PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

Bortezomib Equity 3,5 mg powder for solution for injection

Bortezomib

Contains sugar (35 mg mannitol per vial)

Read all of this leaflet carefully before you are given Bortezomib Equity

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

What is in this leaflet

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

1. What Bortezomib Equity is and what it is used for

Bortezomib Equity 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.

Bortezomib Equity is used for the treatment of:

Multiple Myeloma (a cancer of the bone marrow) in adult patients:

- alone (monotherapy) or together with the medicines pegylated liposomal doxorubicin or dexamethasone for patients whose disease is worsening (progressive) after receiving at least one prior treatment for Multiple

Myeloma and for whom blood stem cell transplantation was not successful or is unsuitable

- in combination with the medicine dexamethasone or dexamethasone together with thalidomide, for patients whose disease has not been previously treated and before receiving high-dose chemotherapy with blood cell transplantation (induction treatment)
- in combination with other medicines (melphalan and prednisone), for patients who have not been previously treated for Multiple Myeloma and are unsuitable for high-dose chemotherapy with blood stem cell transplantation.

Mantle Cell Lymphoma (a blood cancer in the lymph glands) in adults:

- whose disease is worsening (progressive) after receiving at least one prior treatment, one of which should have included the medicine anthracycline (or mitoxantrone) and/or rituximab as part of their chemotherapy treatment
- in combination with the medicine rituximab, cyclophosphamide, doxorubicin and prednisone, for patients whose disease has not been previously treated and for whom blood cell transplantation is unsuitable.

2. What you need to know before you are given Bortezomib Equity

Bortezomib Equity should not be administered to you if:

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

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

Special care should be taken with Bortezomib Equity:

- if you are suffering from diarrhoea, constipation, nausea or vomiting as this may become worse during Bortezomib Equity treatment
- if you have low numbers of red, or white blood cells
- if you have bleeding problems and/or low number of platelets in your blood

- if you have had any problems with numbness, tingling, or pain in the hands or feet (neuropathy) in the past. This effect may become worse during Bortezomib Equity treatment
- if you are suffering of have been suffering from shingles (localised including around the eyes or spread across the body)
- if you have any heart or blood pressure problems
- if you have memory loss, trouble thinking, difficulty with walking or loss of vision. These may be signs of a serious brain condition and your doctor may suggest further testing and follow-up
- if you have kidney problems
- if you have moderate to severe liver problems
- if you suffer from seizures
- if you have experienced or have new or increased shortness of breath or cough
- if you have experienced or have new or increased symptoms of tumour lysis syndrome such as vomiting muscle cramping, muscle weakness, confusion, fits, excess fluid build-up, heart failure, irregular heart rhythm, fainting, visual loss or disturbances and shortness of breath
- if you have a history of fainting, dizziness or light-headedness
- if you have been diagnosed with a condition called amyloidosis (that results from abnormal deposit of a particular protein (called amyloid), in various tissues of the body).

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

If you have mantle cell lymphoma and are given the medicine rituximab with Bortezomib Equity you should tell your doctor:

- if you think you have hepatitis infection now or have had it in the past. In a few cases, patients who have had hepatitis B might have a repeated attack of hepatitis, which can be fatal. If you have a history of hepatitis B infection you will be carefully checked by your doctor for signs of active hepatitis B.

Children and adolescents

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

Other medicines and Bortezomib

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

(This includes all complementary or traditional medicines.)

Tell your doctor if you are taking 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
- carbamazepine, phenytoin or phenobarbital used to treat epilepsy
- St. John's Wort (Hypericum perforatum), used for depression or other conditions
- oral antidiabetics
- pain medicines
- blood pressure or medicines used for your heart e.g., angiotensin inhibitors, beta-blockers, antihypertensives, calcium channel blockers, angiotensin receptor blockers and diuretics
- amiodarone, used for heart rhythm problems
- anti-viral medicines
- isoniazid, an antibiotic used in the treatment of tuberculosis (TB)
- nitrofurantoin, an antibiotic used in the treatment of bladder infections
- statins, used to control blood cholesterol levels

Pregnancy, breastfeeding and fertility

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 healthcare provider for advice before receiving Bortezomib Equity.

You should not use Bortezomib Equity if you are pregnant, unless clearly necessary.

You should not breast-feed while using Bortezomib Equity. Discuss with your doctor when it is safe to restart breastfeeding after finishing your treatment.

Driving and using machines

Bortezomib might cause tiredness, dizziness, fainting, or blurred vision.

It is not always possible to predict to what extent Bortezomib Equity may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or using machines until you are aware of the measure to which Bortezomib Equity affects you.

