

## **Package leaflet: Information for the patient**

### **Polivy 30 mg powder for concentrate for solution for infusion Polivy 140 mg powder for concentrate for solution for infusion polatuzumab vedotin**

▼ 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 the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you are given this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Polivy is and what it is used for
2. What you need to know before you are given Polivy
3. How Polivy is given
4. Possible side effects
5. How to store Polivy
6. Contents of the pack and other information

#### **1. What Polivy is and what it is used for**

##### **What Polivy is**

Polivy is a cancer medicine that contains the active substance polatuzumab vedotin.

##### **What Polivy is used for**

Polivy is given to treat “diffuse large B-cell lymphoma” that has come back or has not got better with at least one previous therapy and when you cannot receive a stem cell transplant.

Diffuse large B-cell lymphoma is a cancer that develops from B lymphocytes also called B-cells. These are a type of blood cells.

##### **How Polivy works**

The active substance in Polivy is made up of a monoclonal antibody linked to MMAE, a substance that can kill cancer cells. The monoclonal antibody part of the medicine attaches to a target on B cells. Once attached to B cells, the medicine releases MMAE into the B cells and kills them.

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

Polivy is given in combination with two other cancer medicines called rituximab and bendamustine.

#### **2. What you need to know before you are given Polivy**

##### **You must not be given Polivy**

- if you are allergic to polatuzumab vedotin or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, talk to your doctor or nurse before you are given Polivy.

### **Warnings and precautions**

Talk to your doctor or nurse before you are given Polivy if any of the following apply to you (or you are not sure):

- you have ever had brain or nerve problems such as:
  - memory problems
  - difficulty moving or sensations in your body such as feeling pins and needles, burning, pain and discomfort even from slight touch
  - eyesight problems
- you have ever had liver problems
- you think you have an infection or have had long-lasting or repeated infections such as herpes (see “Infections” in section 4)
- you are due to have a vaccine or you know you may need to have one in the near future

If any of the above apply to you (or you are not sure) talk to your doctor or nurse before you are given Polivy.

### **Pay attention to the following side effects**

Polivy can cause some serious side effects that you need to tell your doctor or nurse about straight away. These include:

#### **Myelosuppression**

Myelosuppression is a condition in which the production of blood cells is decreased, resulting in fewer red blood cells, white blood cells, and platelets. Your doctor will do blood tests to check your blood cell count.

Tell your doctor or nurse straight away if you:

- develop chills or shivering
- have a fever
- have headaches
- feel tired
- feel dizzy
- look pale
- have unusual bleeding, bruising under the skin, bleeding longer than usual after your blood has been drawn, or bleeding from your gums.

#### **Peripheral neuropathy**

Tell your doctor or nurse straight away if you have any problems with a change in the sensitivity of your skin, especially in your hands or feet, such as:

- numbness
- tingling
- a burning sensation
- pain
- discomfort or weakness.

If you had any of these symptoms before treatment with Polivy, tell your doctor straight away if you notice any changes in them.

If you have symptoms of peripheral neuropathy, your doctor may lower your dose.

### **Infections**

Signs and symptoms of infections vary between individuals, tell your doctor or nurse straight away if you develop symptoms of an infection such as:

- fever
- cough
- chest pain
- tiredness
- painful rash
- sore throat
- burning pain when passing urine
- feeling weak or generally unwell.

### **Progressive multifocal leukoencephalopathy (PML)**

PML is a very rare and life threatening infection in the brain, that has occurred in one patient treated with Polivy together with bendamustine and another medicine called obinutuzumab.

Tell your doctor or nurse straight away if you have:

- memory loss
- trouble speaking
- difficulty walking
- problems with your eyesight.

If you had any of these symptoms before treatment with Polivy, tell your doctor straight away if you notice any changes in them. You may need medical treatment.

### **Tumour lysis syndrome**

Some people may develop unusual levels of some substances (such as potassium and uric acid) in the blood caused by the fast breakdown of cancer cells during treatment. This is called tumour lysis syndrome. Your doctor, pharmacist or nurse will do blood tests to check for the condition.

### **Infusion-related reactions**

Infusion-related reactions, allergic or anaphylactic (more severe allergic) reactions can happen. Your doctor or nurse will check for side effects during your infusion and for 30 to 90 minutes afterwards. If you get any serious reaction, your doctor may stop treatment with Polivy.

### **Liver damage**

This medicine can cause inflammation or damage to cells in the liver that affect the normal function of the liver. Injured liver cells may leak high amounts of certain substances (liver enzymes and bilirubin) into the bloodstream, in which can be detected by blood tests.

