium alloy or PVC with plasticiser [TOTM]. In-line filters (pore size of 0.2 µm with materials listed above) are recommended to be used during administration.

Disposal

Vyloy is for single use only.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.