Package leaflet: Information for the patient

TEVIMBRA® 100 mg concentrate for solution for infusion
tislelizumab

▼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.
- It is important that you keep the Patient Card with you during treatment.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What TEVIMBRA is and what it is used for

TEVIMBRA is a cancer medicine that contains the active substance tislelizumab. It is a monoclonal antibody, a type of protein that is designed to recognise and attach to a specific target in the body called programmed death-1 receptor (PD-1) which is found on the surface of T and B cells (types of white blood cells that form part of the immune system, the body's natural defences). When PD-1 is activated by cancer cells it can switch off the activity of T cells. By blocking PD-1, TEVIMBRA prevents it from switching off your T cells which helps your immune system fight the cancer.

TEVIMBRA is used in adults to treat:
- a type of lung cancer called non-small cell lung cancer.
- a type of lung cancer called extensive-stage small cell lung cancer.
- a type of stomach cancer called gastric or gastroesophageal junction adenocarcinoma
- a type of oesophageal (gullet) cancer called oesophageal squamous cell carcinoma
- a type of head and neck cancer called nasopharyngeal cancer

People get TEVIMBRA when their cancer has spread or cannot be taken out by surgery.

People get TEVIMBRA before surgery (neoadjuvant therapy) to treat non-small cell lung cancer and then continue getting TEVIMBRA after surgery (adjuvant therapy) to help prevent their cancer from coming back.

If you have any questions about how TEVIMBRA works or why this medicine has been prescribed for you, ask your doctor.

TEVIMBRA may be given in combination with other anti-cancer medicines. It is important that you also read the package leaflet for these other medicines. If you have any questions about these medicines, ask your doctor.

2. What you need to know before you are given TEVIMBRA

You must not be given TEVIMBRA
- if you are allergic to tislelizumab or any of the other ingredients of this medicine (listed in section 6). Talk to your doctor if you are not sure.

Warnings and precautions
Talk to your doctor before you are given TEVIMBRA if you have or have had:
- autoimmune disease (a condition where the body's own defence system attacks normal cells)
- inflammation of the liver (hepatitis) or other liver problems
- inflammation of the kidney (nephritis)
- pneumonia or inflammation of the lungs (pneumonitis)
- inflammation of the large bowel (colitis)
- serious rash
- problems with hormone-producing glands (including the adrenal, pituitary and thyroid glands)
- type 1 diabetes mellitus
- a solid organ transplant
- infusion-related reaction
- A rare condition in which the immune system makes too many of otherwise normal infection fighting cells called histiocytes and lymphocytes. It can lead to enlarged liver and/or spleen, heart problems and kidney abnormalities. Symptoms may include fever, skin rash, swollen lymph glands, breathing problems and easy bruising. Tell your doctor immediately if you experience these symptoms at the same time (haemophagocytic lymphohistiocytosis)

TEVIMBRA acts on your immune system. It may cause inflammation in parts of your body. Your risk of these side effects may be higher if you already have an autoimmune disease (a condition where the body attacks its own cells). You may also experience frequent flares of your autoimmune disease, which in the majority of cases are mild.

If any of the above apply to you, or you are not sure, talk to your doctor before you are given TEVIMBRA.

<u>Look out for serious side effects</u>
TEVIMBRA can cause serious side effects, which can sometimes become life-threatening and can lead to death. Tell your doctor immediately if you get any of these serious side effects during treatment with TEVIMBRA:
- inflammation of the liver (hepatitis) or other liver problems
- inflammation of the kidney (nephritis)
- inflammation of the lungs (pneumonitis)
- inflammation of the large bowel (colitis)
- severe skin reactions(including Stevens-Johnson syndrome (SJS) or Toxic epidermal necrolysis (TEN): symptoms may include fever, flu-like symptoms, rash, itching, skin blistering or ulcers in the mouth or on other moist surfaces
- problems with hormone-producing glands (especially the adrenal, pituitary or thyroid glands): symptoms may include fast heart rate, extreme tiredness, weight gain or weight loss, dizziness or fainting, hair loss, feeling cold, constipation, headaches that will not go away or unusual headaches
- type 1 diabetes mellitus
- infusion-related reaction
- inflammation of the muscles (myositis)
- inflammation of the heart muscle (myocarditis)
- inflammation of the membrane around the heart (pericarditis)
- inflammation of the joints (arthritis)
- inflammatory disorder that causes muscle pain and stiffness, especially in the shoulders and hips (polymyalgia rheumatica): symptoms may include pain in the shoulders, neck, upper arms,

buttocks, hips or thighs, stiffness in affected areas, pain or stiffness in the wrists, elbows or knees
- inflammation of the nerves: symptoms may include pain, weakness and paralysis in the extremities (Guillain-Barré syndrome)
- Myocarditis-Myositis-Myasthenia Gravis Overlap Syndrome: an overlap of either two or three conditions including inflammation of the heart muscle (myocarditis) that may cause chest pain, shortness of breath, irregular and/or rapid heartbeat, inflammation of the muscles (myositis) that may cause muscle pain, and a condition in which muscles become weak and tire easily (myasthenia gravis)

