Package leaflet: Information for the patient

KEYTRUDA® 395 mg solution for injection
KEYTRUDA® 790 mg solution for injection
pembrolizumab

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 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 KEYTRUDA is and what it is used for

KEYTRUDA contains the active substance pembrolizumab, which is a monoclonal antibody. KEYTRUDA works by helping your immune system fight your cancer.

KEYTRUDA is used in adults to treat:
- a kind of skin cancer called melanoma
- a kind of lung cancer called non-small cell lung cancer
- a kind of cancer called classical Hodgkin lymphoma
- a kind of cancer called bladder cancer (urothelial carcinoma)
- a kind of head and neck cancer called head and neck squamous cell carcinoma.
- a kind of kidney cancer called renal cell carcinoma
- a kind of cancer that is determined to be microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) in the colon or rectum (called colorectal cancer), uterus (called endometrial cancer), stomach (called gastric cancer), small bowel (called small intestine cancer), or bile duct or gallbladder (called biliary tract cancer)
- a kind of cancer called oesophageal carcinoma
- a kind of breast cancer called triple-negative breast cancer
- a kind of uterine cancer called endometrial carcinoma
- a kind of cancer called cervical cancer
- a kind of stomach cancer called gastric or gastro-oesophageal junction adenocarcinoma
- a kind of bile duct or gallbladder cancer called biliary tract carcinoma

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

People get KEYTRUDA after they have had surgery to remove melanoma, non-small cell lung cancer or renal cell carcinoma to help prevent their cancer from coming back (adjuvant therapy).

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

KEYTRUDA may be given in combination with other anti-cancer medicines with or without radiation therapy. It is important that you also read the package leaflets 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 KEYTRUDA

You should not be given KEYTRUDA
- if you are allergic to pembrolizumab or any of the other ingredients of this medicine (listed in section 6 "Contents of the pack and other information"). Talk to your doctor if you are not sure.

Warnings and precautions
Talk to your doctor or nurse before receiving KEYTRUDA.

Before you get KEYTRUDA, tell your doctor if you:
- have an autoimmune disease (a condition where the body attacks its own cells)
- have pneumonia or inflammation of your lungs (called pneumonitis)
- were previously given ipilimumab, another medicine for treating melanoma, and experienced serious side effects because of that medicine
- had an allergic reaction to other monoclonal antibody therapies
- have or have had chronic viral infection of the liver, including hepatitis B (HBV) or hepatitis C (HCV)
- have human immunodeficiency virus (HIV) infection or acquired immune deficiency syndrome (AIDS)
- have liver damage
- have kidney damage
- have had a solid organ transplant or a bone marrow (stem cell) transplant that used donor stem cells (allogeneic)

KEYTRUDA 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.

When you get KEYTRUDA, you can have some serious side effects. These side effects can sometimes become life-threatening and can lead to death. These side effects may happen anytime during treatment or even after your treatment has ended. You may experience more than one side effect at the same time.

If you have any of the following conditions, call or see your doctor right away. Your doctor may give you other medicines in order to prevent more severe complications and reduce your symptoms. Your doctor may withhold the next dose of KEYTRUDA or stop your treatment with KEYTRUDA.
- inflammation of the lungs, which may include shortness of breath, chest pain or coughing
- inflammation of the intestines, which may include diarrhoea or more bowel movements than usual, black, tarry, sticky stools or stools with blood or mucus, severe stomach pain or tenderness, nausea, vomiting
- inflammation of the liver, which may include nausea or vomiting, feeling less hungry, pain on the right side of stomach, yellowing of skin or whites of eyes, dark urine or bleeding or bruising more easily than normal
- inflammation of the kidneys, which may include changes in the amount or colour of your urine
- inflammation of hormone glands (especially the thyroid, pituitary and adrenal glands), which may include rapid heartbeat, weight loss, increased sweating, weight gain, hair loss, feeling cold, constipation, deeper voice, muscle aches, dizziness or fainting, headaches that will not go away or unusual headache
- type 1 diabetes, including diabetic ketoacidosis (acid in the blood produced from diabetes), symptoms may include feeling more hungry or thirsty than usual, need to urinate more often or weight loss, feeling tired or feeling sick, stomach pain, fast and deep breathing, confusion,

