Early Access to Medicines Scheme – Treatment protocol – Information for patients

UPDATE

Introduction

The aim of the Early Access to Medicines Scheme (EAMS) is to provide earlier availability of promising new unlicensed medicines (medicines that do not have a marketing authorisation) to UK patients that have a high unmet clinical need. The medicines included in the scheme are those that are intended to treat, diagnose or prevent seriously debilitating or life threatening conditions where there are no adequate treatment options. More information about the scheme can be found here: http://www.mhra.gov.uk/Howweregulate/Innovation/EarlyaccesstomedicinesschemeEAMS/index.htm

The information below is intended for you, the patient, and is provided by the pharmaceutical company that manufactures the medicine. This medicine does not yet have a drug licence (also called a marketing authorisation) for its use in patients who have lung cancer that has spread or cannot be taken out by surgery, and who have not received treatment for this disease.

This medicine is however authorised for the treatment of patients with other types of cancer (melanoma and lung cancer which has been previously treated) under the name Keytruda®.

More information about medicines licensing can be found here: http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformationforconsumers/MymedicineFromlaboratorytopharmacyshelf/Licensingmarketingauthorisation/index.htm

This medicine can be prescribed for individual patients to meet specific needs provided they are given sufficient information about the medicine to make an informed decision. Informed consent should be obtained from you prior to treatment.

This information is provided to help you decide with your doctor on whether to use the medicine and helps explain how to use the medicine in accordance with the pharmaceutical company's instructions for safe and proper use. Whilst you are using this medicine, data will be collected on the use and safety profile of the medicine, to ensure that the benefits of taking the medicine outweigh any potential risks.

Information for the Patient

Pembrolizumab 50 mg powder for concentrate for solution for infusion
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 Alert 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 Pembrolizumab is and what it is used for

Pembrolizumab is a medicine which is being used in the Early Access to Medicines Scheme (EAMS) to treat a kind of lung cancer called non-small cell lung cancer, if it expresses a protein called programmed death ligand-1 (PD-L1). This is measured by a test made on a tumour biopsy. Pembrolizumab in this scheme is for patients who have lung cancer that has spread or cannot be taken out by surgery, and who have not received treatment for this disease.

Pembrolizumab is a protein that works by helping your immune system fight your cancer.

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

You should not be given pembrolizumab:
- 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 pembrolizumab.

Before you get pembrolizumab, 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)
- 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 or have had a liver transplant
- have kidney damage or have had a kidney transplant

When you get pembrolizumab, you can have some serious side effects.

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 pembrolizumab or stop your treatment with pembrolizumab.

- 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 which may include feeling more hungry or thirsty than usual, need to urinate more often, or weight loss
- inflammation of the eyes which may include changes in eyesight
- inflammation in the muscles which may include muscle pain or weakness
- inflammation of the pancreas which may include abdominal pain, nausea and vomiting
- inflammation of the skin which may include rash
- infusion reactions which may include shortness of breath, itching or rash, dizziness or fever

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

Other medicines and pembrolizumab
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 pembrolizumab. However, once you are treated with pembrolizumab, your doctor may give you corticosteroids to reduce the side-effects that you may have with pembrolizumab.
- If you are taking, have recently taken or might take any other medicines.

Pregnancy

- You must not use pembrolizumab 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.
- Pembrolizumab 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 pembrolizumab 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 pembrolizumab.
- It is not known if pembrolizumab passes into your breast milk.

Driving and using machines
Do not drive or use machines after you have been given pembrolizumab unless you are sure you are feeling well. Feeling tired or weak is a very common side effect of pembrolizumab. This can affect your ability to drive or to use machines.

3. How you are given pembrolizumab

Pembrolizumab will be given to you in a hospital or clinic under the supervision of an experienced doctor.

- Your doctor will give you pembrolizumab through an infusion into your vein (IV) for about 30 minutes, every 3 weeks.
- Your doctor will decide how many treatments you need.