➢ For more information on the symptoms of any of the above, read section 4 ("Possible side effects"). Talk to your doctor if you have any questions or concerns.

Patient Card
You will also find key information from this package leaflet in the Patient Card that you have been given by your doctor. It is important that you carry the Patient Card with you at all times and show it to a healthcare professional in case of signs and symptoms that may indicate immune-related adverse reactions (listed above under "Look out for serious side effects"), for a prompt diagnosis and adequate treatment.

Monitoring during your treatment with TEVIMBRA
Your doctor will carry out regular tests (liver function tests, kidney function tests, radiographic imaging tests) before and during treatment.

Your doctor will also carry out regular blood tests before and during treatment with TEVIMBRA to monitor the blood sugar and hormone levels in your body. This is because blood sugar and hormone levels can be affected by TEVIMBRA.

Children and adolescents
TEVIMBRA should not be used in children and adolescents below 18 years of age.

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

In particular, tell your doctor if you are taking any medicines that suppress your immune system, including corticosteroids (such as prednisone), since these medicines may interfere with the effect of TEVIMBRA. However, once you have started treatment with TEVIMBRA, your doctor may give you corticosteroids to reduce any side effects that you may have.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.

You should not be given TEVIMBRA if you are pregnant unless your doctor specifically prescribes it for you. The effects of TEVIMBRA in pregnant women are not known, but it is possible that the active substance, tislelizumab, could harm an unborn baby.
- If you are a woman who could become pregnant, you must use effective contraception while you are being treated with TEVIMBRA and for at least 4 months following the last dose of TEVIMBRA.
- If you are pregnant, think you may be pregnant or are planning to have a baby, tell your doctor.

It is not known whether TEVIMBRA passes into breast milk. A risk to the breast-fed infant cannot be ruled out. If you are breast-feeding, tell your doctor. You should not breast-feed during treatment with TEVIMBRA and for at least 4 months after the last dose of TEVIMBRA.

Driving and using machines
TEVIMBRA has a minor effect on your ability to drive or use machines.

Feeling tired or weak are possible side effects of TEVIMBRA. Do not drive or use machines after you have been given TEVIMBRA unless you are sure you are feeling well.

TEVIMBRA contains sodium
Tell your doctor if you are on a low-sodium (low-salt) diet before you are given TEVIMBRA. This medicine contains 1.6 mg sodium (main component of cooking/table salt) in each ml of concentrate. A single infusion of Tevimbra contains 32 mg sodium in two 10 ml vials before dilution. This is equivalent to 1.6% of the recommended maximum daily dietary intake of sodium for an adult. TEVIMBRA is to be diluted in sodium chloride solution for infusion. This should be taken into consideration for patients on a controlled sodium diet.

TEVIMBRA contains polysorbate
This medicine contains 0.2 mg of polysorbate 20 in each ml of concentrate, which is equivalent to 4.0 mg in two 10 ml vials of a single infusion of Tevimbra. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How TEVIMBRA is given

TEVIMBRA will be given to you in a hospital or clinic under the supervision of an experienced doctor.
- The dose of **TEVIMBRA** is either 200 mg given every 3 weeks or 400 mg given every 6 weeks as an intravenous infusion (drip into a vein).
- For 200 mg dosage of Tevimbra, the first dose of **TEVIMBRA** will be given by an infusion over a period of 60 minutes. If you tolerate the first dose well, the next infusion may be given over a period of 30 minutes.
- The infusion of an initial dose of Tevimbra 400 mg should be delivered over 120 minutes (over 90 minutes if it is used as subsequent treatment after the dose of 200 mg). If well tolerated, the second infusion may be administered over 60 minutes. If the second infusion is well tolerated, subsequent infusions may be administered over 30 minutes.
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- When **TEVIMBRA** is given in combination with chemotherapy, you will be given **TEVIMBRA** first and then the chemotherapy.
- Please refer to the package leaflet of the other anti-cancer medicines in order to understand the use of these medicines. If you have questions, ask your doctor.
- Your doctor will decide how many treatments you need.

