

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** **S4**

**BORTEZOMIB ADCO** 3,5 mg powder for solution for injection

Bortezomib

Sugar free

**Read all of this leaflet carefully before you are given Bortezomib Adco**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

### What is in this leaflet

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

#### 1. What Bortezomib Adco is and what it is used for

Bortezomib Adco contains the active substance bortezomib, a proteasome inhibitor. Proteasomes play an important role in controlling cell function and growth. By interfering with their function, bortezomib can kill cancer cells.

Bortezomib Adco is used for the treatment of:

- Multiple myeloma (a cancer of the bone marrow) in combination with the medicines melphalan and prednisone.

- For patients whose disease is worsening (progressive) after receiving at least one prior treatment
- Mantle cell lymphoma (a type of cancer affecting the lymph nodes) for patients who have received at least one prior line of therapy, one which should have included anti-cancer chemotherapy medicine (anthracycline or mitoxantrone and/or rituximab) as part of their chemotherapy

## 2. What you need to know before you receive Bortezomib Adco

### **Bortezomib Adco should not be administered to you**

- If you are hypersensitive (allergic) to bortezomib or any of the other ingredients of Bortezomib Adco (listed in section 6).
- If you have acute diffuse infiltrative pulmonary disease (a disease which causes scarring of the lungs)
- If you have pericardial disease (inflammation of the lining of the heart)

### **Warnings and precautions**

Special care should be taken with Bortezomib Adco

Tell your doctor or health care provider before being given the injection if you suffer from

- shingles (localised including around the eye or spread across the body). Your doctor may give you preventative medicines to prevent an occurrence or re-occurrence of shingles
- low number of red or white blood cells, bleeding problems and/or low number of platelets in your blood. Your doctor will carefully monitor your blood counts. You may require blood/platelet transfusions.
- diarrhoea, constipation, nausea or vomiting. Your doctor will prescribe medicines to help you with these side effects
- damaged nerves outside the brain and spinal cord. Symptoms include numbness, pain or a burning feeling in the feet or hands.
- seizures

- heart or blood pressure problems
- kidney problems
- moderate to severe liver problems or Hepatitis B infection
- symptoms of tumour lysis syndrome such as muscle cramping, muscle weakness, confusion, visual loss or disturbances and shortness of breath
- swelling of joints,
- headache, confusion, memory loss, trouble thinking, difficulty with walking or loss of vision
- fainting, dizziness or light-headedness in the past
- shortness of breath or cough

You will have to take regular blood tests before and during your treatment with Bortezomib Adco to check your blood cell counts regularly.

If you have mantle cell lymphoma, you may experience peripheral neuropathy (disease of the nerves), rash and pruritis (itching of the skin).

If you have multiple myeloma, you may experience thrombocytopenia (low platelets), neutropenia (low white blood cells), anaemia, nausea, vomiting and pyrexia (raised body temperature).

### ***Children and adolescents***

Bortezomib Adco should not be used in children and adolescents because it is not known how the medicine will affect them.

### **Other medicines and Bortezomib Adco**

Always tell your health care provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

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

- Ketoconazole, used to treat fungal infections

- Ritonavir, used to treat HIV infection
- Omeprazole, used to treat ulcers
- Rifampicin, an antibiotic used to treat bacterial infections
- Carbamazepine, phenytoin or phenobarbital used to treat epilepsy
- St. John's Wort, used for depression or other conditions
- Oral antidiabetics

### **Pregnancy, breastfeeding and fertility**

If you are a woman of childbearing potential, you must use an effective method of contraception before, during and up to 8 months after completion of treatment (i.e.: after the final dose) with Bortezomib Adco. If pregnancy occurs during your treatment with Bortezomib Adco you must immediately inform your doctor and should use genetic consultation.

#### **Male fertility**

If you are a man, you should avoid fathering a child during treatment with Bortezomib Adco and for up to 5 months after completion of treatment (i.e.: after the final dose). There is a risk that treatment with Bortezomib Adco will lead to infertility and you may wish to seek advice on conservation of sperm before treatment starts

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving Bortezomib Adco.

### ***Pregnancy***

Safety in pregnancy and lactation has not been established.

You should not use Bortezomib Adco if you are pregnant.

Both men and women receiving Bortezomib Adco must use effective contraception during treatment. If, despite these measures, pregnancy occurs, tell your doctor immediately.

### ***Breastfeeding***

It is not known if Bortezomib Adco is excreted in human milk. Due to the potential for serious undesirable effects, you should not breastfeed while using Bortezomib Adco.

### ***Fertility***

No data on male and female fertility is available.

### **Driving and using machines**

It is not always possible to predict to what extent Bortezomib Adco may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which Bortezomib Adco affects you.

Bortezomib Adco may cause tiredness, dizziness, fainting or blurred vision.

Do not drive or operate tools or machines if you experience such side effects.

### **3. How to use Bortezomib Adco**

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

Bortezomib Adco may be administered subcutaneously (under your skin).

The dose will be decided by your doctor according to your height and weight and will be administered twice a week. Your doctor will tell you how long your treatment with Bortezomib Adco will last. If you

have the impression that the effect of Bortezomib Adco is too strong or too weak, tell your doctor or pharmacist

Bortezomib Adco has to be dissolved before administration. This will be done by a healthcare provider.

#### **If you receive more Bortezomib Adco than you should**

Since a health care provider will administer Bortezomib Adco, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

#### **If you forget to receive Bortezomib Adco**

Since a health care provider will administer Bortezomib Adco, it is unlikely that the dose will be missed.

#### **4. Possible side effects**

Bortezomib Adco can have side effects.

Not all side effects reported for Bortezomib Adco are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking Bortezomib Adco, please consult your health care provider for advice.