unusual sleepiness, a sweet smell to your breath, a sweet or metallic taste in your mouth, or a different odour to your urine or sweat
- inflammation of the eyes, which may include changes in eyesight
- inflammation in the muscles, which may include muscle pain or weakness
- inflammation of the heart muscle, which may include shortness of breath, irregular heartbeat, feeling tired, or chest pain (myocarditis)
- inflammation of the pancreas, which may include abdominal pain, nausea and vomiting
- inflammation of the skin, which may include rash, itching, skin blistering, peeling or sores, and/or ulcers in mouth or in lining of nose, throat, or genital area
- an immune disorder that can affect the lungs, skin, eyes and/or lymph nodes (sarcoidosis)
- inflammation of the brain, which may include confusion, fever, memory problems or seizures (encephalitis)
- pain, numbness, tingling, or weakness in the arms or legs; bladder or bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating and constipation (myelitis)
- inflammation and scarring of the bile ducts, which may include pain in the upper right part of the stomach, swelling of the liver or spleen, fatigue, itching, or yellowing of the skin or the whites of eyes (cholangitis sclerosing)
- inflammation of the stomach (gastritis)
- decreased function of the parathyroid gland, which may include muscle cramps or spasms, fatigue and weakness (hypoparathyroidism)
- inflammation of the covering of the heart, which may include chest pain, shortness of breath or feeling tired (pericarditis)
- infusion reactions, which may include shortness of breath, itching or rash, dizziness or fever

Complications, including graft-versus-host-disease (GVHD), in people with bone marrow (stem cell) transplant that uses donor stem cells (allogeneic). These complications can be severe and can lead to death. They may occur if you had this kind of transplant in the past or if you get it in the future. Your doctor will monitor you for signs and symptoms, which may include skin rash, liver inflammation, abdominal pain, or diarrhoea.

Children and adolescents
Do not give KEYTRUDA solution for injection to children under 18 years of age. Other forms of this medicine may be more suitable for children; ask your doctor or pharmacist.

Other medicines and KEYTRUDA
Tell your doctor
- If you are taking other medicines that make your immune system weak.
    - Examples of these may include corticosteroids, such as prednisone.
    - These medicines may interfere with the effect of KEYTRUDA.
    - However, once you are treated with KEYTRUDA, your doctor may give you corticosteroids to reduce the side-effects that you may have with KEYTRUDA.
    - Corticosteroids may also be given to you before receiving KEYTRUDA in combination with chemotherapy to prevent and/or treat nausea, vomiting, and other side effects caused by chemotherapy.
- If you are taking, have recently taken or might take any other medicines.

Pregnancy
- You must not use KEYTRUDA if you are pregnant unless your doctor specifically recommends it.
- If you are pregnant, think you may be pregnant or are planning to have a baby, tell your doctor.
- KEYTRUDA can cause harm or death to your unborn baby.
- If you are a woman who could become pregnant, you must use adequate birth control while you are being treated with KEYTRUDA and for at least 4 months after your last dose.

Breast-feeding
- If you are breast-feeding, tell your doctor.

- Do not breast-feed while taking KEYTRUDA.
- It is not known if KEYTRUDA passes into your breast milk.

Driving and using machines
KEYTRUDA has a minor effect on your ability to drive or use machines. Feeling dizzy, tired or weak are possible side effects of KEYTRUDA. Do not drive or use machines after you have been given KEYTRUDA unless you are sure you are feeling well.

KEYTRUDA solution for injection contains polysorbate 80
This medicinal product contains 0.2 mg of polysorbate 80 in each mL of solution. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

KEYTRUDA solution for injection contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How you are given KEYTRUDA solution for injection

You will be given KEYTRUDA under the care of a doctor experienced in cancer treatment.
- The recommended dose of KEYTRUDA in adults is either
    - 395 mg every 3 weeks or
    - 790 mg every 6 weeks.
- Your doctor will give you KEYTRUDA as an injection under the skin (subcutaneous) in the stomach area (abdomen) or thigh. This takes 1-2 minutes.
- Your doctor or nurse will inject where the skin is not damaged, sore, bruised, scarred, scaly, or has red patches and will select a new site for each injection.
- Your doctor may switch the way your treatment is given, from KEYTRUDA given as an injection under your skin to KEYTRUDA given as an infusion into your vein.
- Your doctor will decide how many treatments you need.

If you miss an appointment to get KEYTRUDA
- Call your doctor right away to reschedule your appointment.
- It is very important that you do not miss a dose of this medicine.

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

If you have any further questions about your treatment, ask your doctor.