If you miss a dose of TEVIMBRA
- Call your doctor immediately to reschedule your appointment.
- It is very important that you do not miss a dose of this medicine.

If you stop TEVIMBRA treatment
Stopping your treatment may stop the effect of the medicine. Do not stop treatment with **TEVIMBRA** unless you have discussed this with your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some of the side effects of **TEVIMBRA** may be serious (see the list under "Look out for serious side effects" in section 2 of this leaflet). If you experience any of these serious side effects, **tell your doctor immediately.**

The following side effects have been reported with TEVIMBRA when TEVIMBRA is given together with other anti-cancer medicines

Note that it is important that you also read the package leaflets for the other anti-cancer medicines that you receive as they may also cause side effects.

- Increased blood sugar level, thirst, dry mouth, need to pass urine more frequently, tiredness, increased appetite with weight loss, confusion, nausea, vomiting, fruity smelling breath, difficulty breathing and dry or flushed skin – possible symptoms of hyperglycaemia

- High blood sugar, feeling more hungry or thirsty than normal, passing urine more often than normal – possible symptoms of diabetes mellitus
- Chest pain, rapid or abnormal heartbeat, shortness of breath at rest or during activity, fluid buildup with swelling of the legs, ankles and feet, tiredness – possible symptoms of heart muscle problems (myocarditis)
- Severe upper stomach pain, nausea, vomiting, fever, tender abdomen – possible symptoms of pancreas problems (pancreatitis)
- Feeling sick (nausea), vomiting, loss of appetite, pain on the right side of the stomach, yellowing of the skin or the whites of the eyes, drowsiness, dark-coloured urine, bleeding or bruising more easily than normal – possible symptoms of liver problems (hepatitis)

− Disease in which the immune system attacks the glands that make moisture for the body, such as tears and saliva (Sjögren's syndrome).

− Fatigue, swelling at the base of the neck, pain in front of the throat – possible symptoms of thyroid gland problems (thyroiditis)
− Adrenal insufficiency (disorder in which the adrenal glands do not make enough of certain hormones)
− Frequent headaches, vision changes (either low vision or double vision), fatigue and/or weakness, confusion, decreased blood pressure, dizziness – possible symptoms of pituitary gland problems (hypophysitis)

− A condition where the immune system makes too many of otherwise normal infection-fighting cells called histiocytes and lymphocytes. Symptoms can include fever, skin rash, swollen lymph glands, breathing problems, easy bruising (haemophagocytic lymphohistiocytosis)
− Inflammation of the brain, which may cause confusion, fever, memory problems or seizures (encephalitis)
− Serious problems of the nerves, which may cause difficulty breathing, sensation of prickling or pins and needles in the fingers, toes, ankles or wrists, weakness in the legs that spreads to the upper body, unsteady walking or inability to walk or climb stairs, difficulty with facial movements including speaking, chewing or swallowing, double vision or inability to move eyes, difficulty with bladder control or bowel function, rapid heart rate and paralysis – possible symptoms of Guillain-Barré syndrome
− Muscle weakness and tiredness (myasthenia gravis)

− Chest pain, fever, cough, palpitations – possible symptoms of problems affecting the membrane around the heart (pericarditis)
-Itching or peeling skin, skin sores – possible symptoms of severe skin reactions

The following side effects have been reported with TEVIMBRA alone:
Very common (may affect more than 1 in 10 people)
- Weakness, rapid heart rate, shortness of breath (anaemia)
- Spontaneous bleeding or bruising (thrombocytopenia)
- Underactive thyroid gland, which can cause tiredness, weight gain, skin and hair changes (hypothyroidism)
- Cough
- Nausea
- Diarrhoea
- Rash
- Itching (pruritus)
- Tiredness (fatigue)
- Fever
- Decreased appetite
- Increased blood level of the liver enzyme aspartate aminotransferase
- Increased blood level of the liver enzyme alanine aminotransferase
- Increased blood level of bilirubin, a breakdown product of red blood cells, which can cause yellowing of the skin and eyes, indicating liver problems

