

A caregiver's guide to treatment with VYLOY[™] (zolbetuximab)

This booklet is designed for family and friends supporting patients who have been prescribed VYLOY (zolbetuximab). This booklet should be referred to alongside the Patient Information Leaflet (provided with the medicine), which should be consulted throughout the duration of your loved one's treatment.

What is VYLOY (zolbetuximab)?¹

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 and/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 loved one's 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 observe. See page 15 for how to report side effects.



A close-up photograph of two women laughing joyfully. The woman on the left has dark, curly hair and is wearing a grey cardigan over a patterned top. The woman on the right has long, dark hair and is wearing a green top. They are both smiling broadly, showing their teeth, and appear to be in a warm, intimate setting.

There's a plan to help

On the next few pages, you'll learn about treatment with VYLOY (zolbetuximab). You'll find out:

- How VYLOY (zolbetuximab) works
- How you can help your loved one follow their treatment plan
- Tips for caring for your loved one and yourself

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

If you lose the Patient Information Leaflet, ask the 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 24**. Otherwise, please speak to your loved one’s doctor and they will be able to talk through anything you do not understand.

If you have any questions or concerns regarding your loved one’s treatment, please contact their doctor. This booklet should be referred to alongside the Patient Information Leaflet (provided with the medicine), which should be read before your loved one takes VYLOY (zolbetuximab).

If your loved one gets any side effects, talk to their 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 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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Your role as a caregiver

When someone you love is getting treatment for cancer, you can be there for them like no one else can. It's natural to want to do everything, but the key is to take one step at a time. What's the first step? Learning more about the treatment ahead. In this guide, you'll find how to do that with:

Background for support: Learn about advanced stomach cancer and how treatment with VYLOY works

Tips to care for your loved one: Find out how you can help them manage side effects and follow their treatment plan

Advice for caring for yourself: Understand why it is important to take time for yourself as well

Links to support groups: Connect with people who can share their own experiences and insights

Remember: You are not in it alone. You can always reach out to others. Your family, your friends, and your loved one's care team are there to help you both.

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What is stomach cancer?²⁻⁴

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 the stomach (locally advanced) and it might not be possible to remove it with surgery (unresectable). It may also have spread to other parts of the body (metastatic). Before your loved one was diagnosed with the cancer, they 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 they 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 they 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.

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Understanding the treatment: Why VYLOY (zolbetuximab) has been prescribed to your loved one

Testing helps doctors to learn more about your loved one's cancer⁵

Each case of advanced stomach cancer is different. By testing for something called a biomarker, your loved one's doctor learns more about the cancer. This helps doctors understand how they may be able to target that cancer with treatment.

- A biomarker is a molecule that may be found more often on certain cancers
- Biomarker tests may tell doctors what type of tumour is present and how to treat it
- **If your loved one's cancer tests positive for a biomarker called Claudin 18.2,** and is negative for a biomarker called HER2, your loved one may be treated with VYLOY (zolbetuximab)⁶

Treatment with VYLOY (zolbetuximab)

Since VYLOY (zolbetuximab) targets Claudin 18.2, your loved one's doctors believe this treatment could help them. 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 antibody¹**



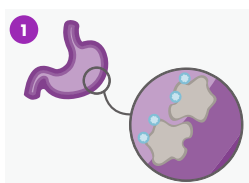
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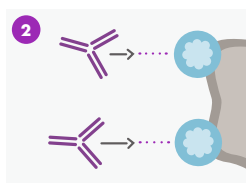


How VYLOY (zolbetuximab) targets your loved one's cancer^{6,7}

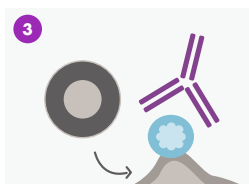
Let's take a look at how VYLOY (zolbetuximab) works with the immune system to fight cancer. VYLOY (zolbetuximab) is a monoclonal antibody. A monoclonal antibody is a type of targeted drug therapy that recognises and finds specific proteins on cancer cells. It attaches to a protein called Claudin 18.2.



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



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



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



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

If you have any questions or concerns regarding your loved one's treatment, please contact their doctor.



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Important safety information

Please talk to your loved one's doctor if you have any concerns about their medicines. Your loved one should not start or stop taking any medicines without seeking medical advice first.