3. How to use Bortezomib Equity

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

This medicine is for intravenous (administered into a vein) or subcutaneous (under the skin) use.

The dose will be calculated from your height and weight (body surface area).

Monotherapy

Relapsed multiple myeloma and relapsed mantle cell lymphoma:

When Bortezomib Equity is given alone, one cycle of treatment with Bortezomib Equity consists of a total of 4 doses. Doses are given on days 1, 4, 8 and 11, followed by a 10-day 'rest period' without treatment.

Therefore, the duration of a treatment cycle is 21 days (3 weeks).

You may receive up to 8 cycles (24 weeks) of treatment.

Combination therapy

Previously untreated multiple myeloma not suitable for blood stem cell transplantation:

If you have not been treated before for multiple myeloma and you are not suitable for blood stem cell transplantation, you will receive Bortezomib Equity together with two other medicines containing melphalan and prednisone.

In this case, the duration of a cycle is 6 weeks. The treatment consists of a total of 9 cycles (54 weeks).

In cycles 1 to 4, Bortezomib Equity is administered twice weekly on days 1, 4, 8, 11, 22, 25, 29 and 32.

In cycles 5 to 9, Bortezomib Equity is administered once weekly on days 1, 8, 22 and 29.

Melphalan and prednisone are both given orally on days 1, 2, 3 and 4 of the first week of each cycle.

Previously untreated multiple myeloma suitable for blood stem cell transplantation:

If you have not been treated before for multiple myeloma, and you are suitable for blood stem cell transplantation, you will receive Bortezomib Equity subcutaneously together with the medicines dexamethasone, or dexamethasone and thalidomide, as induction treatment.

Bortezomib Equity is given twice weekly on Days 1, 4, 8, and 11, followed by a rest period of 10-18 days. This is considered as a treatment cycle. You will be given 3-6 cycles of treatment.

Relapsed multiple myeloma:

If you have been treated before for multiple myeloma and you are unsuitable for blood stem cell transplantation or if you have already received a blood stem cell transplantation, you will receive Bortezomib Equity together with a medicine called pegylated liposomal doxorubicin or a medicine called dexamethasone.

When Bortezomib Equity is given together with pegylated liposomal doxorubicin, you will receive Bortezomib Equity subcutaneously as a 21-day treatment cycle and pegylated liposomal doxorubicin 30 mg/m^2 is given on day 4 of the Bortezomib Equity 21-day treatment cycle as an intravenous infusion after the Bortezomib Equity injection. You might receive up to 8 cycles (24 weeks).

When Bortezomib Equity is given together with dexamethasone, you will receive Bortezomib Equity subcutaneously as a 21-day treatment cycle and dexamethasone 20 mg is given orally on the day of and the day after the Bortezomib Equity injection.

Previously untreated mantle cell lymphoma:

If you have not been treated before for mantle cell lymphoma you will receive Bortezomib Equity subcutaneously together with the following medicines: rituximab, cyclophosphamide, doxorubicin and prednisone. Bortezomib Equity is given subcutaneously on days 1, 4, 8 and 11, followed by a 'rest period' without treatment. The duration of a treatment cycle is 21 days (3 weeks). You might receive up to 8 cycles (24 weeks).

The following medicines are given on day 1 of each Bortezomib Equity 21-day treatment cycle as intravenous

infusions:

Rituximab at 375 mg/m^2, cyclophosphamide at 750 mg/m^2 and doxorubicin at 50 mg/m^2. Prednisone is given orally at 100 mg/m^2 on days 1, 2, 3, 4 and 5 of the Bortezomib Equity treatment cycle.

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

Method of administration

Bortezomib Equity powder has to be dissolved before administration. This will be done by a healthcare professional. The resulting solution is then either injected into a vein or under the skin. Injection into a vein is rapid, taking 3 to 5 seconds. Injection under the skin is in either the thighs or the abdomen.

If you use more Bortezomib Equity than you should

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

If you forget to use Bortezomib Equity

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

4. Possible side effects

Bortezomib Equity can have side effects.

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

If any of the following happens, stop receiving Bortezomib Equity and tell your doctor immediately and 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.

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

If you are given Bortezomib Equity for multiple myeloma or mantle cell lymphoma, 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, headaches
- shortness of breath, swelling of your feet or changes in your heartbeat, high blood pressure, tiredness, fainting
- coughing and breathing difficulties or tightness in the chest.

You may experience a reduction in the number of:

- platelets, which may make you be more prone to bruising, or to bleeding without obvious injury (e.g., bleeding from your bowels, stomach, mouth and gum or bleeding in the brain or bleeding from the liver)
- 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.