Patient card
You will also find this information in the patient card you have been given by your doctor. It is important that you keep this card and show it to your partner or caregivers.

4. Possible side effects

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

When you get KEYTRUDA, you can have some serious side effects. See section 2.

Local reactions at the injection site have been reported when KEYTRUDA is given as an injection under the skin. The frequency of local reactions at the injection site is common (may affect up to 1 in 10 people).

The side effects observed with KEYTRUDA given as an infusion into your vein may be experienced with KEYTRUDA given as an injection under the skin.

The following side effects have been reported with KEYTRUDA given as an infusion into your vein alone:

Very common (may affect more than 1 in 10 people)
- decrease in the number of red blood cells
- reduced thyroid gland activity
- feeling less hungry
- headache
- shortness of breath; cough
- diarrhoea; stomach pain; nausea; vomiting; constipation
- itching; skin rash
- pain in muscle and bones; joint pain
- feeling tired; unusual tiredness or weakness; swelling; fever

Common (may affect up to 1 in 10 people)
- lung infection
- decrease in the number of platelets (bruising or bleeding more easily); decrease in the number of white blood cell (neutrophils; lymphocytes)
- reactions related to the administration of the medicine
- overactive thyroid gland; hot flush
- decreased sodium, potassium, or calcium in the blood
- trouble sleeping
- dizziness; inflammation of the nerves causing numbness, weakness, tingling or burning pain of the arms and legs; lack of energy; change in your sense of taste
- dry eye
- abnormal heart rhythm
- high blood pressure
- inflammation of the lungs
- inflammation of the intestines; dry mouth
- inflammation of the liver
- red raised rash sometimes with blisters; inflammation of the skin; patches of skin which have lost colour; dry, itchy skin; hair loss; acne-like skin problem
- muscle pain, aches or tenderness; pain in arms or legs; joint pain with swelling
- flu-like illness; chills
- increased liver enzyme levels in the blood; increased calcium in the blood; abnormal kidney function test

Uncommon (may affect up to 1 in 100 people)
- a decreased number of white blood cells (leukocytes); inflammation response against platelets; an increased number of white blood cells (eosinophils)
- an immune disorder that can affect the lungs, skin, eyes and/or lymph nodes (sarcoidosis)
- decreased secretion of hormones produced by the adrenal glands; inflammation of the pituitary gland situated at the base of the brain; inflammation of the thyroid
- type 1 diabetes, including diabetic ketoacidosis
- a condition in which the muscles become weak and tire easily; seizure
- inflammation of the eyes; eye pain, irritation, itchiness or redness; uncomfortable sensitivity to light; seeing spots
- inflammation of the heart muscle, which may present as shortness of breath, irregular heartbeat, feeling tired, or chest pain (myocarditis); inflammation of the covering of the heart, which may present as chest pain, shortness of breath or feeling tired (pericarditis); accumulation of fluid around the heart
- inflammation of the pancreas; inflammation of the stomach; a sore that develops on the inside lining of your stomach or upper part of your small intestine
- thickened, sometimes scaly, skin growth; small skin bumps, lumps or sores; hair colour changes

- inflammation of the sheath that surrounds tendons
- inflammation of the kidneys
- increased level of amylase, an enzyme that breaks down starch

Rare (may affect up to 1 in 1000 people)
- inflammation response against red blood cells; a condition called haemophagocytic lymphohistiocytosis, where the immune system makes too many infection fighting cells called histiocytes and lymphocytes that may cause various symptoms; feeling weak, lightheaded, short of breath or if your skin looks pale (signs of low level of red blood cells, possibly due to a type of anaemia called pure red cell aplasia)
- decreased function of the parathyroid gland, which may present as muscle cramps or spasms, fatigue and weakness
- a temporary inflammation of the nerves that causes pain, weakness, and paralysis in the extremities (Guillain-Barré syndrome); inflammation of the brain, which may present as confusion, fever, memory problems or seizures (encephalitis); pain, numbness, tingling, or weakness in the arms or legs; bladder or bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating and constipation (myelitis); swelling of the optic nerve that may result in vision loss in one or both eyes, pain with eye movement, and/or loss of colour vision (optic neuritis); inflammation of the membrane around the spinal cord and brain, which may present as neck stiffness, headache, fever, eye sensitivity to light, nausea or vomiting (meningitis)
- inflammation of the blood vessels
- lack or reduction of digestive enzymes made by the pancreas (pancreatic exocrine insufficiency); a hole in the small intestines; coeliac disease (characterised by symptoms such as stomach pain, diarrhoea, and bloating after consuming gluten-containing foods)
- inflammation of the bile ducts
- itching, skin blistering, peeling or sores, and/or ulcers in mouth or in lining of nose, throat, or genital area (Stevens-Johnson syndrome or toxic epidermal necrolysis); tender red bumps under the skin
- disease in which the immune system attacks the glands that make moisture for the body, such as tears and saliva (Sjogren's syndrome)
- inflammation of the bladder, which may present as frequent and/or painful urination, urge to pass urine, blood in urine, pain or pressure in lower abdomen

