

Applicant: Teva Pharmaceuticals (Pty) Ltd	Product name: VELZOMY
Reg no: 52/26/0471	

PATIENT INFORMATION LEAFLET

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SCHEDULE 4

VELZOMY 3,5 mg bortezomib (as a mannitol boronic ester).
powder for solution for injection.

Read all of this leaflet carefully before you are given VELZOMY.

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

WHAT IS IN THIS LEAFLET:

1. **WHAT VELZOMY IS AND WHAT IT IS USED FOR**
2. **WHAT YOU NEED TO KNOW BEFORE YOU USE VELZOMY**
3. **HOW TO USE VELZOMY**
4. **POSSIBLE SIDE EFFECTS**
5. **HOW TO STORE VELZOMY**
6. **CONTENTS OF THE PACK AND OTHER INFORMATION**

1. WHAT VELZOMY IS AND WHAT IT IS USED FOR:

VELZOMY contains the active substance bortezomib, a so-called 'proteasome inhibitor'. Proteasomes play an important role in controlling cell function and growth by interfering with their function, bortezomib can kill cancer cells.

VELZOMY is used in:

- the treatment of patients with multiple myeloma (a bone marrow cancer), alone or in combination with the medicines melphalan and prednisone
- the treatment of mantle cell lymphoma (a type of cancer affecting the lymph nodes).

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2. WHAT YOU NEED TO KNOW BEFORE YOU USE VELZOMY:

Do not use VELZOMY:

- if you are hypersensitive (allergic) to bortezomib, boron or to any of the other ingredients of **VELZOMY** (listed in **section 6**)
- if you have severe liver problems
- if you have certain severe lung or heart problems.

Warnings and precautions:

Tell your doctor or healthcare professional before being given VELZOMY:

Talk to your doctor if you have any of the following:

- low numbers of red or white blood cells (anaemia or neutropenia), (see symptoms in **section 4**)
- bleeding problems and/or low number of platelets in your blood (thrombocytopenia), (see symptoms in **section 4**)
- diarrhoea, constipation, nausea or vomiting
- low blood pressure, especially when standing up (with symptoms such as fainting, dizziness or light-headedness), in the past or during treatment with **VELZOMY**
- kidney problems
- moderate to severe liver problems or previous liver infection known as hepatitis B
- numbness, tingling, burning sensation, weakness or pain in the hands or feet (peripheral neuropathy)
- heart, blood pressure problems or swelling of your body (fluid retention) and especially if you take medicines for these conditions
- lung problems with symptoms such as shortness of breath or cough
- seizures (fits)
- Herpes zoster, also known as shingles (localised painful skin rash spread across the body or around the eyes)
- symptoms of a so-called 'tumor lysis syndrome', such as muscle cramping, muscle weakness, confusion, visual loss or disturbances and shortness of breath
- headaches, seizures (fits), confusion, changed mental state, vision loss and high blood pressure. These might be symptoms of a neurological disorder called 'posterior reversible encephalopathy syndrome'
- memory loss, trouble thinking, difficulty with walking or loss of vision. These may be signs of a very rare but

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serious brain infection known as 'progressive multifocal leukoencephalopathy' (PML) and your doctor may suggest further testing and follow-up.

You will have to take regular blood tests before and during your treatment with **VELZOMY**, to check your blood cell counts regularly.

If you have mantle cell lymphoma and are given **VELZOMY** you should tell your doctor.

Children and adolescents:

VELZOMY should not be used in children and adolescents because it is not known how **VELZOMY** will affect them.

Other medicines and VELZOMY:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Tell your doctor if you are using any of the following medicines:

- ketoconazole, used to treat fungal infections
- ritonavir, used to treat HIV infection
- rifampicin, an antibiotic used to treat bacterial infections such as tuberculosis (TB)
- carbamazepine, phenytoin or phenobarbital used to treat epilepsy (fits)
- St. John's Wort (*Hypericum perforatum*), used for depression or other conditions
- oral antidiabetics (blood-sugar lowering medicines)
- narcotics (an addictive medicine that reduces pain, induces sleep and may alter mood or behaviour).

