

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using 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 using Polivy?

Polivy contains the active ingredient polatuzumab vedotin. Polivy is used to treat a type of cancer called diffuse large B-cell lymphoma that has never been treated before or when the cancer has come back or has never responded to one or more previous treatments for this type of cancer and when you cannot receive a stem cell transplant.

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

## 2. What should I know before I use Polivy?

Do not use if you have ever had an allergic reaction to polatuzumab vedotin or any of the ingredients listed at the end of the CMI. **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.**

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

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

Some medicines may interfere with Polivy 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 is Polivy given?

Polivy is given by a slow drip into a vein (intravenous (IV) infusion) once every three weeks.

The recommended dose is based on your weight and will be determined by your doctor.

The first infusion will be given over 90 minutes. If the first infusion is well tolerated, your drip time may be shortened to 30 minutes.

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

## 5. What should I know while using Polivy?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>● Remind any doctor, dentist or pharmacist you visit that you are using polatuzumab vedotin.</li><li>● Keep all of your doctor's appointments so that your progress can be checked.</li><li>● Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.</li><li>● If you are about to have any blood tests, tell your doctor that you are taking this medicine.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>● Do not stop your Polivy treatment without talking to your doctor first.</li><li>● Do not take any other medicines, whether they require a prescription or not, without first telling</li></ul>

	your doctor or consulting with a pharmacist.
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful driving or operating machinery until you know how Polivy affects you.</li> <li>• Polivy may cause slight light-headedness, tiredness and dizziness in some people. If you experience infusion-related reactions or nerve damage, or if you feel tired, weak or dizzy, do not drive or use machines until symptoms stop.</li> </ul>

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

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

Tell your doctor or nurse immediately or seek immediate medical attention if you experience:

- Signs or symptoms of a serious allergic reaction such as swelling of the face, lips, tongue, throat or other parts of the body, shortness of breath, wheezing or trouble breathing, wheezing or coughing.
- Serious infections or have had long lasting or repeated infections, including any signs or symptoms of fever.

For more information, including what to do if you have any common or serious 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).

## Polivy<sup>®</sup>

**Active ingredient(s):** *polatuzumab vedotin*

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### Consumer Medicine Information (CMI)

This leaflet provides important information about using Polivy. **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 Polivy.**

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

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

## 1. Why am I using Polivy?

**Polivy contains the active ingredient polatuzumab vedotin.** Polivy belongs to a group of medicines known as anti-neoplastic (or anti-cancer) agents. Polivy is made up of two substances:

- polatuzumab - a monoclonal antibody which recognises the large B-cell cancer cells
- vedotin - an anti-cancer substance

**Polivy is used to treat a type of cancer called diffuse large B-cell lymphoma that has never been treated before.**

**Polivy is used to treat a type of cancer called diffuse large B-cell lymphoma when the cancer has come back or has never responded to one or more previous treatments for this type of cancer and when you cannot receive a stem cell transplant.**

Polivy is designed to target and deliver the anti-cancer substance vedotin to the cancer cells to stop the growth and spread of the cancer cells.

## 2. What should I know before I use Polivy?

### Warnings

**Do not use Polivy if:**

- you currently have an active severe infection

- you are allergic to polatuzumab vedotin, or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

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

- you have ever had nerve problems such as numbness, tingling in the hands or feet or eyesight problems
- you have ever had liver problems such as hepatitis
- you think you may have an infection or have had long lasting or repeated infections

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**

**Tell your doctor right away if you become pregnant during treatment with Polivy.**

Your doctor will advise you about using effective contraception to avoid becoming pregnant while you are being treated with Polivy and for 9 months after stopping treatment. If you are male, you should also use contraception with a female partner for 6 months after treatment with Polivy.

Discuss any future child bearing plans with your doctor before starting Polivy.

## **Breastfeeding**

**Tell your doctor if you are breastfeeding or plan to breastfeed.**

It is not known if Polivy passes into your breastmilk.

**Do not breastfeed during treatment with Polivy for at least 3 months after the last dose'/treatment.**

## **What other medicines Polivy is given with**

Polivy is given in combination other cancer medicines:

- rituximab, cyclophosphamide, doxorubicin and prednisone for diffuse large B-cell lymphoma that has never been treated before.
- rituximab and bendamustine for diffuse large B-cell lymphoma that has come back or has not got better,

after at least one previous therapy – and when you cannot receive a stem cell transplant.

### **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.

**Some medicines may interfere with Polivy and affect how it works.**

- oral antifungal medications, e.g. ketoconazole, itraconazole, voriconazole
- some antibiotics used to treat infections e.g. rifampicin

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

### **4. How is Polivy given?**

**Follow all directions given to you by your doctor or nurse carefully.**

They may differ from the information contained in this leaflet.

Polivy must be prepared by a healthcare professional and will be given in a hospital or clinic by a doctor or nurse.

Polivy is given by a drip into a vein (called an “intravenous infusion” or “IV”).

The recommended dose is based on your weight and will be determined by your doctor.

Polivy is given by a slow drip into a vein (intravenous (IV) infusion) once every three weeks.

The first infusion will be given over 90 minutes. If the first infusion is well tolerated, your drip time may be shortened to 30 minutes.

The number of infusions you will be given depends on how you respond to treatment.