Common (may affect up to 1 in every 10 people)
- Pneumonia
- Frequent infections, fever, chills, sore throat or mouth ulcers due to infections (neutropenia or lymphopenia)
- Overactive thyroid gland, which can cause hyperactivity, sweating, weight loss and thirst (hyperthyroidism)
- Fatigue, swelling at the base of the neck, pain in front of the throat – possible symptoms of thyroid gland problems (thyroiditis)
- Increased blood sugar level, thirst, dry mouth, need to pass urine more frequently, tiredness, increased appetite with weight loss, confusion, nausea, vomiting, fruity smelling breath, difficulty breathing and dry or flushed skin – possible symptoms of hyperglycaemia
- Tiredness, confusion, muscle twitching, convulsions (hyponatraemia)
- Muscle weakness, muscle spasms, abnormal heart rhythm (hypokalaemia)
- Increased blood pressure (hypertension)
- Difficulty breathing (dyspnoea)
- Shortness of breath, cough or chest pain – possible symptoms of lung problems (pneumonitis)
- Mouth sores or ulcers with inflammation of the gums (stomatitis)
- Feeling sick (nausea), vomiting, loss of appetite, pain on the right side of the stomach, yellowing of the skin or the whites of the eyes, drowsiness, dark-coloured urine, bleeding or bruising more easily than normal – possible symptoms of liver problems (hepatitis)
- Joint pain (arthralgia)
- Muscle pain (myalgia)
- Increased blood level of the liver enzyme alkaline phosphatase
- Increased blood level of creatinine
- Chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness or fever which may occur during infusion or up to 24 hours after infusion – possible symptoms of infusion-related reaction
- Low blood level of haemoglobin
- Low blood levels of the following blood cells: lymphocytes, neutrophils and platelets
- High blood levels of the following enzymes: alanine aminotransferase, alkaline aminotransferase, aspartate aminotransferase and creatine kinase
- High blood level of alkaline phosphatase
- High blood level of bilirubin
- High blood level of creatinine

- High blood level of glucose
- Low blood levels of potassium and sodium

Uncommon (may affect up to 1 in every 100 people)
- Disorder in which the adrenal glands do not make enough of certain hormones (adrenal insufficiency)
- Frequent headaches, vision changes (either low vision or double vision), fatigue and/or weakness, confusion, decreased blood pressure, dizziness – possible symptoms of pituitary gland problems (hypophysitis)
- High blood sugar, feeling more hungry or thirsty than normal, passing urine more often than normal – possible symptoms of diabetes mellitus
- Eye redness, eye pain and swelling – possible symptoms of problems affecting the uvea, the layer beneath the white of the eyeball (uveitis)
- Chest pain, rapid or abnormal heartbeat, shortness of breath at rest or during activity, fluid buildup with swelling of the legs, ankles and feet, tiredness – possible symptoms of heart muscle problems (myocarditis)
- Chest pain, fever, cough, palpitations – possible symptoms of problems affecting the membrane around the heart (pericarditis)
- Severe upper stomach pain, nausea, vomiting, fever, tender abdomen – possible symptoms of pancreas problems (pancreatitis)
- Diarrhoea or more bowel movements than normal, black tarry, sticky stools, blood or mucus in stools, severe pain or tenderness in the stomach – possible symptoms of intestinal problems (colitis)
- Skin discolouration (vitiligo)
- Itching or peeling skin, skin sores – possible symptoms of severe skin reactions
- Muscle pain, stiffness, weakness, chest pain or severe tiredness – possible symptoms of muscle problems (myositis)
- Joint pain, stiffness, swelling or redness, decreased range of motion in the joints – possible symptoms of joint problems (arthritis)
- Changes in the amount or colour of the urine, pain while urinating, pain in kidney area – possible symptoms of kidney problems (nephritis)
- High blood levels of haemoglobin
- Low blood level of leukocytes
- High blood level of lymphocytes
- Low blood level of albumin
- Low blood level of glucose
- High blood levels of potassium and sodium

Rare (may affect up to 1 in every 1 000 people)
- Serious problems of the nerves, which may cause difficulty breathing, sensation of prickling or pins and needles in the fingers, toes, ankles or wrists, weakness in the legs that spreads to the upper body, unsteady walking or inability to walk or climb stairs, difficulty with facial movements including speaking, chewing or swallowing, double vision or inability to move eyes, difficulty with bladder control or bowel function, rapid heart rate and paralysis – possible symptoms of Guillain-Barré syndrome
- Coeliac disease (characterised by symptoms such as stomach pain, diarrhoea, and bloating after consuming gluten-containing foods)
- Serious rash and reddening of the skin on upper body and quickly spreading to other body parts, blistering of the lips, eyes or mouth, skin peeling, sometimes with flu-like symptoms such as fever, sore throat, cough, and joint pain (Stevens-Johnson syndrome)
- Inflammation of the bladder. Signs and symptoms may include frequent and/or painful urination, urge to pass urine, blood in urine, pain or pressure in lower abdomen (noninfective cystitis)