Pregnancy, breastfeeding and fertility:

Pregnancy:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before using **VELZOMY**.

You should not use **VELZOMY** if you are pregnant.

Breastfeeding:

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You should not breastfeed while using **VELZOMY**. Discuss with your doctor when it is safe to restart breastfeeding after finishing your **VELZOMY** treatment.

Contraception:

Both men and women receiving **VELZOMY** must use effective contraception during and for up to 3 months after treatment. If, despite these measures, pregnancy occurs, tell your doctor immediately.

Driving and using machines:

VELZOMY might cause tiredness, dizziness, fainting, or blurred vision, therefore you should not engage in activities such as driving or operating machinery until you know how **VELZOMY** affects you.

3. HOW TO USE VELZOMY:

You will not be expected to give yourself **VELZOMY**. It will be given to you by a person who is qualified to do so.

Your doctor will work out your dose of **VELZOMY** according to your height and weight (body surface area).

Your doctor may change the dose and total number of cycles, depending on your response to the treatment on the occurrence of certain side effects and on your underlying conditions.

Your doctor will tell you how long your treatment with **VELZOMY** will last. If you have the impression that the effect of **VELZOMY** is too strong or too weak, tell your doctor or pharmacist.

How VELZOMY is given:

VELZOMY is for intravenous use. **VELZOMY** will be administered by a healthcare provider experienced in the use of cytotoxic medicines.

VELZOMY powder has to be dissolved before administration. This will be done by a healthcare provider. The resulting solution is then injected into a vein. Injection into a vein is rapid, taking 3 to 5 seconds.

If you use more VELZOMY than you should:

Since a healthcare provider will administer **VELZOMY**, he/she will control the dosage. However, in the event of

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overdosage your doctor will manage the overdosage.

If you forget to use VELZOMY:

Since a healthcare provider will administer **VELZOMY**, it is unlikely that the dose will be missed.

4. POSSIBLE SIDE EFFECTS:

VELZOMY can have side effects.

Not all side effects reported for **VELZOMY** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **VELZOMY**, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop receiving **VELZOMY** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting
- yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious reaction to **VELZOMY**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- muscle cramping, muscle weakness
- confusion, visual loss or disturbances, blindness, seizures (fits), headaches
- shortness of breath, swelling of your feet or changes in your heart beat, high blood pressure, tiredness
- coughing and breathing difficulties or tightness in the chest.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following which may occur frequently:

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- herpes zoster, also known as shingles (localised painful skin rash spread across the body or around the eyes), herpes simplex virus infection (skin blisters or cold sores), fungal infections
- decrease in the number of red blood cells, which can cause anaemia with symptoms such as tiredness and paleness
- decrease in the number of white blood cells which may make you more prone to infections or flu like symptoms
- decrease in the number of platelets in your blood which may make you more prone to bruising, or to bleeding without obvious injury
- decreased appetite, dehydrated (feeling thirsty)
- mood swings, anxiety, sleep disturbances
- sensitivity, numbness, tingling or burning sensation of the skin, or pain in the hands or feet due to nerve damage, dizziness, taste disturbances, feeling drowsy and indifferent (lethargy), loss of consciousness
- eye swelling, abnormal vision, infection of the outermost layer of the eye and the inner surface of the eyelids (conjunctivitis)
- low blood pressure, sudden fall of blood pressure on standing which may lead to fainting
- nose bleeds, chest infection
- feeling sick (nausea) or vomiting, diarrhoea (loose stools), constipation, heartburn, mouth sores, bloating, belching, wind, stomach pain, bleeding from your bowels or stomach
- itching of the skin, red lumps on the skin or dry skin
- muscle pain, pain in arm or legs
- reduced functioning of your kidneys (decreased urination)
- fever, tiredness (fatigue), feeling weak, swelling of body, general ill feeling, shivering, pain
- weight loss
- abnormal blood sugar levels.

