Applicant: Ranbaxy Pharmaceuticals (Pty) Ltd
Product Name:BOTIGEN 3,5
Dosage form: Powder for solution for injection
Strength: 3,5 mg Bortezomib (as a mannitol boronic ester) per 10 mL vial

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Patient Information Leaflet

SCHEDULING STATUS: S4

BOTIGEN 3,5 (Powder for solution for injection)

Bortezomib 3,5 mg (as a mannitol boronic ester) /vial

Contains sugar (mannitol 35 mg per vial)

Read all of this leaflet carefully before you are given BOTIGEN 3,5:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- BOTIGEN 3,5 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What BOTIGEN 3,5 is and what it is used for

BOTIGEN 3,5 contains bortezomib as the active ingredient and

belongs to a group of medicines called cytostatic medicines. These

are used to kill cancer cells.

BOTIGEN 3,5 is used for the treatment of :

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

- In combination with other medicines (melphalan and prednisone), for patients who have not been previously treated and are unsuitable for high-dose chemotherapy with blood stem cell transplantation
- Alone or together with the medicines pegylated liposomal doxorubicin or dexamethasone, for patients whose disease is worsening (progressive) after receiving at least one prior treatment and for whom blood stem cell transplantation was not successful or is unsuitable.
- In combination with the medicines dexamethasone or dexamethasone together with thalidomide, for patients whose disease has not been previously treated and before receiving high-dose chemotherapy with blood stem cell transplantation (induction treatment).

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 medicines rituximab, cyclophosphamide, doxorubicin and prednisone, for patients whose disease has not been previously treated and for whom blood stem cell transplantation is unsuitable.

2. What you need to know before you are given BOTIGEN 3,5

You should not be administered BOTIGEN 3,5:

- If you are hypersensitive (allergic) to bortezomib or any of the other ingredients of BOTIGEN 3,5.
- If you are hypersensitive (allergic) to mannitol or boron.
- If you have certain severe lung or heart problems

Warning and Precautions

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

- severe lung, liver or heart problems.
- low numbers of red blood cells, platelets or white blood cells, as these might worsen during treatment
- bleeding problems and/or low number of platelets in your blood
- diarrhoea, constipation, nausea or vomiting, as this might worsen during treatment
- a history of fainting, dizziness or light-headedness in the past
- kidney problems
- liver problems
- numbness, tingling, or pain in the hands or feet (neuropathy) in the past, as it might worsen during treatment
- heart or blood pressure problems
- amyloidosis (as a result of abnormal deposit of amyloid (a protein) in various tissues in the body)
- shortness of breath or cough
- seizures
- Shingles (localised including around the eyes or spread across the body)

- symptoms of tumor lysis syndrome such as muscle cramping, muscle weakness, confusion, visual loss or disturbances and shortness of breath
- memory loss, trouble thinking, difficulty with walking or loss of vision. These may be signs of a serious brain infection and your doctor may suggest further testing and follow-up.
- mantle cell lymphoma and are given the medicine rituximab with BOTIGEN 3,5 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

BOTIGEN 3,5 has not been studied in children or adolescents and therefore should not be used in this patient population.

Other medicines and BOTIGEN 3,5

Always tell your healthcare 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
- 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
- Ritonavir used to treat HIV infection

BOTIGEN 3,5 with food and drink

Refer to Section 3 (How BOTIGEN 3,5 is given).

Pregnancy and breastfeeding

This medicine may harm a baby developing in the womb. It is important not to become pregnant or father a child while you are having treatment with this medicine and for 3 months afterwards.
If you are pregnant or breastfeeding, think that you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before you are given this medicine.

BOTIGEN 3,5 must not be used if you are pregnant or breastfeeding.
You must make sure that you do not become pregnant while receiving BOTIGEN 3,5. Both men and women must ensure adequate birth control measures are taken whilst receiving BOTIGEN 3,5, and for 3 months after treatment.

If you do become pregnant or are breastfeeding your baby while receiving BOTIGEN 3,5, please consult your doctor, pharmacist or other healthcare provider for advice.

If you wish to restart breastfeeding after BOTIGEN 3,5 treatment, you must discuss this with your doctor, pharmacist or other healthcare provider, who will tell you when it is safe to do so.