### **If you miss a dose of Polivy**

As Polivy is given under the supervision of your doctor, you are unlikely to miss a dose. However, if you forget or miss your appointment to receive Polivy, make another appointment as soon as possible. Do not wait for your next planned appointment. Your doctor will decide when your next dose of Polivy will be.

### **If you use too much Polivy**

As Polivy is given 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 Polivy, tell your doctor or nurse immediately.

## **5. What should I know while using Polivy?**

### **Things you should do**

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Polivy.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**Tell your doctor if you become pregnant or intend to start a family while receiving Polivy.**

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Remind any doctor, dentist or pharmacist you visit that you are using Polivy.

### **Things you should not do**

- **Do not stop your Polivy treatment without talking to your doctor first.**

- **Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting with a pharmacist.**

## **Driving or using machines**

**Be careful driving or operating machinery until you know how Polivy affects you.**

Polivy may cause slight light-headedness, tiredness and dizziness in some people. If you experience infusion-related reactions or nerve damage, or if you feel tired, weak or dizzy, do not drive or use machines until symptoms stop.

## **Looking after your medicine**

Polivy will be stored in the pharmacy or on the hospital ward in a refrigerator at a temperature between 2°C and 8°C.

## **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.

Because Polivy is given with other medicines to treat cancer it may be difficult for your doctor to tell whether the side effects are due to Polivy or due to other medicines.

You may experience side effects during an infusion or after an infusion, these can be serious or less serious.

**Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>During an infusion:</b></p> <ul style="list-style-type: none"> <li>● swelling of your face, lips, tongue or throat with difficulty breathing</li> <li>● swelling of other parts of your body such as your hands or feet</li> <li>● shortness of breath, wheezing or trouble breathing</li> <li>● abnormal or irregular heartbeat</li> <li>● rash, itching or hives on the skin</li> <li>● flushing (warm, red) skin</li> <li>● pain or swelling at site of injection</li> <li>● feeling sick (nausea) or vomiting, diarrhoea</li> </ul>	<p><b>Tell your doctor or nurse immediately if you notice any of the following while receiving an infusion (particularly during the first infusion)</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● pain or discomfort (including stomach pain, back pain, chest or neck pain)</li> <li>● fever or chills</li> </ul>	
<p><b>After an infusion:</b></p> <ul style="list-style-type: none"> <li>● flu and/or cold-like symptoms, chest pain, coughing, sweating</li> <li>● fever, sore throat, tiredness, sores in the mouth or gums</li> <li>● bruising, bleeding gums or nose, rash on legs with red dots, blood in urine or stools</li> <li>● numbness or tingling in the hands or feet, sharp or jabbing pain, burning or freezing sensation, pins and needles</li> <li>● difficulty walking</li> <li>● weakness, lack of energy, feeling unsteady</li> <li>● muscle cramps or spasms, heart palpitations, breathing</li> </ul>	<p><b>Tell your doctor straight away if you notice any of the side effects below or if they get worse. They may happen weeks or months after your last dose. Do not try to treat yourself with other medicines.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>difficulties, mood changes</p> <ul style="list-style-type: none"> <li>● swelling of the hands or feet, yellow skin or eyes, rapid heartbeat, appetite changes</li> <li>● skin infection</li> <li>● urinary tract infection</li> <li>● upper respiratory tract infection</li> <li>● breathlessness and difficulty in breathing</li> <li>● changes in blood tests</li> <li>● Confusion or memory loss, muscle spasms and cramps, facial twitching, numbness</li> </ul>	

### **Less serious side effects**

<b>Less serious side effects</b>	<b>What to do</b>
<p><b>After an infusion:</b></p> <ul style="list-style-type: none"> <li>● nose bleeds, feeling dizzy, tired, looking pale</li> <li>● nausea or vomiting</li> <li>● constipation or abdominal pain</li> </ul>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● diarrhoea</li> <li>● rash, itching or hives on the skin</li> <li>● decreased appetite, weight decrease</li> <li>● changes in blood tests</li> <li>● dry skin</li> </ul>	

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

Other side effects not listed above may also occur in some people.

Some side effects can only be found when your doctor does tests from time to time to check your progress. (for example, elevated liver enzymes, low potassium or sodium levels, low platelet count, low blood pressure).

## **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 Polivy contains

<b>Active ingredient (main ingredient)</b>	● <b>polatuzumab vedotin</b>
<b>Other ingredients (inactive ingredients)</b>	succinic acid sodium hydroxide sucrose polysorbate 20
<b>Potential allergens</b>	This medicine does not contain lactose, gluten, tartrazine or any other azo dyes.

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

### What Polivy looks like

Polivy is a white to grey powder which is dissolved in sterile water before use. It is diluted before infusion into a vein. Polivy is supplied as single-dose glass vials containing;

- 140 mg of active ingredient (AUST R 314866)
- 30 mg of active ingredient (AUST R 374135)

## **Who distributes Polivy**

Polivy is distributed in Australia by:

Roche Products Pty Limited

ABN 70 000 132 865

Level 8, 30 – 34 Hickson Road

Sydney NSW 2000

AUSTRALIA

Customer enquiries: 1800 233 950

<https://medinfo.roche.com/au/en.html>

Please check with your pharmacist for the latest Consumer Medicine Information.

This leaflet was prepared in February 2023.