

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about being given this medicine, speak to your doctor or pharmacist.

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- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

## 1. Why am I being given VYLOY?

VYLOY contains the active ingredient zolbetuximab. VYLOY is used in combination with other anti-cancer medicines to treat people with a kind of cancer called stomach (gastric) or gastro-oesophageal junction cancer.

For more information, see Section [1. Why am I being given VYLOY?](#) in the full CMI.

## 2. What should I know before I am given VYLOY?

VYLOY should not be given if you have ever had an allergic reaction to zolbetuximab or any of the ingredients listed at the end of the CMI.

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**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** VYLOY is not used in children and adolescents.

For more information, see Section [2. What should I know before I am given VYLOY?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with VYLOY and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How am I given VYLOY?**

- Your doctor will give you VYLOY through an infusion (a drip) into a vein (intravenously) over at least 2 hours.
- You will get 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.

More instructions can be found in Section [4. How am I given VYLOY?](#) in the full CMI.

## 5. What should I know while being given VYLOY?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>● <b>Remind any doctor, dentist or pharmacist you visit that you are being given VYLOY.</b></li><li>● <b>Call your doctor straight away or go to the Emergency Department at the nearest hospital if you have any symptoms of serious allergic reactions, infusion related reactions, nausea and vomiting.</b></li><li>● <b>Tell your doctor if you are taking any other medicines, including medicines obtained without a prescription.</b></li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>● It is very important that you do not miss a dose of this medicine (call your doctor if you cannot make it to your appointment to receive your next dose).</li></ul>

<p><b>Things you should do</b></p>	<ul style="list-style-type: none"> <li>● <b>Remind any doctor, dentist or pharmacist you visit that you are being given VYLOY.</b></li> <li>● <b>Call your doctor straight away or go to the Emergency Department at the nearest hospital if you have any symptoms of serious allergic reactions, infusion related reactions, nausea and vomiting.</b></li> <li>● <b>Tell your doctor if you are taking any other medicines, including medicines obtained without a prescription.</b></li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● <b>Be careful before you drive or use any machines or tools until you know how VYLOY affects you.</b></li> </ul>
<p><b>Looking after your medicine</b></p>	<ul style="list-style-type: none"> <li>● <b>You will not be asked to store VYLOY. It will usually be stored in the pharmacy or on the ward. Any unused portion of the solution</b></li> </ul>

<p><b>Things you should do</b></p>	<ul style="list-style-type: none"> <li>● <b>Remind any doctor, dentist or pharmacist you visit that you are being given VYLOY.</b></li> <li>● <b>Call your doctor straight away or go to the Emergency Department at the nearest hospital if you have any symptoms of serious allergic reactions, infusion related reactions, nausea and vomiting.</b></li> <li>● <b>Tell your doctor if you are taking any other medicines, including medicines obtained without a prescription.</b></li> </ul>
	<p>will be disposed of by your doctor.</p>

For more information, see Section [5. What should I know while being given VYLOY?](#) in the full CMI.

## **6. Are there any side effects?**

Some possible side effects may be serious, and can include serious allergic reactions such as itchy, swollen pink or red areas of the skin, breathing problems like wheezing, or throat tightness, infusion related reactions, nausea and vomiting.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ 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. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

## VYLOY™

**Active ingredient:** *zolbetuximab*

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### Consumer Medicine Information (CMI)

This leaflet provides important information about using VYLOY. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VYLOY.**

#### Where to find information in this leaflet:

- [1. Why am I being given VYLOY?](#)
- [2. What should I know before I am given VYLOY?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I given VYLOY?](#)
- [5. What should I know while being given VYLOY?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I being given VYLOY?

**VYLOY contains the active ingredient zolbetuximab.**

**VYLOY is used in combination with other anti-cancer medicines to treat people with stomach (gastric) or gastro-oesophageal junction cancer.** VYLOY is given to people whose tumours are positive for the “Claudin18.2 (CLDN18.2)”, and negative for the “Human epidermal growth factor receptor 2 (HER2)” proteins. People get VYLOY when their cancer has spread or cannot be taken out by surgery. 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 should I know before I am given VYLOY?

### Warnings

#### **Do not use VYLOY if:**

- you are allergic to zolbetuximab, or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can be given this medicine.

## **Check with your doctor if you:**

- are currently experiencing nausea and/or vomiting. Nausea and vomiting 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

### **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.

### **Breast-feeding**

- Breast-feeding is not recommended during treatment with VYLOY.