Tell your doctor if you notice any of the following which may occur less frequently:

- infections, including chest, skin, ear and tooth infections
- benign or malignant tumours, cancer of the kidney
- blood clot in small blood vessels (thrombotic microangiopathy)
- thyroid gland disorders
- vitamin B deficiency, gout (painful swelling of joints), increased appetite, inability to tolerate alcohol

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consumption

- hallucinations (seeing or hearing things), confusion, suicidal thoughts, stress-related mental illness (adjustment disorder), disorientation, decreased sex drive
- trembling, twitching, abnormal movements, balance disturbances, memory loss, speech disorder, restless leg syndrome, migraine, disturbance in attention, stroke (bleeding in the brain), coma, drooling, paralysis
- serious nerve inflammation, which may cause paralysis and difficulty breathing (Guillain-Barré syndrome)
- bleeding in eye, dry eye, eye irritation, decreased tears, eye discharge, light sensitivity
- lump in the eyelid (chalazion) and red and swollen eyelids
- hearing loss, deafness or ringing in the ears, ear discomfort
- heart failure, heart attack, chest pain, chest discomfort, increased or reduced heart rate, inflammation of the lining around your heart or fluid around your heart
- inflammation of a vein, flushes, blood clots in your veins and lungs, problems with blood clotting, insufficient circulation
- disorders that affect your lungs, preventing your body from getting enough oxygen some of these include difficulty breathing, shortness of breath, difficulty breathing (becomes shallow or stops), wheezing, difficulty breathing during sleep, coughing blood, throat tightness, dry throat, throat irritation, runny nose
- infections or inflammation of the mouth, oesophagus, stomach and intestines, sometimes associated with pain or bleeding, mouth ulcers, poor movement of the intestines (including blockage), bleeding gums, coated tongue, abdominal or throat discomfort, difficulty swallowing, vomiting of blood
- swelling of the liver, bleeding from the liver
- inflammation or haemorrhage of the blood vessels that can appear as small red or purple dots (usually on the legs) to large bruise like patches under the skin or tissue, increased sweating, acne, nail disorder
- arthritis, including inflammation of the joints in the fingers, toes, and the jaw, lower back pain and leg pain, unpleasant sensations in the legs
- increased or decreased urine production (due to kidney damage), painful passing of urine or blood/proteins in the urine, fluid retention, bladder infection
- vaginal bleeding, genital pain, difficulty with erections, pain in the pelvis area, breast disorders, vaginal tears
- bruises, falls and injuries
- death

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the '6.04 Adverse Drug reaction reporting Form', found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of **VELZOMY**.

5. HOW TO STORE VELZOMY:

Store at or below 25 °C.

Keep the vial in the outer carton in order to protect from light.

Store all medicines out of reach of children.

Do not use this medicine after the expiry date which is stated on the vial and the carton.

Chemical and physical in-use stability of the reconstituted solution has been demonstrated for 8 hours at 25 °C stored in the original vial and/or a syringe.

From a microbiological point of view, unless the method of reconstitution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

The reconstituted solution must be inspected visually for particulate matter and discolouration prior to administration. If any discolouration or particulate matter is observed, the reconstituted solution must be discarded.

VELZOMY is for single use only. Discard any unused portion.

6. CONTENTS OF THE PACK AND OTHER INFORMATION:**What VELZOMY contains:**

- The active substance is bortezomib. Each vial contains 3,5 mg of bortezomib (as a mannitol boronic ester).
- The other ingredient is mannitol (E421).
- Contains sugar (35 mg mannitol).

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Intravenous reconstitution:

After reconstitution, 1 ml of solution for intravenous injection contains 1 mg bortezomib.

What VELZOMY looks like and contents of the pack:

VELZOMY 3,5 mg powder for solution for injection is a white to off-white cake or powder.

Each carton of **VELZOMY** contains one Type I colourless glass, 10 ml vial with a bromobutyl rubber stopper and sealed with aluminium metallic cap with polypropylene disk, containing 3,5 mg bortezomib.

Each pack contains 1 single use vial.

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd
Maxwell Office Park, Magwa Crescent West,
Waterfall City,
Midrand,
Gauteng,
2090
Tel: 011 055 0200

This leaflet was last revised in:

30 November 2021

Registration number:

52/26/0471