



# A guide to your treatment with **VYLOY**<sup>™</sup> (zolbetuximab)

**This booklet is designed for patients who have been prescribed VYLOY (zolbetuximab). This booklet should be referred to alongside the Patient Information Leaflet (provided with your medicine), which should be consulted throughout the duration of your treatment.**

## **What is VYLOY (zolbetuximab)?<sup>1</sup>**

VYLOY (zolbetuximab) 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 (zolbetuximab) 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 claudin 18.2 (CLDN18.2) protein
- Are negative for the human epidermal growth factor receptor 2 (HER2) protein

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.

**▼ 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 page 14 for how to report side effects.**



## There's a plan to help you

This guide describes what you can expect with your treatment with VYLOY (zolbetuximab). You'll find out:

- Why your doctor chose VYLOY (zolbetuximab)
- What your treatment does
- How to follow your treatment plan

This booklet should be referred to alongside the Patient Information Leaflet (provided with your medicine), which should be consulted throughout the duration of treatment.

If you lose your Patient Information Leaflet, ask your pharmacist for another.

**Please read Important Safety Information on pages 8–10.**



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If any of the words in this guide are new or difficult to understand, then please see the [glossary on page 20](#).

Otherwise, please speak to your doctor and they will be able to talk through anything you do not understand.

If you have any questions or concerns regarding your treatment, please contact your doctor. This booklet should be referred to alongside the Patient Information Leaflet (provided with your medicine), which should be consulted throughout the duration of treatment.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

Side effects should be reported. You can 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.

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# After your diagnosis

Gastric and gastro-oesophageal junction cancer can be referred to as stomach cancer. When your doctor tells you that you have stomach cancer, they're also telling you they're there to help. And they won't be the only one. Your doctor is the first of many people who will be there for you every step of the way, such as:



**Your medical team:** Every doctor, oncologist, nurse, pharmacist, or dietitian you meet wants to give you the best care



**Your family and friends:** The people in your personal life who are always there for you



**Support groups:** People whose lives have been affected by cancer can share insight and advice. Ask your doctor about support groups in your local area

**During treatment, reach out to these people for support. Talk to them about how you are feeling. Tell them how they can help you. You don't have to go through it on your own.**

Please read Important Safety Information on pages 8–10.





## What is stomach cancer?<sup>2-4</sup>

The most common type of stomach cancer in the UK is adenocarcinoma. Adenocarcinomas are cancers that develop in gland cells. These cells make mucus and stomach juices. It can also grow in areas next to it, like the oesophagus (which is the tube between your mouth and your stomach). This cancer may have spread to areas near your stomach (locally advanced) and it might not be possible to remove it with surgery (unresectable). It may also have spread to other parts of your body (metastatic). Before your doctor diagnosed the cancer, you may have had symptoms like:



Stomach upset (indigestion) that doesn't go away



Stomach pain



Feeling full after a few bites of food



Trouble swallowing



Losing weight without trying



Feeling tired or weak because you don't have enough red blood cells (anaemia)



Bloating



Passing black, tarry stools because of bleeding in the gastrointestinal tract

These are just some of the symptoms you may experience.

People often think that these symptoms come from other illnesses. That is why they usually don't know they have cancer until it's in late stages.

Please read [Important Safety Information](#) on pages 8–10.



# Understanding your treatment: Why VYLOY (zolbetuximab) has been prescribed to you

## Testing helps doctors to learn more about your cancer<sup>5</sup>

Each case of advanced stomach cancer is different. By testing for something called a biomarker, your doctor learns more about your cancer. This helps them decide what treatment may be suitable for you.

- A biomarker is a molecule that may be found more often on certain cancers
- Biomarker tests may tell doctors what type of cancer you have

## You may be treated with VYLOY (zolbetuximab) if:<sup>6</sup>

- Your cancer tests positive for a biomarker called Claudin 18.2, and
- Your cancer tests negative for a biomarker called HER2

## Treatment with VYLOY (zolbetuximab)

Since VYLOY (zolbetuximab) targets Claudin 18.2, your doctors believe this treatment could help you. On the next page, you'll learn more about how this treatment works.