- Tell your doctor if you are breast-feeding or plan to breastfeed.
- It is not known if VYLOY passes into your breast milk.

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VYLOY.**

### **4. How am I given VYLOY?**

#### **How much to receive VYLOY**

- You will receive VYLOY in a hospital or clinic under the supervision of a doctor experienced in cancer treatment.
- Your doctor will give you VYLOY through an infusion (a drip) into a vein (intravenously) over at least 2 hours.
- Your doctor will decide how much VYLOY you will receive.

#### **When to receive VYLOY**

- You will get 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.

## **If you forget to receive VYLOY**

**If you miss a dose, call your doctor right away to reschedule your appointment. It is very important that you do not miss a dose of this medicine.**

## **If you are given too much VYLOY**

As VYLOY is given to you under the supervision of your doctor, it is unlikely that you will be given too much. However, if you experience any side effects after being given VYLOY, tell your doctor immediately.

### **You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while being given VYLOY?**

### **Things you should do**

#### **Call your doctor straight 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. These can happen during or after you receive your infusion.
- 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). These can happen during or after you receive your infusion.
- are currently experiencing nausea and/or vomiting and/or bleeding in the digestive tract: nausea and vomiting 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.
- have any of the following symptoms of a rare, reversible condition involving the brain called Posterior Reversible Encephalopathy Syndrome (PRES): seizure, worsening headache, confusion, blindness or other vision problems.

Remind any doctor, dentist or pharmacist you visit that you are being given VYLOY.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how VYLOY affects you.**

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

## **Looking after your medicine**

You will not be asked to store VYLOY. It will usually be stored in the fridge (at 2°C to 8°C) at the pharmacy or on the ward. Unused portion of the infusion solution will not be stored for reuse.

## **Getting rid of any unwanted medicine**

Any unused medicine or waste material will be disposed of by your doctor in accordance with local requirements.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<p><b>General:</b></p> <ul style="list-style-type: none"><li>• swelling of the lower legs or hands (oedema peripheral)</li><li>• low levels of albumin in the blood (hypoalbuminaemia)</li></ul> <p><b>Eating related:</b></p> <ul style="list-style-type: none"><li>• decreased appetite</li><li>• increased saliva (salivary hypersecretion)</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<p><b>Hypersensitivity (allergic) reactions (including hypersensitivity and anaphylactic reactions) – common (may affect up to 1 in 10 people):</b></p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>Tell your doctor or get medical help right away if you have any of these symptoms of a serious allergic reaction:</p> <ul style="list-style-type: none"> <li>● itchy, swollen pink or red areas of the skin (hives)</li> <li>● coughing that doesn't go away, breathing problems such as wheezing, or throat tightness/change in voice.</li> </ul> <p><b>Infusion related reaction – common</b> (may affect up to 1 in 10 people):</p> <p>Tell your doctor or get medical help right away if you have any of these symptoms of an infusion related reaction:</p> <ul style="list-style-type: none"> <li>● nausea, vomiting</li> <li>● stomach pain</li> <li>● increased saliva (salivary hypersecretion)</li> <li>● fever</li> <li>● chest discomfort</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● chills or shaking</li> <li>● back pain</li> <li>● cough</li> <li>● high blood pressure (hypertension).</li> </ul> <p><b>Nausea and vomiting – very common</b> (may affect more than 1 in 10 people):</p> <p>Tell your doctor if these symptoms do not go away or become worse.</p>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What VYLOY contains

<b>Active ingredient (main ingredient)</b>	<b>Vyloy contains 100 mg or 300 mg of zolbetuximab as the active ingredient</b>
<b>Other ingredients (inactive ingredients)</b>	arginine, phosphoric acid, sucrose, and polysorbate 80

**Do not take this medicine if you are allergic to any of these ingredients.**

### What VYLOY looks like

VYLOY 100 mg (AUST R 428330) contain 100 mg zolbetuximab in a single-dose vial.

VYLOY 300 mg (AUST R 489557) contain 300 mg zolbetuximab in a single-dose vial.

## **Who distributes VYLOY**

Astellas Pharma Australia Pty Ltd

Suite 2.01, 2 Banfield Road

Macquarie Park NSW 2113

Tel: 1800 751 755 (Medical Information)

Email: [aaumedinfo@astellas.com](mailto:aaumedinfo@astellas.com) (Medical Information)

Website: [www.astellas.com/au](http://www.astellas.com/au)

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