Driving and using machines:

It is not always possible to predict to what extend BOTIGEN 3,5 may interfere with daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which BOTIGEN 3,5 affects them.
BOTIGEN 3,5 might cause low blood pressure, tiredness, dizziness, fainting, or blurred vision.

Do not drive or operate tools or machines if you experience such side effects; even if you do not, you should still be cautious.

BOTIGEN 3,5 contains mannitol (35 mg/5 mL)

BOTIGE 3,5 contains mannitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before being given this medicine.

3. How BOTIGEN 3,5 is given

You will not be expected to give yourself BOTIGEN 3,5. It will be given to you by a person who is qualified to do so.

The usual starting dose of BOTIGEN 3,5 is 1,3 mg/m^2 body surface area twice a week.

Your doctor will work out your dose of BOTIGEN 3,5 according to your height and weight (body surface area).

You will receive BOTIGEN 3,5 in a specialised medical unit, under the supervision of a doctor experienced in the use of cytotoxic medicines.

You will be given BOTIGEN 3,5 intravenously (in a vein) or subcutaneously (under the skin).

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

Your doctor will tell you how long your treatment with BOTIGEN 3,5 will last. Your doctor may change the dose and total number of treatment cycles, depending on your response to the treatment, on the occurrence of certain side effects and on your underlying conditions (e.g. liver problems).

Progressive multiple myeloma

When BOTIGEN 3,5 is given alone, you will receive 4 doses of BOTIGEN 3,5 intravenously on days 1, 4, 8 and 11, followed by a 10-day ‘rest period’ without treatment.

This 21-day period (3 weeks) corresponds to one treatment cycle. At least 72 hours should elapse between consecutive doses of BOTIGEN 3,5. You might receive up to 8 cycles (24 weeks).

You may also be given BOTIGEN 3,5 together with the medicines pegylated liposomal doxorubicin or dexamethasone.

When BOTIGEN 3,5 is given together with pegylated liposomal doxorubicin, you will receive BOTIGEN 3,5 intravenously as a 21-day treatment cycle and pegylated liposomal doxorubicin 30 mg/m^2 is given on day 4 of the BOTIGEN 3,5, 21-day treatment cycle as an intravenous infusion after the BOTIGEN 3,5 intravenous injection. You might receive up to 8 cycles (24 weeks).

Previously untreated multiple myeloma

Patients with previously untreated multiple myeloma may also be given BOTIGEN 3,5 together with the medicines melphalan and prednisone.

In this case, the duration of a treatment cycle is 42 days (6 weeks). You will receive 9 cycles (54 weeks).

- In cycles 1 to 4, BOTIZEN 3,5 is administered twice weekly on days 1, 4, 8, 11, 22, 25, 29 and 32.
- In cycles 5 to 9, BOTIZEN 3,5 is administered once weekly on days 1, 8, 22 and 29.

Melphalan (9 mg/m^2) and prednisone (60 mg/m2) are both given orally on days 1, 2, 3 and 4 of the first week of each cycle.

If you have not been treated before for multiple myeloma, and you are suitable for blood stem cell transplantation you will receive BOTIGEN 3,5 intravenously together with the medicines dexamethasone, or dexamethasone and thalidomide, as induction treatment.

When BOTIGEN 3,5 is given together with dexamethasone, you will receive BOTIGEN 3,5 intravenously as a 21-day treatment cycle and dexamethasone 40 mg is given orally on days 1, 2, 3, 4, 8, 9, 10 and 11 of the BOTIGEN 3,5,21-day treatment cycle. You will receive 4 cycles (12 weeks).

When BOTIGEN 3,5 is given together with thalidomide and dexamethasone, the duration of a treatment cycle is 28 days (4 weeks).
Dexamethasone 40 mg is given orally on days 1, 2, 3, 4, 8, 9, 10 and 11 of the BOTIGEN 3,5, 28-day treatment cycle and thalidomide is given orally daily at 50 mg up to day 14 of the first cycle, and if tolerated the thalidomide dose is increased to 100 mg on days 15-28 and may be further increased to 200 mg daily from the second cycle onwards. You might receive up to 6 cycles (24 weeks).