The following side effects have been reported in clinical studies with KEYTRUDA given as an infusion into your vein in combination with chemotherapy or chemotherapy with radiation therapy:

Very common (may affect more than 1 in 10 people)
- decrease in the number of red blood cells; decreased number of white blood cells (neutrophils); decrease in the number of platelets (bruising or bleeding more easily)
- reduced thyroid gland activity
- decreased potassium in the blood; feeling less hungry
- trouble sleeping
- inflammation of the nerves causing numbness, weakness, tingling or burning pain of the arms and legs; headache; dizziness
- shortness of breath; cough
- diarrhoea; nausea; vomiting; stomach pain; constipation
- hair loss; itching; skin rash
- pain in the muscles and bones; joint pain
- feeling tired; unusual tiredness or weakness; fever; swelling
- increased blood level of the liver enzyme alanine aminotransferase; increased blood level of the liver enzyme aspartate aminotransferase; abnormal kidney function test

Common (may affect up to 1 in 10 people)
- lung infection

- decreased number of white blood cells (neutrophils) with a fever; decreased number of white blood cells (leukocytes, lymphocytes)
- reaction related to the administration of the medicine
- decreased secretion of hormones produced by the adrenal glands; overactive thyroid gland; inflammation of the thyroid
- decreased sodium or calcium in the blood
- change in your sense of taste; lack of energy
- dry eye
- abnormal heart rhythm
- high blood pressure
- inflammation of the lungs
- inflammation of the intestines; inflammation of the stomach; dry mouth
- inflammation of the liver
- red raised rash, sometimes with blisters; inflammation of the skin; acne-like skin problem; dry, itchy skin
- muscle pain, aches or tenderness; pain in arms or legs; joint pain with swelling
- sudden kidney damage
- flu-like illness; chills
- increased bilirubin in the blood; increased blood level of the liver enzyme alkaline phosphatase; increased calcium in the blood

Uncommon (may affect up to 1 in 100 people)
- inflammation response against red blood cells; an increased number of white blood cells (eosinophils)
- inflammation of the pituitary gland situated at the base of the brain
- type 1 diabetes, including diabetic ketoacidosis
- inflammation of the brain, which may present as confusion, fever, memory problems or seizures (encephalitis); seizure
- inflammation of the eyes; eye pain, irritation, itchiness or redness; uncomfortable sensitivity to light; seeing spots
- inflammation of the heart muscle, which may present as shortness of breath, irregular heartbeat, feeling tired, or chest pain (myocarditis); inflammation of the covering of the heart, which may present as chest pain, shortness of breath or feeling tired (pericarditis); accumulation of fluid around the heart
- inflammation of the blood vessels
- inflammation of the pancreas; a sore that develops on the inside lining of your stomach or upper part of your small intestine
- thickened, sometimes scaly, skin growth; patches of skin which have lost colour; small skin bumps, lumps or sores
- inflammation of the sheath that surrounds tendons
- inflammation of the kidneys; inflammation of the bladder, which may present as frequent and/or painful urination, urge to pass urine, blood in urine, pain or pressure in lower abdomen
- increased level of amylase, an enzyme that breaks down starch

Rare (may affect up to 1 in 1000 people)
- inflammation response against platelets
- an immune disorder that can affect the lungs, skin, eyes and/or lymph nodes (sarcoidosis)
- decreased function of the parathyroid gland, which may present as muscle cramps or spasms, fatigue and weakness
- a condition in which the muscles become weak and tire easily; a temporary inflammation of the nerves that causes pain, weakness, and paralysis in the extremities (Guillain-Barré syndrome); swelling of the optic nerve that may result in vision loss in one or both eyes, pain with eye movement, and/or loss of colour vision (optic neuritis); inflammation of the membrane around the spinal cord and brain, which may present as neck stiffness, headache, fever, eye sensitivity to light, nausea or vomiting (meningitis)

