Medicines & Healthcare products Regulatory Agency

MHRA

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 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) and is to be used in combination with other medicines that are authorised but prescribed off-label. 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

Polatuzumab vedotin 140 mg powder for concentrate for solution for infusion

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.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Polatuzumab vedotin is and what it is used for

What Polatuzumab vedotin is
Polatuzumab vedotin, an anti-cancer agent, is made up of a monoclonal antibody linked to a substance intended to kill cancer cells. This substance is delivered to cancer cells by the monoclonal antibody, which is designed to recognise and attach to cancer cells with a certain protein that is found on the surface of B-lymphocytes.

What is Polatuzumab vedotin used for
Polatuzumab vedotin is given to treat diffuse large B-cell lymphoma that has come back or never responded to at least one previous therapy and when you cannot receive a stem cell transplant.
Diffuse large B-cell lymphoma is a cancer that develops from B-lymphocytes, a type of blood cells in the lymphatic system.

Polatuzumab vedotin is given in combination with two other medicines for cancer called rituximab and bendamustine.

2. What you need to know before you are given polatuzumab vedotin

You must not be given polatuzumab vedotin
- if you are allergic to polatuzumab vedotin or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, talk to your doctor or nurse before you are given polatuzumab vedotin.

Warnings and precautions
Talk to your doctor or nurse before you are given polatuzumab vedotin if any of the following apply to you (or you are not sure):

- you have ever had brain or nerve problems (such as memory problems, difficulty moving or feeling sensations in your body, eyesight problems)
- you have ever had liver problems
- you think you may have an infection currently or have had long-lasting or repeated infections (see “Infections” in section 4).

If any of the above apply to you (or you are not sure) talk to your doctor or nurse before you are given polatuzumab vedotin.

Polatuzumab vedotin can cause some serious side effects that you need to tell your doctor or nurse about straight away (see section 4).

Children and adolescents

This medicine should not be used in children or young people under the age of 18. This is because there is no information about its use in this age group.

Other medicines and polatuzumab vedotin

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

Contraception, pregnancy and breast-feeding

Contraception (women and men)

Women must use contraception during treatment and for 9 months following the last dose of polatuzumab vedotin.

Men must use contraception during treatment and for 6 months following the last dose of polatuzumab vedotin.

Pregnancy

It is important to tell your doctor before and during treatment if you are pregnant, think you may be pregnant, or are planning to get pregnant. This is because polatuzumab vedotin can affect your baby's health. You should not receive this medicine if you are pregnant unless you and your doctor decide that the benefit to you outweighs the potential risk to the unborn baby.

Breast-feeding

Do not breast-feed while receiving polatuzumab vedotin.

Driving, cycling and using machines

Polatuzumab vedotin may have a minor influence on your ability to drive, cycle or use any tools or machines. If you get infusion-related reactions or nerve damage, or if you feel tired, weak or dizzy (see section 4) do not drive, cycle or use any tools or machines until the reaction stops.

3. How polatuzumab vedotin is given

Polatuzumab vedotin is given under the supervision of a doctor experienced in the administration of anti-cancer treatments. It is given into a vein, as a drip over 90 minutes.

How much polatuzumab vedotin is given

The dose of this medicine depends on your body weight.

The usual starting dose of this medicine is 1.8 mg for each kilogram of your body weight. You will be given 6 treatment cycles of polatuzumab vedotin in combination with two other medicines called rituximab and bendamustine. Each cycle lasts 21 days.

If you have symptoms of peripheral neuropathy, your doctor may lower your dose to 1.4 mg for each kilogram of your body weight.

Before receiving polatuzumab vedotin, you will receive premedication with anti-allergic and anti-fever medicines.

The Patient Leaflets for the combination medicines, bendamustine and rituximab, will provide you with information on how these medicines will be given to you.

If you miss a dose of polatuzumab vedotin

If you miss an appointment, make another one straight away. For the treatment to be fully effective, it is very important to not miss a dose.

If you stop receiving polatuzumab vedotin
Do not stop treatment with polatuzumab vedotin unless you have discussed this with your doctor. This is because stopping treatment may stop the effect of the medicine.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects have been reported with this medicine:

Serious side effects
Tell your doctor or nurse straight away if you notice any of the following serious side effects – you may need urgent medical treatment. These may be new symptoms or a change in your current symptoms.

Myelosupression
This is a condition in which bone marrow activity is decreased, resulting in fewer red blood cells, white blood cells, and platelets. Tell your doctor or nurse straight away if you:

- develop chills or shivering
- have a fever
- have headaches
- feel tired
- experience dizziness
- look pale (anaemia)
- have unusual bleeding, or bruising under the skin, longer than usual bleeding after your blood has been drawn, or bleeding from your gums (thrombocytopenia).

Blood tests may show:

- low levels of red blood cells
- low levels of neutrophils (a type of white blood cell)
- low levels of lymphocytes (a type of white blood cells)
- low level of platelets (a type of blood cell that helps your blood to clot)
- low levels of all types of white blood cell (combined).