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

Tell your doctor if you notice any of the following:

If you are given Bortezomib Equity for the treatment of multiple myeloma the side effects you may get are listed below:

Frequent side effects:

- infections, including lung infection, respiratory infections, bronchitis, fungal infections, coughing with phlegm, flu like illness
- shingles (localised including around the eyes or spread across the body)
- loss of appetite, dehydration, reduced potassium, reduced sodium, reduced calcium levels in your blood
- anxiety, mood swings and disorders, sleep disorders
- sensitivity, numbness, weakness, tingling or burning sensation of the skin, or pain in the hands or feet, due to

nerve damage

- loss of consciousness, progressive, asymmetric muscle weakness and atrophy (wasting), abnormal sense of touch, bad taste, headache, lack of energy
- eye swelling, abnormal vision and inflammation/infection of the conjunctiva
- spinning sensation
- low blood pressure, sudden fall of blood pressure on standing which may lead to fainting, high blood pressure
- difficulty breathing, nose bleeding, respiratory infection, cough
- feeling sick (nausea) or vomiting, diarrhoea, constipation, indigestion, stomach pain, wind, any problem that affects your mouth can make it hard to eat, drink, or even smile, inflammation of the mucous membrane of the mouth, bloating or swelling of the belly, bleeding from your bowels or stomach
- alteration of liver functioning
- itching of the skin, lumps on the skin or dry skin
- muscle pain, muscle spasms, muscle weakness, pain in your limbs
- reduced functioning of your kidneys
- fever, chills, tiredness, swelling of body, to include around eyes and other parts of the body, physical weakness
- decreased weight.

Less frequent side effects:

- bacterial and viral infections
- infections including urinary tract infections, the flu, herpes virus infections, ear infection and cellulitis
- a red, painful lump near the edge of the eyelid that may look like a boil or pimple, tooth infection, injection site or injection device related disorders
- a severe reversible brain condition which includes seizures, high blood pressure, headaches, tiredness, confusion, blindness or other vision problems
- sexually transmitted infection marked by genital pain and sores, infection of the tonsils, an infection that affects the mastoid bone, located behind the ear
- a disease characterised by profound fatigue, sleep abnormalities, pain and other symptoms that are made worse by exertion

- cancer of the kidney, a large body of matter with no definite shape, mass of slow growing localized tumour, skin cancer
- low numbers of white blood cells, problems with blood clotting, swelling of your lymph glands, 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
- thrombosis in capillaries and arterioles, blood disorders include anaemia, bleeding disorders such as haemophilia, blood clots, and blood cancers such as leukaemia, lymphoma, and myeloma
- abnormal protein deposits in your vital organs
- overactive thyroid gland, underactive thyroid gland, hormone abnormality which may affect salt and water absorption
- a condition that occurs from exposure to high cortisol levels for a long time and include symptoms such as stretch marks, weight gain
- condition that occurs when a large number of cancer cells die within a short period, releasing their contents into the blood (Tumour lysis syndrome), electrolyte disturbances such as low levels of magnesium or phosphate and high levels such potassium, calcium, sodium, magnesium, phosphate, chloride ions
- inability to tolerate alcohol consumption, increased appetite, wasting or loss of body mass, vitamin B complex deficiency or B12 deficiency
- dehydration, high sodium levels accompanied by low level of chloride in the blood
- mood swings, depressed mood, restlessness or agitation, changes in your mental status, adjustment disorder, decreased sex drive, confused thinking, seeing things that do not exist, thinking about suicide or wanting to take your own life
- paralysis, seizures, falling, movement disorders, abnormal or change in, or reduced sensation (feeling, hearing, tasting, smelling), attention disturbance, trembling, twitching, hiccups, speech disorders
- altered levels of consciousness, confusion, memory impairment or loss
- bleeding in the brain, stroke, uncontrolled, involuntary muscle movement, migraine, pain radiating along the sciatic nerve, which runs down one or both legs from the lower back
- abnormal reflexes, muscular weakness caused by nerve damage or disease, a condition affects nerve fibres and skin, causing burning pain that lasts long after the rash and blisters of shingles disappear