Progressive mantle cell lymphoma

When BOTIGEN 3,5 is given alone, you will receive 4 doses of BOTIGEN 3,5 intravenously on days 1, 4, 8 and 11, followed by a 10-day 'rest period' without treatment. This 21-day period (3 weeks) corresponds to one treatment cycle. You might receive up to 8 cycles (24 weeks)

Previously untreated mantle cell lymphoma

If you have not been treated before for mantle cell lymphoma you will receive BOTIGEN 3,5 intravenously together with the medicines rituximab, cyclophosphamide, doxorubicin and prednisone. BOTIGEN 3,5 is given intravenously 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 BOTIGEN 3,5 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 BOTIGEN 3,5 treatment cycle

If you received too much BOTIGEN 3,5

Since a healthcare provider will administer this medicine, he/she will control the dosage.

However in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of BOTIGEN 3,5:

Since a health care provider will administer BOTIGEN 3,5, it is unlikely that the dose will be missed.

4. POSSIBLE SIDE EFFECTS

BOTIGEN 3,5 can have side effects.

Not all side effects reported for BOTIGEN 3,5 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while given BOTIGEN 3,5, please consult your health care provider for advice.

If any of the following happens stop using BOTIGEN 3,5 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- Peeling and blistering of the skin, mouth, eyes and genitals
- Rash or itching affecting your whole body
- Fainting

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BOTIGEN 3,5. You may need urgent medical attention or hospitalisation.

If you are given BOTIGEN 3,5, tell your doctor immediately or go to the casualty department of your nearest hospital if you notice any of the following:

- muscle cramping
- muscle weakness

- tingling, burning, pain, and loss of feeling in your hands and
- feet, any of which can be severe.
- confusion
- visual loss or disturbances
- blindness
- seizures
- headaches
- shortness of breath
- swelling of your feet or changes in your heartbeat
- high or low blood pressure
- tiredness
- fainting
- dizziness
- wheezing, coughing and breathing difficulties or tightness in the chest.
- chest pressure or pain
- yellow discoloration of the eyes and skin (jaundice) and changes in liver enzymes measured in blood tests.

These are all serious side-effects. You may need medical attention. Treatment with BOTIGEN 3,5 can frequently cause a decrease in the numbers of red and white blood cells and platelets in your blood. Therefore, you will have to take regular blood tests before and during your treatment with BOTIGEN 3,5, to check your blood cell counts regularly.

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.

The following side-effects have been reported, tell your doctor if you notice any of the following:

Frequent:

- Herpes zoster infection (including disseminated).
- Pneumonia, bronchitis, infection of the sinus passages.
- Reduction in the number of red blood cells and or white blood cells (see above).
- Dehydration and loss of appetite
- Changes in potassium in your blood, too much sugar in your blood.
- Depression which may be severe, confusion
- Difficulty in sleeping, sweating, anxiety.
- Sensitivity, numbness, tingling or burning sensation of the skin, or pain in the hands or feet, due to nerve damage.
- Fever, shivering fits.
- Blurred vision, eye pain
- General ill feeling, dizziness, light-headedness, or a feeling of weakness.
- Sudden fall of blood pressure on standing which may lead to fainting, high blood pressure, infection or swelling of a vein or tissue
- Chest pains or coughing with phlegm, shortness of breath with exercise.
- Difficulty in breathing, nose bleeds, cough, runny nose
- Heartburn, bloating, belching, wind or stomach pain, hiccups
- A sore mouth or lip, dry mouth, mouth ulcers or throat pain.
- Constipation with or without bloating (can be severe), abdominal pain
- Feeling sick (nausea) or vomiting, loss of appetite.
- Diarrhoea: if this happens, it is important that you drink more water than usual. Your doctor may give you another medicine to control diarrhoea.
- Rash

- Different types of rash and/or itching, lumps on the skin or dry skin.
- Muscle pain or weakness, tiredness, headache.
- Muscle cramps, bone pain, pain in your limbs or back.
- Kidney problems and painful or difficult urination
- Fatigue, fever, weakness, flu-like symptoms, swelling, chest pain
- Weight loss, loss of taste.
- Shortness of breath without exercise.
- Overtiredness (fatigue).
- Redness of the skin or redness and pain at the injection site.
- Infection of the outermost layer of the eye and inner surface of the eyelids (conjunctivitis)

Less frequent:

- General infections and infections of e.g. lungs, respiratory track, kidney and bladder, intestines, mouth, eyes caused by bacteria or fungus
- Low blood counts of white and red blood cells and platelets
- swollen or enlarged lymph nodes
- Swelling of your lymph nodes.
- Tumor lysis syndrome with symptoms such as nausea, vomiting, diarrhoea, muscle cramps or twitches, weakness, numbness or tingling, fatigue, decreased urination
- Allergic reactions.
- Hormone abnormality affecting salt and water absorption.
- Changes in calcium, sodium, magnesium, uric acid, lower Vit B_{12}, and phosphates in your blood, too little sugar in your blood
- Loss of attention, restlessness or agitation, changes in your mental status, mood swings, sleep disorders
- Paralysis, seizures, migraine, restless legs, speech disorder

- Irritated eyes, excessively wet or dry eyes, discharge from the eyes, abnormal vision, eye infections (including herpes zoster), bleeding of the eye or sensitivity to light.
- Damage to the optic nerve and blindness.
- Hearing loss, deafness or ringing in the ears.
- Palpitations (sensation of rapid or irregular heart beat), changes in heartbeat, heart failure, heart attack, chest pain, chest discomfort or decreased ability of the heart to work.
- Facial blushing, hot flushes or tiny broken capillaries.
- Inflammation of the blood vessels that can appear as small red or purple dots (usually on the legs) to bruise-like patches on the skin.
- Bleeding from your bowels or stomach, bloody stools, bleeding in the brain, bleeding from the liver or bleeding from mucosal membranes e.g. mouth.
- Breathing becomes shallow, difficult or stops, wheezing, and difficulty in breathing, asthma, cough that produces frothy sputum that may be tinged with blood or coughing blood.
- Yellow discolouration of eyes and skin (jaundice).
- Mouth pain, retching.
- Abdominal pain.
- Poor movement in the intestines (including blockages).
- Severe skin reactions, which may have blisters and involve the mouth, throat, eyes and genitals that can be life-threatening (Stevens Johnson Syndrome and toxic epidermal necrolysis).
- Nail and skin disorders, such as hair loss
- Joint or muscle stiffness, muscle spasms or twitching, pain in
- jaw or your bottom, joint swelling and swelling
- Kidney problems such as an increased or decreased urine production (due to kidney damage), painful passing of urine or blood/proteins in the urine.
- Reversible Posterior Leukoencephalopathy Syndrome
- (RPLS), a severe reversible brain condition which includes

seizures, high blood pressure, headaches, tiredness,

confusion, blindness or other vision problems.

- Progressive multifocal leukoencephalopathy, a rare usually fatal viral disease characterised by progressive damage or inflammation of the white matter of the brain at multiple locations.
- Poor circulation
- Problems with blood clotting
- Swelling of the lining around your heart or fluid around your heart
- Cerebrovascular disorders
- Arthritis, including welling of the joints in the fingers, toes and the jaw
- 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
- Overactive thyroid gland
- Inability to produce enough insulin or resistance to normal levels of insulin
- Infections or swelling of the mouth, mouth ulcers, oesophagus, stomach and intestines, sometimes associated with pain or bleeing, poor movement of the intestines (including blockage), abdominal or oesophageal discomfort, difficulty swallowing, vomiting of blood.
- Skin infections
- Tooth infections
- Swelling of the pancreas, blockage of the bile duct
- Genital pain, problem having an erection
- Weight increase
- Thirst
- Injection site or injection device related disorders
- Bruises, falls and injuries
- Swelling 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

- Benign (non-cancerous) cysts
- Heart probleems to include heart attack, angina
- Flushing
- Discolouration of the veins
- Swelling of the spinal nerve
- Problems with your ear, bleeding from your ear
- Underactivity of your thyroid gland
- Budd–Chiari syndrome (the clinical symptoms caused by blockage of the hepatic veins)
- Changes in or abnormal bowel function
- Breast disorders
- Vaginal tears
- Genital swelling
- Inability to tolerate alcohol consumption
- Wasting, or loss of body mass
- Increased appetite
- Fistula (abnormal connection between two spaces)
- Joint effusion
- Cysts in the lining of joints (synovial cysts)
- Fracture
- Breakdown of muscle fibers leading to other complications
- Cancer of the kidney
- Psoriasis like skin condition
- Cancer of the skin
- Increase of platelets or plasma cells (a type of white cell) in the blood
- Blood clot in small blood vessels (thrombotic microangiopathy)
- Abnormal reaction to blood transfusions
- Decreased sex drive