Peripheral neuropathy
This condition develops when nerves in the body's extremities, such as the hands, feet and arms, are damaged. Tell your doctor or nurse straight away if you experience:

- any problems with a change in the sensitivity of the skin, especially in the hands or feet
- numbness
- tingling
- burning sensation
- pain
- discomfort
- weakness.

Infections
You may be more likely to get an infection during and for a period after treatment with polatuzumab vedotin. Some infections may be serious and may lead to death. Tell your doctor or nurse straight away if you get any signs of infection during and after your polatuzumab vedotin treatment. These include:

- fever
- fatigue, feeling weak or generally unwell
- cough or chest pain (symptoms of pneumonia)
- painful rash (shingles)
- sore throat, sinusitis
- burning pain when passing urine (urinary infection).

Progressive multifocal leukoencephalopathy (also called PML)
PML is a very rare and life-threatening brain infection that has been reported in one patient treated with polatuzumab vedotin together with bendamustine and another medicine called obinutuzumab. Tell your doctor or nurse straight away if you have:

- memory loss
- trouble speaking
- difficulty walking
- problems with your eyesight.

If you had any of these symptoms before treatment with polatuzumab vedotin, tell your doctor straight away if you notice any changes in them. You may need medical treatment.

Tumour lysis syndrome (also called TLS)
Some people may develop unusual levels of some chemicals in their blood (such as potassium or uric acid). This is caused by the fast breakdown of cancer cells during treatment (called 'tumour lysis syndrome' or TLS). Your doctor, pharmacist or nurse will do blood tests to check for TLS.

Hepatic toxicity
This medicine can cause inflammation or damage to cells in the liver that can affect the normal function of the liver. This can be detected as injured liver cells may leak higher than normal amounts of certain substances (liver enzymes and bilirubin) into the bloodstream, resulting in elevated values in blood tests. In most cases you will not have any symptoms but tell your doctor or nurse straight away if you get:

- yellowing of your skin and whites of your eyes (jaundice)

Your doctor will check your blood to test your liver function before and regularly during treatment.

Other side effects
Tell your doctor or nurse if you notice any of the following side effects:

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

- infusion-related reactions during or shortly after infusions, such as fever, chills, breathing problems, skin rashes
- diarrhoea or constipation
- feeling sick (nausea), vomiting
- abdominal pain
- feeling tired
- not feeling hungry, loss of weight
- itchiness
- dizziness
- low blood levels of potassium, calcium, albumin

Common (may affect up to 1 in 10 people)

- inflammation of the lungs (pneumonitis)
- joint pain
- headache
- indigestion (dyspepsia)
- low blood phosphate levels

5. How to store polatuzumab vedotin

Polatuzumab vedotin will be stored by the healthcare professionals at the hospital or clinic. The storage details are as follows

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

- Store in a refrigerator.
- Do not freeze.
- Do not shake.
- Keep the container in the outer carton in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Your healthcare professional will properly dispose of any medicines that are no longer being used. These measures will help protect the environment.

6. Contents of the pack and other information

What polatuzumab vedotin contains

- The active substance is polatuzumab vedotin. Each vial contains 140 mg polatuzumab vedotin. After reconstitution each millilitre (mL) contains 20 mg polatuzumab vedotin.
- The other ingredients are: succinic acid, sodium hydroxide, sucrose, polysorbate 20.

What polatuzumab vedotin looks like and contents of the pack

Polatuzumab vedotin is a white to slightly greyish-white cake provided in a glass vial.
Each pack of polatuzumab vedotin consists of one vial.

Scientific Opinion Holder and manufacturer

Roche Products Limited
6 Falcon Way
Shire Park
Welwyn Garden City
AL7 1TW
United Kingdom

This protocol was revised in June 2019

Additional information

Informed Consent Form

All patients will have the Early Access to Medicines Scheme explained to them using the informed consent form. The patient will be asked to sign this form and a copy will be given to them to keep.

Patient Alert Card

Each patient must be given a Patient Alert Card before they start treatment with polatuzumab vedotin. The patient must keep this alert card with them at all times during the treatment and for at least 1 month after completing their treatment with polatuzumab vedotin. The card summarises that they are currently receiving polatuzumab vedotin, the important side effects for which patients need to seek assistant should they occur, details of the patients treating haematologist/oncologist managing their treatment, out of hours contact details and the company contact details.

Contact information

Contact details for reporting Adverse Events/Pregnancies:

SAE Email Address: welwyn.uk_dsc@roche.com

SAE Facsimile Transmission: +44 1707 367582

SAE TELEPHONE CONTACT: +44 1707 367554

Name: UK Drug Safety Centre

Contact email for the EAMS programme (excluding AE reporting):

Welwyn.polatuzumabEAMS@roche.com

Contact Details for Medical Information

Roche Medical Information on 0800 328 1629 or email medinfo.uk@roche.com