In most cases you will not have any symptoms but tell your doctor or nurse straight away if you get:

- yellowing of your skin and of the whites of your eyes (jaundice).

Your doctor will check your blood to test your liver function before and regularly during treatment.

### **Children and adolescents**

This medicine should not be used in children or young people under the age of 18. This is because there is no information about its use in this age group.

## **Other medicines and Polivy**

Tell your doctor or nurse if you are taking, have recently taken or might start taking any other medicines. This includes medicines obtained without a prescription and herbal medicines.

## **Contraception (women and men)**

If you are a woman of childbearing age, you must use effective contraception during treatment and for 9 months after the last dose of Polivy.

Men must use contraception during treatment and for 6 months after the last dose of Polivy.

## **Pregnancy**

It is important to tell your doctor before and during treatment if you are pregnant, think you may be pregnant, or are planning to get pregnant. This is because Polivy can affect your baby's health. You should not use this medicine if you are pregnant unless you and your doctor decide that the benefit to you outweighs possible risk to the unborn baby.

## **Breast-feeding**

Do not breast-feed while receiving Polivy and for at least 3 months after the last dose, because small amount of Polivy may pass into your breast milk.

## **Fertility**

Men being treated with this medicine are advised to have sperm samples preserved and stored before treatment.

## **Driving and using machines**

Polivy has a minor influence on your ability to drive, cycle or use any tools or machines. If you get infusion-related reactions or nerve damage, or if you feel tired, weak or dizzy (see section 4) do not drive, cycle or use tools or machines until the reaction stops.

See section 4 for more information about side effects.

## **Polivy contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

## **3. How Polivy is given**

Polivy is given under the supervision of a doctor experienced in giving such treatments. It is given into a vein, as a drip over 90 minutes.

### **How much Polivy is given**

The dose of this medicine depends on your body weight.

- The usual starting dose is 1.8 mg for each kilogram of your body weight.
- If you have peripheral neuropathy, your doctor may lower your dose to 1.4 mg for each kilogram of your body weight.

You will be given 6 treatment cycles of Polivy in combination with two other medicines called rituximab and bendamustine.

Each cycle lasts 21 days.

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

If you miss an appointment, make another one straight away. For the treatment to be fully effective, it is very important not to miss a dose.

### **If you stop receiving Polivy**

Do not stop treatment with Polivy unless you have discussed this with your doctor. This is because stopping treatment may make your condition worse.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects have been reported with this medicine:

### **Serious side effects**

Tell your doctor or nurse straight away if you notice any of the following serious side effects – you may need urgent medical treatment. These may be new symptoms or a change in your current symptoms.

- fevers and chills
- rash/hives
- severe infections
- pneumonia (lung infection)
- herpes infection
- viral infections
- unusual bleeding or bruising under the skin
- memory loss, trouble speaking, difficulty walking or problems with your eyesight
- yellowing of skin or whites of your eyes

### **Other side effects**

Tell your doctor or nurse if you notice any of the following side effects:

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

- severe infections
- fever
- cough
- vomiting
- pneumonia (lung infection)
- diarrhoea or constipation
- feeling sick (nausea)
- abdominal (belly) pain
- feeling tired (anaemia)
- not feeling hungry
- loss of weight
- infusion-related reactions
- common cold
- dizziness

- unusual sensations

**Common (may affect up to 1 in 10 people)**

- chills
- viral infections
- herpes infection
- problems walking
- inflammation of the lungs
- raised liver enzymes
- joint pain
- itchiness

## **5. How to store Polivy**

Polivy will be stored by the healthcare professionals at the hospital or clinic. The storage details are as follows

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and the vial after EXP. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C – 8°C).
- Do not freeze.
- Keep the container in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Polivy contains**

- The active substance is polatuzumab vedotin.
- Polivy 30 mg: Each vial contains 30 milligrams (mg) polatuzumab vedotin.
- Polivy 140 mg: Each vial contains 140 milligrams (mg) polatuzumab vedotin.
- After reconstitution each millilitre (mL) contains 20 mg polatuzumab vedotin.
- The other ingredients are: succinic acid, sodium hydroxide, sucrose, polysorbate 20. See section “Polivy contains sodium”.

### **What Polivy looks like and contents of the pack**

Polivy powder for concentrate for solution for infusion is a white to slightly greyish-white cake provided in a glass vial.

Each pack of Polivy consists of one vial.