**For full details, please see the Patient Information Leaflet
(provided with the medicine)¹**

What you need to know before your loved one is given VYLOY (zolbetuximab)



Who shouldn't be given VYLOY (zolbetuximab)¹

Your loved one must not be given VYLOY (zolbetuximab) if they 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 loved one's doctor before they are given VYLOY (zolbetuximab), as it may cause the following:

- **Allergic (hypersensitivity) reactions, including anaphylaxis.** Serious allergic reactions can happen during or after your loved one receives their infusion. Tell the doctor or get medical help right away if your loved one has 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 your loved one receives their infusion. Tell their doctor or get medical help right away if they have any of the following symptoms:



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 starting this medicine, tell the doctor if your loved one is currently experiencing nausea and/or vomiting. Nausea (feeling sick) and vomiting (being sick) could be common during treatment and can sometimes be severe. The doctor may give your loved one medicine before each infusion to help relieve nausea and vomiting

Tell the doctor immediately if your loved one has have any of these signs or symptoms or if they get worse. Their doctor may:

- Give other medicines in order to prevent complications and reduce their symptoms
- Slow the rate of their VYLOY (zolbetuximab) infusion
- Stop their treatment for a period of time (temporarily) or completely



Important safety information



Other medicines and VYLOY (zolbetuximab)

Tell your loved one's doctor if your loved one is taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.



Pregnancy

- VYLOY (zolbetuximab) should not be used if your loved one is pregnant, unless their doctor specifically recommends it
- If your loved one is pregnant, think they might be pregnant or is planning to have a baby, please encourage your loved one to ask their doctor for advice before taking this medicine
- It is not known whether VYLOY (zolbetuximab) will harm your loved one's unborn baby

Breastfeeding

- Breastfeeding is not recommended during treatment with VYLOY (zolbetuximab)
- Please encourage your loved one to tell the doctor if they are breastfeeding or plans to breastfeed
- It is not known if VYLOY (zolbetuximab) passes into breast milk



Driving and using machines

- VYLOY (zolbetuximab) can cause side effects that may affect the ability to drive or use machines. Make sure your loved one uses caution when deciding to drive or use machines after they have been given VYLOY (zolbetuximab) if they are feeling unwell





How VYLOY (zolbetuximab) is given

How to follow your loved one's treatment plan

- Your loved one will receive VYLOY (zolbetuximab) in a hospital or clinic under the supervision of a doctor experienced in cancer treatment¹
- Your loved one's doctor may help them mark their calendar for treatments. They may also help your loved one find ways to follow their plan

VYLOY (zolbetuximab) and chemotherapy can be given at the same visit

(every 2 or 3 weeks, based on your loved one's treatment plan)



VYLOY (zolbetuximab) is an infusion (given through the vein)^{1,6}

- VYLOY (zolbetuximab) will be given to your loved one by intravenous infusion over at least 2 hours, but it might take longer
- Following the infusion with VYLOY (zolbetuximab), an infusion with chemotherapy will be given, that will add to the treatment duration for the day. The doctor might add more time to help with side effects
- The doctor will decide how much of this medicine your love one will receive. Your loved one will usually receive VYLOY (zolbetuximab) every 2 or 3 weeks based on the other anti-cancer medicines chosen by their doctor. Their doctor will decide how many treatments they need

Each treatment appointment is very important. Staying on schedule gives your loved one's treatment the best chance to work for them.

Please read Important Safety Information on pages 8–10.





It is very important that your loved one does not miss a dose of this medicine. If they miss an appointment, make sure they call their doctor to reschedule their appointment as soon as possible.¹

Your loved one should not stop treatment with VYLOY (zolbetuximab) unless they have discussed this with their doctor. Stopping their treatment may stop the effect of the medicine. If you have questions about your loved one's plan or infusions, talk with their doctor. They can:

- Help your loved one stay on their plan
- Keep track of how they're feeling between visits
- Help your loved one manage their side effects

Prior to infusion

- If your loved one is experiencing nausea or vomiting before treatment, their doctor will resolve their symptoms before they receive the first infusion⁶
- Before each infusion of this medication, the doctor may prescribe anti-sickness medication (anti-emetics) for the prevention of nausea and vomiting¹

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Talking about side effects

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

Possible side effects¹

Like with any treatment, your loved one may feel certain side effects during treatment with VYLOY (zolbetuximab) and chemotherapy.

Serious side effects



Hypersensitivity (allergic) reactions (including hypersensitivity and anaphylactic reaction). Tell the doctor or get medical help right away if your loved one has 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 the doctor or get medical help right away if your loved one has 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 the doctor if these symptoms do not go away or become worse



Vomiting (being sick). Tell the 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 the doctor is there to help your loved one. Your loved one should not stop treatment unless they have discussed this with their doctor. Stopping their treatment may stop the effect of the medicine.






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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 loved one's doctor.

Reporting of side effects

If you observe any side effects, talk to your loved one's 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.

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Caring for your loved one

Try to understand their needs⁸

You'll find a lot of information and advice on how to help your loved one during treatment. But here are some simple ways to make a difference:

Keep talking: Open and honest talks are key during treatment. This is even more true when your loved one may not want to ask for help.

Do the little things: Cooking, laundry, filling out papers: Taking over small daily tasks can make life much easier for them.

Stay connected with the doctor: Talk with them at each visit. Help them understand what your loved one needs and how they feel. See if the doctor has advice on how you can help.

Listen to how they're feeling: Let them share their feelings. Opening up about stress or anxiety can let you know how you can help them emotionally.