VYLOY (zolbetuximab) is given in combination with other anti-cancer medicines.

**VYLOY (zolbetuximab) is a  
monoclonal antibody<sup>1</sup>**



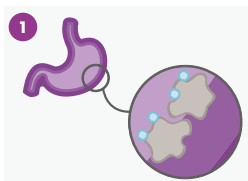
Please read [Important Safety Information](#) on pages 8–10.



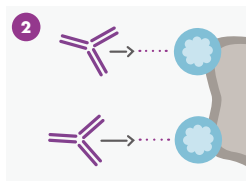


## How VYLOY (zolbetuximab) targets your cancer<sup>6,7</sup>

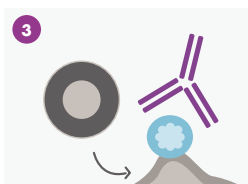
Let's take a look at how VYLOY (zolbetuximab) works with your immune system to fight your type of cancer. VYLOY (zolbetuximab) is a monoclonal antibody. A monoclonal antibody is a type of targeted drug therapy that recognises and finds specific proteins on cancer cells. It attaches to a protein called Claudin 18.2.



In some people, the biomarker Claudin 18.2 is **found** on the surface of stomach cancer cells



VYLOY (zolbetuximab) is **attracted** to that biomarker and attaches to it



VYLOY (zolbetuximab) tells the immune system to **attack** the cancer cell



The immune system then **destroys** the cancer cells

**If you have any questions or concerns regarding your treatment, please contact your doctor.**



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zolbetuximab

# Important safety information

Please talk to your doctor if you have any concerns about your medicines. Do not start or stop taking any medicines without seeking medical advice first.

**For full details, please see the Patient Information Leaflet (provided with your medicine)<sup>1</sup>**

## What you need to know before you are given VYLOY (zolbetuximab)



### Who shouldn't be given VYLOY (zolbetuximab)<sup>1</sup>

**You must not** be given VYLOY (zolbetuximab) if you are allergic to zolbetuximab or any of the other ingredients of this medicine.

VYLOY (zolbetuximab) is not for use in patients below 18 years of age.



### Warnings and precautions

Talk to your doctor before you are given VYLOY (zolbetuximab), as it may cause the following:

- **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



Chest discomfort



Vomiting



Chills or shaking



Stomach pain



Back pain



Increased saliva  
(salivary hypersecretion)



Cough



Fever



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 (zolbetuximab) infusion
- Stop your treatment for a period of time (temporarily) or completely



# Important safety information



## **Other medicines and VYLOY (zolbetuximab)**

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



## **Pregnancy**

- VYLOY (zolbetuximab) 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 whether VYLOY (zolbetuximab) will harm your unborn baby

## **Breastfeeding**

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



## **Driving and using machines**

- VYLOY (zolbetuximab) 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 (zolbetuximab) if you are feeling unwell



# How VYLOY (zolbetuximab) is given

## How to follow your treatment plan

- You will receive VYLOY (zolbetuximab) in a hospital or clinic under the supervision of a doctor experienced in cancer treatment<sup>1</sup>
- Your doctor may help you mark your calendar for treatments. They may also help you find ways to follow your plan

## VYLOY (zolbetuximab) and chemotherapy are given at the same visit

(every 2 or 3 weeks, based on your doctor's plan)



## VYLOY (zolbetuximab) is an infusion (given through your vein)<sup>1,6</sup>

- VYLOY (zolbetuximab) will be given to you by intravenous infusion over at least 2 hours
- Following the infusion with VYLOY (zolbetuximab), an infusion with chemotherapy will be given. This will add to the treatment duration for the day. Ask your doctor what treatment duration to expect so that you can plan your visit. Your doctor might add more time to help with side effects
- Your doctor will decide how much of this medicine you will receive. You will usually receive VYLOY (zolbetuximab) 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

**Each treatment appointment is very important. Staying on schedule gives your treatment the best chance to work for you.**

Please read [Important Safety Information](#) on pages 8–10.