- lack or reduction of digestive enzymes made by the pancreas (pancreatic exocrine insufficiency); a hole in the small intestines; coeliac disease (characterised by symptoms such as stomach pain, diarrhoea, and bloating after consuming gluten-containing foods)
- inflammation of the bile ducts
- itching, skin blistering, peeling or sores, and/or ulcers in mouth or in lining of nose, throat, or genital area (Stevens-Johnson syndrome); tender red bumps under the skin; hair colour changes
- disease in which the immune system attacks the glands that make moisture for the body, such as tears and saliva (Sjogren's syndrome)

The following side effects have been reported in clinical studies with KEYTRUDA given as an infusion into your vein in combination with axitinib or lenvatinib:

Very common (may affect more than 1 in 10 people)
- urinary infections (increased frequency in urination and pain in passing urine)
- decrease in the number of red blood cells
- reduced thyroid gland activity
- feeling less hungry
- headache; change in your sense of taste
- high blood pressure
- shortness of breath; cough
- diarrhoea; stomach pain; nausea; vomiting; constipation
- skin rash; itching
- joint pain; pain in the muscles and bones; muscle pain, aches or tenderness; pain in arms or legs
- feeling tired; unusual tiredness or weakness; swelling; fever
- increased levels of lipase, an enzyme that breaks down fats; increased liver enzyme levels in the blood; abnormal kidney function test

Common (may affect up to 1 in 10 people)
- lung infection
- decreased number of white blood cells (neutrophils, lymphocytes, leukocytes); decrease in the number of platelets (bruising or bleeding more easily)
- reaction related to the administration of the medicine
- decreased secretion of hormones produced by the adrenal glands; overactive thyroid gland; inflammation of the thyroid
- decreased sodium, potassium, or calcium in the blood
- trouble sleeping
- dizziness; inflammation of the nerves causing numbness, weakness, tingling or burning pain of the arms and legs; lack of energy
- dry eye
- abnormal heart rhythm
- inflammation of the lungs
- inflammation of the intestines; inflammation of the pancreas; inflammation of the stomach; dry mouth
- inflammation of the liver
- red raised rash, sometimes with blisters; inflammation of the skin; dry skin; acne-like skin problem; hair loss
- joint pain with swelling
- inflammation of the kidneys
- flu-like illness; chills
- increased levels of amylase, an enzyme that breaks down starch; increased bilirubin in the blood; increased blood levels of a liver enzyme known as alkaline phosphatase; increased calcium in the blood

Uncommon (may affect up to 1 in 100 people)
- an increased number of white blood cells (eosinophils)
- inflammation of the pituitary gland situated at the base of the brain
- type 1 diabetes, including diabetic ketoacidosis

- a condition in which the muscles become weak and tire easily; inflammation of the brain, which may present as confusion, fever, memory problems or seizures (encephalitis)
- inflammation of the eyes; eye pain, irritation, itchiness or redness; uncomfortable sensitivity to light; seeing spots
- inflammation of the heart muscle, which may present as shortness of breath, irregular heartbeat, feeling tired, or chest pain (myocarditis); accumulation of fluid around the heart
- inflammation of the blood vessels
- a sore that develops on the inside lining of your stomach or upper part of your small intestine
- dry, itchy skin; thickened, sometimes scaly, skin growth; patches of skin which have lost colour; small skin bumps, lumps or sores; hair colour changes
- inflammation of the sheath that surrounds tendons

Rare (may affect up to 1 in 1000 people)
- decreased function of the parathyroid gland, which may present as muscle cramps or spasms, fatigue and weakness
- swelling of the optic nerve that may result in vision loss in one or both eyes, pain with eye movement, and/or loss of colour vision (optic neuritis)
- a hole in the small intestines
- itching, skin blistering, peeling or sores, and/or ulcers in mouth or in lining of nose, throat, or genital area (toxic epidermal necrolysis or Stevens-Johnson syndrome)
- disease in which the immune system attacks the glands that make moisture for the body, such as tears and saliva (Sjogren's syndrome)
- inflammation of the bladder, which may present as frequent and/or painful urination, urge to pass urine, blood in urine, pain or pressure in lower abdomen

Other side effects that have been reported with frequency not known (cannot be estimated from the available data)
- lack or reduction of digestive enzymes made by the pancreas (pancreatic exocrine insufficiency); coeliac disease (characterised by symptoms such as stomach pain, diarrhoea, and bloating after consuming gluten-containing foods)

Rash is more common when KEYTRUDA is given in combination with enfortumab vedotin than when KEYTRUDA is given alone.