- Drooling
- Bulging eyes
- Rapid breathing
- Rectal pain
- Gallstones
- Hernia
- Injuries
- Brittle or weak nails
- Abnormal protein deposits in your vital organs
- Coma
- Intestinal ulcers
- Multi-organ failure
- Death

If you are given BOTIGEN 3,5 together with the other medicines for the treatment of mantle cell lymphoma the side effects you may get are listed below and tell your doctor if you notice any of the following:

Frequent side effects:

- Pneumonia
- Loss of appetite
- Sensitivity, numbness, tingling or burning sensation of the skin, or pain in the hands or feet, due to nerve damage
- Nausea and vomiting
- Diarrhoea
- Mouth ulcers
- Constipation
- Muscle pain, bone pain

- Hair loss and abnormal hair texture
- Tiredness, feeling weak
- Fever
- Shingles (localised including around the eyes or spread across the body)
- Herpes virus infections (Epstein-Barr virus infection)
- Bacterial and viral infections
- Respiratory infections, bronchitis, coughing with phlegm, flu like illness
- Fungal infections
- Inability to produce enough insulin or resistance to normal
- levels of insulin
- Fluid retention
- Difficulty or problems in sleeping
- Loss of consciousness
- Altered level of consciousness, confusion
- Feeling dizzy
- Increased heartbeat, high blood pressure, sweating,
- Abnormal vision, blurred vision
- Heart failure, heart attack, chest pain, chest discomfort, increased or reduced heart rate
- High or low blood pressure
- Sudden fall of blood pressure upon standing which may lead to fainting
- Shortness of breath with exercise
- Cough
- Hiccups
- Ringing in the ears, ear discomfort
- Bleeding from your bowels or stomach
- Heartburn
- Stomach pain, bloating

- Difficulty swallowing
- Infection or inflammation of the stomach and intestines
- Stomach pain
- Sore mouth or lip, throat pain
- Alteration of liver function
- Itching of skin
- Redness of skin
- Rash
- Muscle spasms
- Infection of the urinary tract
- Pain in limbs
- Swelling of body, to include eyes and other parts of the body
- Shivering
- Redness and pain at injection site
- General ill feeling
- Weight loss
- Weight increase

Less frequent side effects

- Hepatitis (swelling of the liver)
- Severe allergic reaction
- Movement disorders, paralysis, twitching
- Vertigo
- Hearing loss, deafness
- 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

- Yellow discoloration of the eyes and skin (jaundice)
- Lump in the eyelid (chalazion), red and swollen eyelids
- Blood clot in small blood vessels (thrombotic microangiopathy)
- Inflammation (swelling) of the protective membranes covering the brain and spinal cord (meningitis)
- Itching, burning or tenderness in the genital area (genital virus)
- Inflammation of the tonsils
- Pain in a nerve pathway (neuralgia)

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 pharmacist 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 BOTIGEN 3,5.

5. HOW TO STORE BOTIGEN 3,5

BOTIGEN 3,5 will be stored in the pharmacy.

Store all medicines out of reach of children.

Do not use this medicine after the expiry date stated on the vial and

the carton after EXP:

Before reconstitution:

Store at or below 25 °C.

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

Reconstituted solutions:

The reconstituted solution should be used immediately after preparation. If the reconstituted solution is not used immediately, in-use storage times and conditions prior to use are the responsibility of the user. However, the reconstituted solution is stable for 8 hours at 25 °C stored in the original vial and/or a syringe, with a total storage time for the reconstituted medicine not exceeding 8 hours prior to administration. BOTIGEN 3,5 is for single use only. Discard any unused portion as per current requirements.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What BOTIGEN contains

The active substance is: bortezomib

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

After reconstitution, 1 mL of solution for subcutaneous injection contains 2,5 mg bortezomib.

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

The other ingredients are: mannitol (35 mg per vial)

What BOTIGEN 3,5 looks like and the contents of the pack

BOTIGEN 3,5 is supplied as a white to off white lyophilized cake or powder in a 10 ml Type 1 tubular colourless glass vial with a grey bromobutyl rubber stopper, sealed with a light green flip off aluminium seal.

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

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This leaflet was last revised in

27 January 2025

Registration number

51/26/0163