**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.<sup>1</sup>**

Do not stop treatment with VYLOY (zolbetuximab) 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. They can:

- Help you stay on your plan
- Keep track of how you're feeling between visits
- Help you manage side effects

### **Prior to infusion**

- If you are experiencing nausea or vomiting before treatment, your doctor will resolve your symptoms before you receive the first infusion<sup>6</sup>
- Before each infusion of this medication, your doctor may give you medicine to help relieve nausea and vomiting<sup>1</sup>

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# Talking about side effects


**Please refer to the Patient Information Leaflet (provided with your medicine) for a full list of side effects.**

## **Possible side effects<sup>1</sup>**


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

 **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)

 **Nausea (feeling sick).** Tell your doctor if these symptoms do not go away or become worse

 **Vomiting (being sick).** Tell your doctor if these symptoms do not go away or become worse

The side effects listed on this page may affect up to 1 in 10 people.

Everyone responds to treatment in different ways, but your doctor is there to help you. Do not stop treatment unless you have discussed this with your doctor. Stopping your treatment may stop the effect of the medicine.






Please read Important Safety Information on pages 8–10.







### Other possible side effects

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

-  Decreased appetite
-  Pain in the upper abdomen
-  Decreased weight
-  Low levels of a protein called 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

If these side effects become severe, tell your doctor.

### 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](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.

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# Supporting your nutrition



## Tips on getting the nutrition you need<sup>8</sup>

You may have a hard time with meals. This may be because of your cancer or a reaction to your treatment. It may not be easy to swallow some foods. You might not like the smell of cooking certain foods. But getting nutrition is important, and you can still take control of your diet. When you're changing the way you eat, try these tips:

- ✓ Have smaller meals, more often
- ✓ Drink something before or after meals
- ✓ Cut down on sweet foods and drinks
- ✓ Ask a dietitian about finding new foods

**Reach out to your doctor** for more help. You could ask them:

- Are there foods or drinks that I should avoid?
- Are there foods or drinks that can help alleviate nausea?
- What kind of vitamins, supplements or liquid meal replacements can I take?
- Should I take any medicine to help with my symptoms?
- Is there anything I should know about coming home after treatment?

**Talk to your family and friends.** Let them know about any food issues you're having, and tell them how they can help you so that you don't miss out on shared mealtime moments.

**Remember, you're not alone. Others who have been through cancer are here to help. See page 18 for groups that can offer advice on living with cancer, taking treatment, and managing meals.**

Please read [Important Safety Information](#) on pages 8–10.





### **Get the most out of every visit**

Talk with your doctor at each visit. Help them understand what you need and how you feel. Let them know how they can help.

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

### **You might want to ask:**

- Do I have to change how I take other medicines?
- What should I know to get ready for my first treatment with VYLOY (zolbetuximab)?
- Will I need any tests between treatments?
- When should I talk to you about side effects? What's the best way to do that?
- Is there anything else I should do during treatment?
- What support programmes can help me deal with stress or anxiety?

### **Doctor contact information**

Write down the contact information of your doctor. Having this information in an easily accessible place may be helpful to you and you family members or friends.

Name: \_\_\_\_\_

Contact: \_\_\_\_\_

Please read Important Safety Information on pages 8–10.



# Every question you have is important

There's no such thing as a bad question. It's all part of staying in touch with your doctor and helping them understand what is most important to you. Use this space to write down anything you want to discuss.

Notes:

Scheduling notes:

Your first infusion is on \_\_\_\_\_.

Your next infusions will happen every \_\_\_\_\_ weeks.