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 KEYTRUDA

Unopened vial
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 – 8 °C).
Do not freeze.
Store in the original carton in order to protect from light.

Prepared syringe
Once transferred from the vial into the syringe, chemical and physical in-use stability has been demonstrated for KEYTRUDA solution for injection for up to 30 days at 2 °C to 8 °C (protected from light) and for up to 24 hours at room temperature (under ambient room light). From a microbiological

point of view, the solution, should be used immediately once transferred from the vial to the syringe. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 8 hours at room temperature or 24 hours at 2 °C to 8 °C, unless the preparation has taken place in controlled and validated aseptic conditions. The 24-hour period may include up to 8 hours at room temperature (at or below 25 °C). Discard if storage time exceeds these limits. If refrigerated, the filled syringe must be allowed to come to room temperature for at least 30 minutes prior to administration. The filled syringe must not be frozen.

Do not store any unused portion of the solution for injection 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 KEYTRUDA contains
The active substance is pembrolizumab.

One vial of 2.4 mL solution for injection contains 395 mg of pembrolizumab. One vial of 4.8 mL solution for injection contains 790 mg of pembrolizumab.
Each mL of solution for injection contains 165 mg of pembrolizumab.

The other ingredients are recombinant berahyaluronidase alfa, L-histidine, L-histidine hydrochloride monohydrate, L-methionine, sucrose, polysorbate 80 and water for injections.

What KEYTRUDA looks like and contents of the pack
KEYTRUDA is a clear to slightly opalescent, colourless to slightly yellow solution, pH 5.3 – 5.9.
It is available in cartons containing one glass vial.

Marketing Authorisation Holder
Marketing Authorisation Holder: Merck Sharp & Dohme (UK) Limited, 120 Moorgate, London, EC2M 6UR, UK.

Manufacturer
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This leaflet was last revised in September 2025

MA/089

The following information is intended for healthcare professionals only:

Preparation and administration
KEYTRUDA solution for injection should be administered by a healthcare professional only. KEYTRUDA solution for injection is ready to use. Do not dilute KEYTRUDA solution for injection. Do not shake the vial.

Preparation of the syringe
- Equilibrate the vial of KEYTRUDA solution for injection to room temperature for at least 30 minutes.
- The unpunctured vial can be out of refrigeration (temperatures at or below 25 °C) for up to 24 hours prior to the preparation for administration.
- Parenteral medicinal products should be inspected visually for particulate matter and discolouration prior to administration. KEYTRUDA solution for injection is a clear to slightly opalescent, colourless to slightly yellow solution. Discard the vial if visible particles are observed.
- KEYTRUDA solution for injection is compatible with polypropylene and polycarbonate syringe material and stainless steel transfer and injection needles.
- Withdraw the required volume either 2.4 mL (395 mg) or 4.8 mL (790 mg) using a sterile syringe and a transfer needle (18-21G recommended), according to the recommended dosage. To avoid needle clogging, change the needle to a 25-30G, 13 mm hypodermic injection needle immediately prior to subcutaneous injection.

Storage of prepared syringe
- The product does not contain preservative and should be used immediately after withdrawing from the vial. If not used immediately, store the syringe containing KEYTRUDA solution for injection with the transfer needle and cap in place (see storage time of prepared syringe at section 5).
- If refrigerated, the filled syringe must be allowed to come to room temperature for at least 30 minutes prior to use.
- The filled syringe must not be frozen.

Administration
- Inject KEYTRUDA solution for injection into the subcutaneous tissue of the thigh or abdomen, avoiding the 5 cm area around the navel. Do not inject into skin that is damaged, sore, bruised, scarred, scaly, or has red patches. Inject one 2.4 mL dose of KEYTRUDA solution for injection (395 mg) subcutaneously every 3 weeks over 1 minute. Inject one 4.8 mL dose of KEYTRUDA solution for injection (790 mg) subcutaneously every 6 weeks over 2 minutes. Rotate injection sites for subsequent injections. During treatment with KEYTRUDA solution for injection, do not administer other medicinal products for subcutaneous use at the same site as KEYTRUDA solution for injection.
- KEYTRUDA is for single use only. Discard any unused portion left in the vial.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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