- external compression of the spinal cord causing neurological symptoms
- drooling, weak muscle tone
- (systemic) process that damages nerve cells, nerve fibres (axons), and nerve covering, a dysfunction of the nerves that regulate non-voluntary body functions, such as heart rate, blood pressure and sweating
- brain disease that alters brain function or structure, coma
- 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
- loss of vision, with colours appearing subtly washed out in the affected eye
- bulging of the eye, blind spot, light sensitivity, visual distortion caused by something inside the eye or brain, corneal ulcer, visual impairment
- hearing loss, deafness or ringing in the ears, ear discomfort, bleeding in the ear
- compression of the heart caused by fluid collecting in the sac surrounding the heart, cardiac heartbeat irregularities
- heart problems to include heart attack, angina, heart failure, chest pain, chest discomfort, increased or reduced heart rate, heart muscle disease
- specific type of abnormal heart rhythm that can lead to sudden cardiac death (torsades de pointes)
- heart valve disorders, sinus arrest implies a failure of atrial activation, damage or disease in the heart's major blood vessels
- stroke, inflammation of your blood vessels, 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
- discoloration of the veins, insufficient circulation, an arterial embolism is a blood clot that has travelled through your arteries and become stuck
- swelling in an arm or leg caused by a lymphatic system blockage, paleness of the skin, condition characterised by episodes of pain, redness, and swelling in various parts of the body, particularly the hands and feet
- improper functioning of the vein valves in the leg, causing swelling and skin changes
- blockage in one of the pulmonary arteries in your lungs, water on the lungs, pulmonary bleeding, low level of oxygen in the blood, low level of oxygen in the body tissue

- coughing up blood, collapsed lung
- a type of high blood pressure that affects arteries in the lungs and in the heart
- deep or rapid breathing, known as hyperventilation, dry throat, chest tightness, postnasal drip, discomfort when breathing while lying down flat
- temporary inability to breath, throat irritation
- inflammation of the tissues that line the lungs and chest cavity
- a group of disorders that cause progressive scarring of lung tissue
- inflammation of the pancreas, obstruction of the bile duct
- 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
- lip pain, inflammation of lips, one or more painful sores on inner lips, gums, tongue, roof of the mouth or throat that may interfere with eating
- stone of faeces, fistula, inflammation of the membrane lining the abdominal wall and covering the abdominal organs, pain due to a spasm of the pelvic floor muscles, abnormal faeces
- swelling of the liver, bleeding from the liver
- Budd–Chiari syndrome (the clinical symptoms caused by blockage of the hepatic veins), gall stones
- any condition in which the flow of bile from the liver stops or slows, liver failure
- skin infections, hives, skin reactions and disorders (which may be severe and life threatening), skin ulcers, psoriasis, nail disorder, lace-like purplish discoloration of the skin, tiny round, brown-purple spots due to bleeding under the skin, non-cancerous lumps on the skin
- skin colouration due to bruising, night sweats, acne, blisters, excessive sweating, hand-foot syndrome causes redness, swelling, and pain on the palms of the hands and/or the soles of the feet, deep thickening of the skin
- a skin condition that causes scaly patches and red skin, mainly on the scalp
- reddish colour of the skin and mucous membrane (erythrosis)
- joint or muscle stiffness, sense of heaviness, pain in your groin, joint effusion, breakdown of muscle fibres leading to other complications, pain and compromised movement of the jaw joint and the surrounding muscles
- cysts in the lining of joints (synovial cysts), primary symptom of muscle weakness due to dysfunction of

muscle fibre

- kidney failure (acute or chronic), blood in the urine, difficulty urinating and completely emptying the bladder, an excess of protein in the urine, storage and voiding of urine (micturition disorder), need to urinate more often than normal, urinary tract infection, elevated levels of urea and other nitrogen compounds in the blood, urine output below normal, bladder irritation
- vaginal bleeding, genital pain and swelling, impotence, breaks in the skin around the vagina or mucous membranes of the vulva, breast disorder
- inflammation of the tube at the back of the testicle that stores and carries sperm, bacterial or sexually transmitted infection, pain or discomfort, ranging from a sharp jab to a dull ache, in the lowest part of the abdomen and pelvis
- the failure of an organ or tissue to develop or to function normally
- a group of skin disorders characterised by dry, scaly or thickened skin
- a segment of bowel is very narrow or is disconnected from the rest of the GI tract
- physical health deterioration, face swelling, reaction at the injection site
- diseases of the mucous membranes of the mouth and genitals caused by yeast, viruses and bacteria, chest pain, feeling cold, unable to walk in the usual way
- leakage of a fluid out of its container into the surrounding area, especially blood or blood cells from vessels
- multi-organ failure
- hernia, bleeding at the injection site, inflammation of a vein and blood clots
- non-cardiac chest pain, sensation of foreign body, catheter site pain, delayed healing
- abnormal increase in bilirubin, increased weight, protein analysis abnormal, increased C-reactive protein, abnormal urine analysis, abnormal ECG, abnormal blood gases
- decrease in gastric pH, abnormal time it takes for a patient's blood to clot (INR), increased platelet aggregation
- fall, fracture, burns, a deep cut or tear in skin or flesh, joint injury
- blood or bleeding under the skin due to trauma of any kind, feeling of cold (shivering)
- tissue damage or changes caused by exposure to ionizing radiation
- pain that is related to wound care or stretching of the patient's scar tissue.

