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

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 and the MHRA can be found here:

https://www.gov.uk/apply-for-the-early-access-to-medicines-scheme-eams

https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about

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). More information about medicines licensing can be found here: http://www.nhs.uk/Conditions/Medicinesinfo/Pages/Safetyissues.aspx

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.

MHRA
March 2015

Information for the patient:

Pembrolizumab 50 mg powder for concentrate for solution for infusion

Read all of this leaflet carefully before you start receiving this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you only. It should not be used by others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. 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 skin cancer called melanoma. It may be used when your melanoma has spread or cannot be removed by surgery (advanced melanoma) and
- after you have tried a medicine called ipilimumab and it did not work or is no longer working

and,
- if your tumour has an abnormal "BRAF" gene, and you also have tried a different medicine called a BRAF or MEK inhibitor, and it did not work or is no longer working.

2. What you need to know before you take pembrolizumab

Pembrolizumab is a medicine that may treat your melanoma by helping your immune system to kill cancer cells. It can cause your immune system to also attack normal organs and tissues in various areas of your body and can affect the way they work. These problems can sometimes become serious or life-threatening. It is important to read section 4 "Possible side effects" for a list of potential problems.

What should I tell my doctor before receiving pembrolizumab?
Tell your doctor if you:
- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have had an organ transplant
- have lung or breathing problems
- have liver problems
- have any other medical problems
- are pregnant or plan to become pregnant or are breastfeeding see "Pregnancy and breastfeeding"

If any of the above apply to you (or you are not sure), talk to you doctor, pharmacist or nurse before taking pembrolizumab.

Children

Pembrolizumab may be used in children aged 12 years and above in the EAMS.

Other medicines and pembrolizumab

Tell your doctor before starting treatment with pembrolizumab if you take other medicines that make your

immune system weak. Examples of these may include steroids, such as prednisone.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist.

Pregnancy and breast-feeding
Tell your doctor if you are pregnant or plan to become pregnant.
- Pembrolizumab may harm your unborn baby.

- Females who are able to become pregnant should use an effective method of birth control during and for at least 4 months after the last dose of pembrolizumab. Talk to your doctor about birth control methods that you can use during this time.

- Tell your doctor right away if you become pregnant during treatment with pembrolizumab.

Tell your doctor if you are breastfeeding or plan to breastfeed.
- It is not known if pembrolizumab passes into your breast milk.
- Do not breastfeed during treatment with pembrolizumab.

Driving and using machines
You may feel tired while taking pembrolizumab, which may affect your ability to drive or use tools or machines. If this happens, do not drive or use any tools or machines.

3. How should pembrolizumab be taken
- Your doctor will give you pembrolizumab into your vein through an intravenous (IV) line over 30 minutes.
- Pembrolizumab is usually given every 3 weeks.
- Your doctor will decide for how long you will need to be treated.
- Your doctor will do blood tests to check you for side effects.

If you miss any appointments, call your doctor as soon as possible to reschedule your appointment. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects
Like all medicines, this medicine can cause side effects. Call or see your doctor right away if you develop any symptoms of the following problems or these symptoms get worse:

Lung problems (pneumonitis). Symptoms of pneumonitis may include:
- shortness of breath
- chest pain
- new or worsening cough

Intestinal problems (colitis) that can lead to tears or holes in your intestine. Signs and symptoms of colitis may include:
- diarrhoea or more bowel movements than usual
- stools that are black, tarry, sticky, or have blood or mucous
- severe stomach-area (abdomen) pain or tenderness

Liver problems (hepatitis). Signs and symptoms of hepatitis may include:
- yellowing of your skin or the whites of your eyes
- dark urine
- nausea or vomiting
- feeling less hungry than usual

- pain on the right side of your stomach area (abdomen)
- bleeding or bruising more easily than normal

Hormone gland problems (especially the thyroid, pituitary, and adrenal glands). **Signs and symptoms that your hormone glands are not working properly may include:**
- rapid heart beat
- weight loss or weight gain
- hair loss
- increased sweating
- feeling cold
- constipation
- your voice gets deeper
- muscle aches
- dizziness or fainting
- headaches that will not go away or unusual headache

Blood sugar problems needing insulin (type 1 diabetes). Signs and symptoms of blood sugar problems may include:
- feeling more hungry or thirsty
- needing to urinate more often
- weight loss

Kidney problems, including nephritis and kidney failure. Signs of kidney problems may include:
- change in the amount or colour of your urine.

Problems in other organs. Signs of these problems may include:
- rash
- changes in eyesight
- severe or persistent muscle or joint pains
- severe muscle weakness

Reactions to injection (in vein). Signs and symptoms of reactions may include:
- shortness of breath
- itching or rash
- dizziness
- fever

Getting medical treatment right away may help keep these problems from becoming more serious.

Your doctor will check you for these problems during treatment with pembrolizumab. Your doctor may treat you with corticosteroid medicines and delay or completely stop treatment with pembrolizumab if you have severe side effects.

The most common side effects of pembrolizumab include:
- feeling tired
- cough
- nausea
- decreased appetite
- constipation
- diarrhoea
- itching
- rash
- joint pain

Some of your blood tests may also be abnormal, like decreased red cells (anaemia) or increased blood sugar.

5. How to store pembrolizumab

Store in a refrigerator (2°C to 8°C). Do not freeze.

The product does not contain preservative. The reconstituted and/or diluted product should be used immediately.
If not used immediately, reconstituted and diluted pembrolizumab solutions may be stored at room temperature for a cumulative time of up to 4 hours. This includes room temperature storage of reconstituted drug product solution in vials, room temperature storage of admixture solutions in the IV bags and the duration of infusion. In addition, reconstituted vials and/or IV bags may be stored under refrigeration at 2°C to 8 °C for up to 20 hours. If refrigerated, allow the vials and/or IV bags to come to room temperature prior to use.

6. Contents of the pack and other information

What pembrolizumab contains
The active substance is pembrolizumab. Each vial contains 50 mg pembrolizumab.
After reconstitution 1 ml of solution contains 25 mg pembrolizumab.

The other ingredients are: L-histidine, polysorbate 80, and sucrose. May contain hydrochloric acid/sodium hydroxide.

What pembrolizumab looks like and contents of the pack
Pembrolizumab is a white to off-white powder supplied in a clear glass vial with grey stopper and an aluminium seal with an avocado coloured flip-off cap.

Scientific Opinion Holder
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Date of leaflet preparation: March 2015

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 credit-card 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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