

PATIENT INFORMATION

VYLOY® (vye-LOY)
(zolbetuximab-clzb)
for injection

What is VYLOY?

VYLOY is a prescription medicine used to treat adults with cancer of the stomach (gastric cancer) or cancer located where the esophagus joins the stomach (gastroesophageal junction cancer). VYLOY is used in combination with chemotherapy that contains fluoropyrimidine and platinum as the first treatment when your gastric or gastroesophageal junction cancer:

- cannot be removed with surgery or has spread to other parts of the body,
- is HER2-negative, **and**
- your tumor tests positive for “claudin (CLDN) 18.2.”

It is not known if VYLOY is safe and effective in children.

Before receiving VYLOY, tell your healthcare provider about all of your medical conditions, including if you:

- have nausea or vomiting.
- are pregnant or plan to become pregnant. It is not known if VYLOY will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if VYLOY passes into your breast milk. Do not breastfeed during treatment with VYLOY and for 8 months after the last dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive VYLOY?

- VYLOY will be given to you by intravenous (IV) infusion into your vein.
- Your healthcare provider will decide how much VYLOY you will receive.
- You will usually receive VYLOY every 2 or 3 weeks based on the chemotherapy chosen by your healthcare provider.
- Your healthcare provider will decide how many treatments you need.

What are the possible side effects of VYLOY?

VYLOY may cause serious side effects, including:

- **Allergic reactions, including anaphylaxis and infusion related reactions.** Allergic reactions are common during treatment with VYLOY and can sometimes be serious. Serious allergic reactions can happen during or after your VYLOY infusion, including life-threatening allergic reactions and serious infusion-related reactions that may lead to death. Your healthcare provider will monitor you during your infusion and for 2 hours after or longer if needed. Tell your healthcare provider or get emergency medical help right away if you get any of the following symptoms of a serious allergic reaction during or after your infusion of VYLOY:
 - itchy, raised bumps on the skin (hives)
 - coughing that does not go away
 - nausea or vomiting
 - stomach (abdominal) pain
 - increased saliva
 - breathing problems such as wheezing
 - throat tightness or change in voice
 - fever
 - chest discomfort
 - chills or shaking
 - back pain
- **Severe nausea and vomiting.** Nausea and vomiting are common during treatment with VYLOY and can sometimes be severe. Nausea and vomiting happened more often during the first treatment cycle. Before you receive each VYLOY infusion, your healthcare provider will give you medicines to help prevent nausea and vomiting. Tell your healthcare provider right away if nausea or vomiting does not go away or gets worse.

The most common side effects of VYLOY include:

- tiredness
- decreased appetite
- diarrhea
- tingling or numbness of the arms or legs
- stomach (abdominal) pain
- constipation
- decreased weight
- fever
- decreased white blood cells, red blood cells and platelets
- decreased protein (albumin) in the blood
- changes in kidney function tests
- changes in blood sugar (glucose)
- changes in liver function tests
- changes in body salts (electrolytes) in your blood

Your healthcare provider may slow the rate of your infusion, temporarily stop, or completely stop treatment with VYLOY if you have certain side effects.

These are not all of the possible side effects of VYLOY.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of VYLOY.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about VYLOY that is written for health professionals.

What are the ingredients in VYLOY?

Active ingredient: zolbetuximab-clzb

Inactive ingredients: arginine, polysorbate 80, sucrose, and phosphoric acid to adjust pH.

Manufactured by:

Astellas Pharma US, Inc.

Northbrook, Illinois 60062

U.S. License 2124

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For more information, go to www.VYLOY.com or call 1-888-727-7003.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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