If you are given Bortezomib Equity together with other medicines for the treatment of mantle cell lymphoma the side effects you may get are listed below:

Frequent side effects:

- pneumonia, bacterial and fungal infection
- herpes infection, shingles, (localized including around the eyes or spread across the body), respiratory infection
- sepsis
- abnormally low levels of platelets, a condition in which the blood doesn't have enough healthy red blood cells
- abnormally low number of types of white blood cell in the blood (neutropenia, leukopenia and lymphopenia)
- decreased appetite, decreased levels of potassium, abnormal blood glucose levels, fluid retention
- difficulty or problems in sleeping
- altered level or loss of consciousness, confusion, altered taste, painful burning, prickling, or aching feeling (dysaethesia), stabbing, burning, and often severe pain due to an irritated or damaged nerve, weakness, numbness and pain from nerve damage, usually in the hands and feet, a dysfunction of the nerves that regulate non-voluntary body functions, such as heart rate, blood pressure and sweating
- a broad term for any brain disease that alters brain function or structure
- abnormal vision
- impaired hearing
- heart failure, heart attack, chest pain, chest discomfort, increased or reduced heart rate
- increased heartbeat, high blood pressure, sweating
- high or low blood pressure, sudden fall of blood pressure upon standing which may lead to fainting
- difficulty breathing, cough, hiccups
- stomach pain, bloating, swelling, nausea, vomiting, diarrhoea, constipation, oral ulcers, stomach bleeding, infection or inflammation of the stomach and intestines, difficulty swallowing
- mouth problems include cold sores, canker sores, thrush, dry mouth, and bad breath, pain or irritation in the throat that can occur with or without swallowing, often accompanies infections, such as a cold or flu
- chemical-driven liver damage
- hair disorder, an uncomfortable, irritating sensation that creates an urge to scratch that can involve any part of the body, itchy, dry skin or a rash on swollen, reddened skin (dermatitis)

- pain in limbs, muscle spasms, pain that affects the muscles, ligaments and tendons, and bones
- urinary tract infections
- fever, tiredness, lack of energy, build-up of fluid causes affected tissue to become swollen, chills, a general sense of being unwell, often accompanied by fatigue, diffuse pain or lack of interest in activities, injection site reaction
- abnormal levels of bilirubin, abnormal protein analysis, decreased weight, increased weight

Less frequent side effects:

- hepatitis, bronchopneumonia
- low counts for all three types of blood cells
- large amounts of tumour cells are killed off (lysed) at the same time by the treatment, releasing their contents into the bloodstream
- a dysfunction of the nerves that regulate non-voluntary body functions, such as heart rate, blood pressure and sweating
- spinning feeling, impaired hearing
- heart conditions that include diseased vessels, structural problems and blood clots
- 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
- blood clots in your lungs
- an inflammatory reaction in the colon, often autoimmune or infectious
- liver failure.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA

website. By reporting side effects, you can help provide more information on the safety of Bortezomib Equity.

5. How to store Bortezomib Equity

Store all medicines out of reach of children.

Store at or below 25 °C and protect from light.

Do not freeze.

Do not use this medicine after the expiry date which is stated on the syringe or pen label and on the outer carton after EXP. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What Bortezomib Equity contains

The active substance is bortezomib. Each vial contains 3,5 mg bortezomib (as a mannitol boronic ester).

The other ingredients are mannitol and nitrogen.

What Bortezomib Equity looks like and contents of the pack

White to off-white lyophilised powder.

Bortezomib Equity is supplied in a 10 mL/20 mm flint flat bottom tubular type-I glass vial with 20 mm dark grey bromo butyl rubber stopper (RFS) and 20 mm aluminium flip off light blue colour seals.

The vial is contained in a transparent blister pack consisting of a tray with a lid. Each pack contains 1 single-use vial.

Holder of Certificate of Registration

Equity Pharmaceuticals (Pty) Ltd.

100 Sovereign Drive

Route 21 Corporate Park

Nellmapius Drive

Irene

Pretoria

0157

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This leaflet was last revised in

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56/26/0040

Access to the corresponding translated Patient Information Leaflet:

An electronic copy of the translated Patient Information Leaflet (PIL) is available on the Equity website:

http://www.equitypharmaceuticals.co.za