Other side effects that have been reported (frequency not known):
- A condition where the immune system makes too many of otherwise normal infection-fighting cells called histiocytes and lymphocytes. Symptoms can include fever, skin rash, swollen lymph glands, breathing problems, easy bruising (haemophagocytic lymphohistiocytosis)
- Lack or reduction of digestive enzymes made by the pancreas (pancreatic exocrine insufficiency)

The following side effects have been reported with TEVIMBRA when TEVIMBRA is given together with other anti-cancer medicines

Note that it is important that you also read the package leaflets for the other anti-cancer medicines that you receive as they may also cause side effects.

Very common (may affect more than 1 in 10 people)
- Pneumonia
- Weakness, rapid heart rate, shortness of breath (anaemia)
- Spontaneous bleeding or bruising (thrombocytopenia)
- Frequent infections, fever, chills, sore throat or mouth ulcers due to infections (neutropenia or lymphopenia)
- Underactive thyroid gland which can cause tiredness, weight gain, skin and hair changes (hypothyroidism)
- Muscle weakness, muscle spasms, abnormal heart rhythm (hypokalaemia)
- Cough
- Nausea
- Diarrhoea
- Rash
- Itching (pruritus)
- Joint pain (arthralgia)
- Tiredness (fatigue)
- Fever
- Decreased appetite
- Increased blood level of the liver enzyme aspartate aminotransferase
- Increased blood level of the liver enzyme alanine aminotransferase
- Increased blood level of bilirubin, a breakdown product of red blood cells, which can cause yellowing of the skin and eyes, indicating liver problems
- Increased blood level of creatinine, a substance normally eliminated by the kidneys into the urine. This may mean that your kidneys are not functioning properly.
- Low blood level of haemoglobin
- Low blood levels of the following blood cells: leukocytes, lymphocytes, neutrophils and platelets
- Low blood level of sodium

Common (may affect up to 1 in every 10 people)
- Overactive thyroid gland, which can cause hyperactivity, sweating, weight loss and thirst (hyperthyroidism)
- Increased blood pressure (hypertension)
- Difficulty breathing (dyspnoea)
- Shortness of breath, cough or chest pain – possible symptoms of lung problems (pneumonitis)
- Mouth sores or ulcers with inflammation of the gums (stomatitis)
- Diarrhoea or more bowel movements than normal, black tarry, sticky stools, blood or mucus in stools, severe pain or tenderness in the stomach – possible symptoms of intestine problems (colitis)
- Muscle pain (myalgia)
- Joint pain, stiffness, swelling or redness, decreased range of motion in the joints – possible symptoms of joint problems (arthritis)
- Increased blood level of the liver enzyme alkaline phosphatase

- Chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness or fever which may occur during infusion or up to 24 hours after infusion – possible symptoms of infusion-related reaction
- High blood levels of the following enzymes: alanine aminotransferase and aspartate aminotransferase
- High blood level of bilirubin
- High blood levels of creatine kinase and creatinine
- High blood level of glucose
- High blood level of potassium
- Low blood level of potassium

Uncommon (may affect up to 1 in every 100 people)
- Eye redness, eye pain and swelling – possible symptoms of problems affecting the uvea, the layer beneath the white of the eyeball (uveitis)
- Muscle pain, stiffness, weakness, chest pain, or severe tiredness – possible symptoms of muscle problems (myositis)
- Myocarditis-Myositis-Myasthenia Gravis Overlap Syndrome: an overlap of either two or three conditions, including inflammation of the heart muscle (myocarditis), inflammation of the muscles (myositis), and a condition in which muscles become weak and tire easily (myasthenia gravis)
- Skin discolouration (vitiligo)
- High blood level of lymphocytes
- Low blood level of albumin
- High blood level of alkaline phosphatase
- Low blood level of glucose
- High blood level of sodium

Tell your doctor immediately if you experience any of the serious side effects listed above.

Using TEVIMBRA should be stopped and medical attention should be sought immediately if you notice any of the following symptoms:

Frequency not known (cannot be estimated from the available data)
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (TEN)

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store TEVIMBRA

Your doctor, pharmacist or nurse is responsible for storing this medicine and disposing of any unused product correctly. The following information is intended for healthcare professionals.