Ask about side effects: Some patients might not tell their doctor about side effects because they don't want to risk stopping treatment. Being open about these side effects helps doctors know how to manage them.

Try to balance the caregiving between friends and family. The caregiving doesn't have to be left to one individual. It is important for the patient and yourself to keep talking and interacting with as many people as possible.

If you have questions about your loved one's treatment, talk to their doctor. They can help your loved one keep track of how they're feeling between visits. And they can give advice when you need it.

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Advice on getting the nutrition they need⁹

Your loved one may have a hard time with meals. This may be because of their cancer or a reaction to treatment. It may not be easy to swallow some foods. They might not like the smell of cooking certain foods. But getting nutrition is important, and you can help them take control of their diet. When doing so, try these tips:

Talk to your loved one:

- Ask about any food-related problems that they're dealing with
- Find out what kinds of foods they're trying to avoid
- Stock up on foods they can tolerate

Talk to their doctor:

- A dietitian may be able to help them identify gastric cancer-friendly foods and recipes
- Ask about vitamins, supplements, or liquid meal replacements
- Ask about medications or other therapies that can help manage symptoms
- Ask about cancer stress management support to help address stress and anxiety

Don't let your loved one miss out on the everyday moments that have to do with mealtimes. Talking about their needs can make a big difference.

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Caring for yourself

Don't forget about yourself⁸

While you're caring for a loved one, take care of yourself as well. It is important to stay fit, both in body and mind. Here are some ways you can do this:

- Get active or play a sport a few times each week
- Eat a healthy diet
- Set a healthy sleep routine
- Ask for help when you need it
- Be aware of your own stress and anxiety
- Spend time with friends and family
- Look for support groups with others who have gone through what you are going through now

Remember: The person you're caring for also cares about you. They want you to stay healthy.



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Manage your time⁸

Don't forget to take time for yourself. A number of support groups say that you could:

Relax every day: Spend at least 30 minutes each day doing something for yourself.

Keep in touch with family and friends: You may have to cut back on hobbies or free time, but don't neglect your own life.

Keep up with your plans: You can lower your stress level if you find time for an everyday routine and the things you normally do.

Learn about your rights and benefits: As a caregiver, you may be able to get unpaid leave from your job. Talk to your employer about your options.

Your stress level can change from day to day.
Be mindful of your changing needs. Ask for support
when you need it.

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Talk to your loved one's doctor

Get the most out of every visit

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

Tell your loved one's doctor about all the medicines that they take, including medicines obtained without a prescription.

You might want to ask:

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

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

Notes:

Your loved one's first infusion is on _____.

The next infusions will happen every _____ weeks.

Doctor contact information

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

Name: _____

Contact: _____

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Growing your support network: Resources for you

Reach out when you need help

As a caregiver, there are resources for you that you can turn to.

- **The National Alliance for Caregiving** is committed to making life better for family caregivers. Learn more at [caregiving.org](https://www.caregiving.org)
- **CancerCare** provides free, professional support services for caregivers and loved ones. Learn more at www.cancercares.org

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Connecting with a community of support

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

- **The Gastric Cancer Foundation** empowers patients and caregivers to face their diagnosis with information and tools to navigate through treatment. They can connect your loved one to a caring community that offers support. You can find them at [GastricCancer.org](https://www.gastriccancer.org)
- **Debbie's Dream Foundation** is 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
- **Cancer Research UK**, a charity that is raising awareness, funding research and supporting patients with cancer. www.cancerresearchuk.org/about-cancer/stomach-cancer
- **Macmillan Cancer Support**, a charity offering information, advice and support to patients with cancer. 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/
- **Guts UK**, a national charity that provides information and support for people affected by digestive conditions and symptoms. gutscharity.org.uk
- **Ochre**, a charity raising awareness for oesophageal cancer amongst public, professionals, politicians and patients. ochrecharity.org.uk

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Here are some tips for your loved one that have helped other patients^{10,11}

- ✓ **Keep a treatment journal** to share with the doctor
- ✓ **Stay hydrated.** Drink plenty of water and other fluids
- ✓ **Ask the doctor** to help your loved one 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 fluids¹²

Anaphylaxis (anaphylactic reaction): A severe and sometimes life-threatening immune system reaction to an antigen that a person has been previously exposed to¹³

Antibody: A protein most commonly made by the body's immune system. The antibody that makes up VYLOY (zolbetuximab) is made in a laboratory¹⁴

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 molecule⁵

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 cells¹⁵

Gastro-oesophageal junction: The place where the oesophagus is connected to the stomach¹⁶

Intravenous infusion: A way of giving a medicine or other substance through a needle or a tube inserted into a vein¹⁷

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 cancer¹⁸

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Always remember to:

- **Keep talking** with your loved one throughout their treatment
- **Stay connected** to the people who care for your loved one, and let them know how they can help
- **Take care of yourself** whilst you're caring for them
- **Reach out** to your loved one's doctor, family members or friends when you need them

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

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