Please read Important Safety Information on pages 8–10.



# Connecting with a community of support

Beyond your doctor and your personal caregivers, there are other groups ready to support you during treatment. Here are some that you may find helpful:

- **The Gastric Cancer Foundation**, which empowers patients and caregivers to face their diagnosis with information and tools to navigate the journey. They can connect you to a caring community that offers support. You can find them at [GastricCancer.org](https://www.gastriccancer.org)
- **Debbie's Dream Foundation**, a nonprofit organisation that is raising awareness, funding research and supporting patients with stomach cancer. Visit [DebbiesDream.org](https://www.debbiesdream.org) to learn about all their offerings
- **Maggie's**, a charity that offers support for free to anyone with cancer and their families. Maggie's centres can be found alongside NHS hospitals or accessed online. [www.maggies.org](https://www.maggies.org)
- **Cancer Research UK**, a charity that is raising awareness, funding research and supporting patients with cancer. [www.cancerresearchuk.org/about-cancer/stomach-cancer](https://www.cancerresearchuk.org/about-cancer/stomach-cancer)
- **Macmillian Cancer Support**, a charity offering information, advice and support to patients with cancer. [www.macmillan.org.uk](https://www.macmillan.org.uk)
- **OPA Cancer Charity**, a charity offering support for patients, caregivers and families of those with oesophageal and gastric cancer. [opa.org.uk/](https://opa.org.uk/)
- **Guts UK**, a national charity that provides information and support for people affected by digestive conditions and symptoms. [gutscharity.org.uk](https://gutscharity.org.uk)
- **Ochre**, a charity raising awareness for oesophageal cancer amongst public, professionals, politicians and patients. [ochrecharity.org.uk](https://ochrecharity.org.uk)

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**Here are some tips that have helped other patients living with cancer:<sup>9,10</sup>**

- Keep a treatment journal** to share with your doctor
- Stay hydrated.** Drink plenty of water and other fluids
- Ask your doctor** to help you make a plan for good nutrition
- Take a walk or sit outside** for fresh air
- Talk** with friends and family

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# Glossary

**Adenocarcinoma:** A cancer that forms in the glandular tissue, which lines certain internal organs and makes and releases substances in the body, such as mucus, digestive juices, and other fluids<sup>11</sup>

**Anaphylaxis (anaphylactic reaction):** A severe and sometimes life-threatening immune system reaction to an antigen that a person has been previously exposed to<sup>12</sup>

**Antibody:** A protein most commonly made by the body's immune system. The antibody that makes up VYLOY (zolbetuximab) is made in a laboratory<sup>6,13</sup>

**Biomarker:** A biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease. A biomarker may be used to see how well the body responds to a treatment for a disease or condition. Also called molecular marker and signature molecule<sup>5</sup>

**Chemotherapy:** Treatment that uses medicines to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. This can affect cancer cells and normal cells<sup>11</sup>

**Gastro-oesophageal junction:** The place where the oesophagus is connected to the stomach<sup>15</sup>

**Intravenous infusion:** A way of giving a medicine or other substance through a needle or a tube inserted into a vein<sup>16</sup>

**Monoclonal antibody:** A type of protein that is made in the laboratory and can bind to certain targets in the body, such as antigens on the surface of cancer cells. Each monoclonal antibody is made so that it binds to only one antigen. Monoclonal antibodies are being used in the diagnosis and treatment of many diseases, including some types of cancer<sup>17</sup>

Please read Important Safety Information on pages 8–10.



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**Always remember to:**

- **Stay connected** to the people who care for you, and let them know how they can help you
- **Take care of yourself** during your treatment, and get the nutrition you need
- **Reach out** to your doctor, family members or friends when you need them

If you have any questions or concerns regarding your treatment, please contact your doctor. This booklet should be referred to alongside the Patient Information Leaflet (provided with your medicine), which should be consulted throughout the duration of your treatment.

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