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 vial label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C).

Do not freeze.

'Keep the vial in the outer carton in order to protect from light'
TEVIMBRA does not contain a preservative. Chemical and physical in-use stability has been demonstrated for 10 days (240 hours) at 2°C to 8°C. The 10 days (240 hours) include storage of the diluted solution under refrigeration (2°C to 8°C), time required for returning to room temperature (25°C or below) and time to complete the infusion within 4 hours.

From a microbiological point of view, once diluted, the product should be used immediately.

If not used immediately, in-use storage times and conditions are the responsibility of the user. The diluted solution must not be frozen.

Do not store any unused portion of the infusion solution for reuse. Any unused medicine or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What TEVIMBRA contains
- The active substance is tislelizumab. Each ml of concentrate for solution for infusion contains 10 mg of tislelizumab.
- Each vial contains 100 mg of tislelizumab in 10 ml of concentrate.

The other ingredients are sodium citrate dihydrate (see section 2, “TEVIMBRA contains sodium”), citric acid monohydrate, L-histidine hydrochloride monohydrate, L-histidine, trehalose dihydrate, polysorbate 20 and water for injections.

What TEVIMBRA looks like and contents of the pack
TEVIMBRA concentrate for solution for infusion (sterile concentrate) is a clear to slightly opalescent, colourless to slightly yellowish solution.

TEVIMBRA is available in packs containing 1 vial and in multipacks containing 2 (2 packs of 1) vials.

Marketing Authorisation Holder
BeOne Medicines UK, Ltd.
c/o Regus London Paddington,
2 Kingdom Street,
London,
W2 6BD

Manufacturer

BeOne Medicines I GmbH – Dutch Branch
Evert Van De Beekstraat 1/104, Schiphol,
1118 CL,
Netherlands

For any information about this medicine, please contact the Marketing Authorisation Holder.

United Kingdom
BeOne Medicines UK, Ltd.
Tel. 0800 917 6799

This leaflet was last revised in July 2026.

The following information is for healthcare professionals only:

TEVIMBRA vials are for single use only. Each vial contains 100 mg of tislelizumab.

The diluted solution for infusion should be prepared by a healthcare professional using aseptic technique.

Preparation of solution for infusion

- Remove the required number of vials from the refrigerator, taking care not to shake them.
- Inspect each vial visually for particulate matter and discolouration prior to administration. The concentrate is a clear to slightly opalescent, colourless to slightly yellowish solution. Do not use a vial if the solution is cloudy, or if visible particles or discolouration are observed.
- Invert the vials gently without shaking. Withdraw the required volume from the vial(s) into a syringe and transfer into an intravenous infusion bag containing sodium chloride 9 mg/ml (0.9%) solution for injection, to prepare a diluted solution with a final concentration ranging from 2 to 5 mg/ml. Mix the diluted solution by gentle inversion to avoid foaming or excessive shearing of the solution.

Administration

- Administer the diluted **TEVIMBRA** solution by infusion through an intravenous administration line with a sterile, non-pyrogenic, low-protein-binding 0.2 micron or 0.22 micron in-line or add-on filter with a surface area of approximately 10 cm^2.
- For 200 mg once every 3 weeks, the first infusion should be delivered over 60 minutes. If well tolerated, subsequent infusions may be administered over 30 minutes.

  The infusion of an initial dose of Tevimbra 400 mg should be delivered over 120 minutes (over 90 minutes if it is used as subsequent treatment after the dose of 200 mg once every 3 weeks). If well tolerated, the second infusion may be administered over 60 minutes. If the second infusion is well tolerated, subsequent infusions may be administered over 30 minutes.
- Other medicinal products should not be co-administered through the same infusion line.
- **TEVIMBRA** must not be administered as an intravenous push or single bolus injection.
- **TEVIMBRA** does not contain a preservative. Chemical and physical in-use stability has been demonstrated for 10 days (240 hours) at 2°C to 8°C. The 10 days (240 hours) include storage of the diluted solution under refrigeration (2°C to 8°C), time required for returning to room temperature (25°C and below) and time to complete the infusion within 4 hours. From a microbiological point of view, once diluted the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.
- The diluted solution must not be frozen.
- Discard any unused portion left in the vial.
- The intravenous line must be flushed at the end of the infusion.
- **TEVIMBRA** vials are for single use only.