If any of the following happens, stop receiving Bortezomib Adco and tell your doctor immediately:

- Muscle cramping, muscle weakness
- Confusion, visual loss or disturbances, blindness, seizures, headaches
- Shortness of breath, swelling of your feet or changes in your heart beat, high blood pressure, tiredness, fainting
- Coughing and breathing difficulties or tightness in the chest.

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

Treatment with Bortezomib Adco can commonly cause a decrease in the numbers of red and white blood cells and platelets in your blood. You will have to take regular blood tests before and during your treatment to check your blood counts regularly. You may experience a reduction in the number of:

- Platelets, which maybe make you more prone to bruising, or to bleeding without obvious injury
- Red blood cells, which can cause anaemia, with symptoms such as tiredness and paleness
- White blood cells may make you more prone to infections or flu-like symptoms

Tell your doctor immediately if you notice any of the following:

- Sensitivity, numbness, tingling or burning sensation of the skin, or pain in the hands or feet, due to nerve damage
- Fever
- Nausea, vomiting, loss of appetite, diarrhoea
- Constipation with or without bloating
- Tiredness

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Infection of the lungs (pneumonia), respiratory infection, infection caused by fungus
- Reduction in the number of red blood cells and or white blood cells
- Loss of appetite, dehydration
- Low levels of potassium, sodium and calcium in the blood

- Anxiety, mood and sleep disorders
- Sensitivity, numbness, tingling or burning sensation of the skin, or pain in the hands or feet, due to nerve damage
- Dizziness, tiredness, headache, a feeling of weakness, loss of consciousness
- Swelling or redness of the lining of the white part of the eye caused by an infection (conjunctivitis), blurred vision
- Low and high blood pressure
- Shortness of breath, nose bleeds, cough
- Nausea, vomiting, diarrhoea, constipation
- Rash, itching of the skin, dry skin
- Muscle spasms, muscle pain, muscle weakness, bone pain, pain in the limbs
- Reduced kidney function
- Painful or difficulty in urinating
- Fever, chills
- Weight loss
- Herpes infections

Less frequent side effects:

- Infection caused by bacteria or virus, infection of the skin, ear, tooth
- Abnormal tissue growth
- Blood clotting problems
- Increase of platelets or plasma cells (a type of white cell) in the blood
- Blood clot in small blood vessels (thrombotic microangiopathy)
- Skin reactions and disorders
- Swelling of joints
- Serious allergic reaction (anaphylactic shock) signs of which may include difficulty breathing, chest pain or chest tightness, and/or feeling dizzy/faint, severe itching of the skin or raised

lumps on the skin, swelling of the face, lips, tongue and /or throat, which may cause difficulty in swallowing, collapse

- Over and under active thyroid gland
- High levels of potassium, sodium and calcium in the blood, Vitamin B deficiency
- Gout
- Increased appetite, unable to tolerate alcohol
- Paralysis, seizures, falling, movement disorders, abnormal or change in, or reduced sensation (feeling, hearing, tasting, smelling), attention disturbance, trembling, twitching
- Irritated or inflamed eyes, excessively wet eyes, painful eyes, dry eyes, eye infections, lump in the eyelid (chalazion), red and swollen eyelids, discharge from the eyes, abnormal vision, bleeding of the eye
- Hearing loss, deafness or ringing in the ears, ear discomfort
- Heart failure, heart attack, angina, chest pain, chest discomfort, increased or reduced heart rate
- Inflammation of the lining around your heart or fluid around your heart
- Insufficient circulation, causing sudden exhaustion or weakness
- 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
- Disorders that affect your lungs, preventing your body from getting enough oxygen. Some of these include difficulty breathing, shortness of breath, shortness of breath without exercise, breathing that becomes shallow, difficult or stops, wheezing
- Infections or inflammation of the mouth, mouth ulcers, oesophagus, stomach and intestines, sometimes associated with pain or bleeding, poor movement of the intestines (including blockage), abdominal or oesophageal discomfort, difficulty swallowing, vomiting of blood
- Budd–Chiari syndrome (the clinical symptoms caused by blockage of the hepatic veins)
- Liver disorders such as inflammation, bleeding, failure

- Arthritis including inflammation of the joints in the fingers, toes and the jaw
- Muscle twitching, muscle stiffness
- Kidney failure, kidney damage causing increased or decreased urine production, painful passing of urine or blood/proteins in the urine
- Genital pain, erection problems
- Breast disorders, vaginal bleeding
- Injection site reactions, such as bleeding, pain, allergic reaction

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

### Reporting of side effects

If you get side effects, talk to your doctor or nurse. 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 Bortezomib Adco.

For reporting of side effects directly to the HCR, contact +27 11 635 0134 or email [Adcock.aereports@adcock.com](mailto:Adcock.aereports@adcock.com)

### 5. How to store Bortezomib Adco

Store all medicines out of reach of children.

Store at or below 25 °C. Keep the vial in the outer carton, protected from light.

#### Reconstituted solution:

The reconstituted solution may be stored up to 8 hours at 25 °C in the dark, both in a vial and in a polypropylene syringe.

For single use only, discard any unused portion.

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

### **What Bortezomib Adco contains**

The active substance is bortezomib.

The other ingredient is Mannitol (Pearlitol PF)

### **What Bortezomib Adco looks like and contents of the pack**

Bortezomib Adco is a white to off-white, lyophilized cake or powder.

Bortezomib Adco powder for solution for injection is packed in a 10 ml clear tubular Type 1 glass vial with a grey rubber stopper and an aluminium flip-off seal with blue colour plastic disc.

### **Holder of Certificate of Registration**

Adcock Ingram Critical Care (Pty) Ltd

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