The recommended dose is 2 mg of pembrolizumab per kilogram of your body weight.

If you miss an appointment to get pembrolizumab

- 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 pembrolizumab

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

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

You will also find this information in the Patient Alert Card you have been given by your doctor. It is important that you keep this Alert 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.

The following side effects have been reported in clinical trials:

Very common (may affect more than 1 in 10 people)

- diarrhoea; nausea
- itching; skin rash
- joint pain
- feeling tired

Common (may affect up to 1 in 10 people)

- decrease in the number of red blood cells
- thyroid gland problems; hot flush
- feeling less hungry
- headache; dizziness; change in your sense of taste
- inflammation of the lungs; shortness of breath; cough
- inflammation of the intestines; dry mouth
- dry eye
- stomach pain; constipation; vomiting
- red raised rash sometimes with blisters; patches of skin which have lost colour; acne-like skin problem; dry, itchy skin
- muscle pain, aches or tenderness; pain in the muscles and bones; pain in arms or legs; joint pain with swelling
- swelling; unusual tiredness or weakness; chills; flu-like illness; fever
- increased liver enzyme levels in the blood; abnormal kidney function test
- reaction related to the infusion of the medicine

Uncommon (may affect up to 1 in 100 people)
- a decreased number of white blood cells (neutrophils, leukocytes, lymphocytes and eosinophils); decrease in the number of platelets (bruising or bleeding more easily)
- inflammation of the pituitary gland situated at the base of the brain; decreased secretion of hormones produced by the adrenal glands; inflammation of the thyroid
- type 1 diabetes; decreased sodium, potassium and calcium in the blood
- trouble sleeping
- seizure; lack of energy; inflammation of the nerves causing numbness, weakness, tingling or burning pain of the arms and legs
- inflammation of the eyes; eye pain, irritation, itchiness or redness; uncomfortable sensitivity to light; seeing spots
- high blood pressure
- inflammation of the pancreas
- inflammation of the liver
- thickened, sometimes scaly, skin growth; hair loss; tender red bumps under the skin; inflammation of the skin; hair colour changes; small skin bumps, lumps or sores
- inflammation of the sheath that surrounds tendons
- inflammation of the kidneys
- increased level of amylase, an enzyme that breaks down starch; increased calcium in the blood

Rare (may affect up to 1 in 1,000 people)
- inflammation response against platelets or red blood cells
- a temporary inflammation of the nerves that cause pain, weakness, and paralysis in the extremities; a condition in which the muscles become weak and tire easily
- a hole in the small intestines

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

5. How to store pembrolizumab

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).

Chemical and physical in-use stability of the reconstituted and diluted solution has been demonstrated for 24 hours at room temperatures (at or below 25°C). From a microbiological point of view, the product must be used immediately. Do not freeze the reconstituted or diluted solution. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and must not be longer than a total of 24 hours. This 24 hour hold may include up to 6 hours at room temperatures (at or below 25°C); any additional hold time must be at 2°C-8°C.

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 pembrolizumab contains
Each vial contains 50 mg of pembrolizumab.

After reconstitution, 1 mL of solution contains 25 mg of pembrolizumab.

The other ingredients are L-histidine, L-histidine hydrochloride monohydrate, sucrose, and polysorbate 80.

What pembrolizumab looks like and contents of the pack
Pembrolizumab is a white to off-white lyophilised powder.
It is available in cartons containing one glass vial.

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Additional information:

Before treatment starts, all patients will have the scheme explained to them using the **Information and Consent Document**. They will be asked to sign this document and will be given a copy to keep.

They will also be given a **Patient Alert Card,** which is a wallet sized card that they must carry at all times. This card summarises the important side effects for which patients need to seek assistance should they occur. In addition, it alerts any other healthcare professional that may treat the patient that they are receiving pembrolizumab through an early access scheme, and has the details of their own oncologist and specialist nurse, out of hours contact details and the Company's contact details.

Contact information:

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