Medicines & Healthcare products Regulatory Agency

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 or are used outside their licence) to UK patients that have a high unmet clinical need. The medicines included in the scheme after they have received a positive scientific opinion 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 (called scientific opinion holder) that manufactures the EAMS medicine. This medicine, which does not yet have a drug licence or is used outside its licence, may also be used in combination with other medicines. More information about medicines licensing can be found here:
http://www.nhs.uk/conditions/medicines-information

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. Your physician will be responsible for giving you all the information you need to make this decision and for obtaining informed consent from you prior to treatment. You will be asked to sign a form to confirm that you are providing informed consent to receiving the EAMS treatment. Information on consent can be found here:
https://www.nhs.uk/conditions/Consent-to-treatment

The information below is provided to help you decide with your physician on whether to use the EAMS medicine and helps explain how to use it in accordance with the pharmaceutical company's instructions for safe and proper use. A positive scientific opinion is not a recommendation for use of the medicine and should not be interpreted as such. Under EAMS, the risk and legal responsibility for prescribing the medicine remains with the physician, and the opinion and EAMS documentation published by the MHRA are intended only to inform physicians' decision making and not to recommend use. An EAMS scientific opinion does not affect the civil liability of the manufacturer or any physician in relation to the product.

The information below may change during the time you are using the medicine if more data become available. Your physician will highlight to you any changes that you need to be aware of.

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 continue to outweigh any potential risks. Your physician will answer all your questions during and after the treatment and will provide you with contact details that you should use in case of any events or problems.

Each patient enrolled in the scheme will continue to receive the EAMS product until the end of the treatment in line with prescribing and NHS guidance and as long as benefit is seen. In

rare cases where the EAMS treatment may not be available anymore, your physician will discuss other options with you.

Information for the patient

Dostarlimab 500 mg 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, nurse, or pharmacist.
- If you get any side effects, talk to your doctor, nurse, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4 for more details.

What is in this leaflet

1. What dostarlimab is and what it is used for
2. What you need to know before you are given dostarlimab
3. How dostarlimab is given
4. Possible side effects
5. How to store dostarlimab
6. Contents of the pack and other information

1. What dostarlimab is and what it is used for

Dostarlimab is a *monoclonal antibody*, a type of protein designed to recognise and attach to a specific target substance in the body.

Dostarlimab works by helping your immune system fight your cancer.

Dostarlimab is used in combination with platinum-containing treatment (like carboplatin and paclitaxel) in adults to treat a kind of cancer called *endometrial cancer* (cancer of the lining of the womb) that has a gene abnormality called mismatch repair deficient (dMMR) / microsatellite instability-high (MSI-H).

Carboplatin and paclitaxel work by preventing the growth of cancer cells. It is important that you also read the package leaflets for these other anticancer medicines you may be receiving. If you have any questions about these medicines, ask your doctor.

This treatment is given when the cancer is advanced (meaning it has spread at the time it is first diagnosed) or if it is recurrent (meaning it was treated and has returned).

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

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

Warnings and precautions

Talk to your doctor or nurse before you are given dostarlimab if you have:
- immune system problems;

- lung or breathing problems;
- liver or kidney problems;
- serious rash;
- any other medical problems.

Symptoms you need to look out for

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

You need to be aware of possible symptoms, so your doctor can give you treatment for side effects if necessary.

➔ **Read the information** under "Symptoms of serious side effects" in section 4. Talk to your doctor or nurse if you have any questions or worries.

Children and adolescents

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

Other medicines and dostarlimab

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

Some medicines may interfere with the effect of dostarlimab:

- Medicines that make your immune system weak — for example, *corticosteroids*, such as prednisone.

➔ **Tell your doctor** if you are taking any of these.

However, once you are treated with dostarlimab, your doctor may give you corticosteroids to reduce any side effects that you may have.

Contraception, pregnancy and breast-feeding

Pregnancy
- **You must not be given dostarlimab 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, ask your doctor for advice before you are given this medicine.
- Dostarlimab can cause harmful effects or death to your unborn baby.

If you are a woman who could become pregnant, you must use effective **contraception** while you are being treated with dostarlimab and for at least 4 months after your last dose.

Breast-feeding

- If you are breast-feeding, **ask your doctor** for advice before you are given this medicine.
- **You must not breast-feed** during treatment and for at least 4 months after your last dose of dostarlimab.
- It is not known if the active ingredient of dostarlimab passes into your breast milk.

Driving, cycling, and using machines

Dostarlimab is unlikely to affect your ability to drive, cycle and use machines. However, if you have side effects that affect your ability to concentrate and react, you should be careful when driving, cycling, or operating machines.

Dostarlimab contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free.' However, before dostarlimab is given to you, it is mixed with a solution that may contain sodium. Talk to your doctor if you are on a low salt diet.

3. How dostarlimab is given

Dostarlimab will be given to you in a hospital or clinic under the supervision of a doctor experienced in cancer treatment.

When dostarlimab is given in combination with chemotherapy, the recommended dose of dostarlimab is 500 mg every 3 weeks for 6 doses, followed by 1000 mg every 6 weeks for all doses thereafter.

The doses of the platinum-containing treatment like paclitaxel and carboplatin are calculated individually for every patient and given every 3 weeks for 6 doses.

Your doctor will give you dostarlimab as a drip into a vein *(intravenous infusion)* for about 30 minutes. After your dostarlimab dose, you should receive intravenous infusions of the platinum containing treatment like paclitaxel and carboplatin on the same day.

Your doctor will decide how many treatments you need and whether any dose adjustments or treatment interruptions are needed. Your doctor also may also discontinue your treatment if you have certain side effects or you cannot tolerate the treatment.

If you forget an appointment to receive dostarlimab

➔ **Contact your doctor or hospital immediately** to reschedule your appointment.

It is very important that you do not miss a dose of this medicine.

If you stop receiving dostarlimab

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

Patient Card

Important information from this leaflet can be found in the ***EAMS Patient Card*** you have been given by your doctor. It is important that you keep this Patient Card and show it to partner or caregivers.

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.

Some of the side effects can be serious, and you need to know what symptoms to look out for.

Symptoms of serious side effects

Dostarlimab can cause serious side effects. If you develop symptoms, **you must tell your doctor or nurse as soon as possible.** Your doctor may give you other medicines to prevent more serious complications and reduce your symptoms. Your doctor may decide that you should miss a dose of dostarlimab or stop your treatment altogether.

Conditions	**Possible symptoms**
Inflammation of lungs *(pneumonitis)*	• shortness of breath • chest pain • new or worse cough
Inflammation of intestines *(colitis, enteritis, vasculitis gastrointestinal)*	• diarrhoea, or more bowel movements than usual • black, tarry, sticky stools; blood or mucus in stools • severe stomach pain or tenderness • feeling sick *(nausea)*, being sick *(vomiting)*
Inflammation of food pipe and stomach *(oesophagitis, gastritis)*	• trouble swallowing • decreased appetite • burning in the chest (heartburn) • chest or upper belly pain • feeling sick *(nausea)*, being sick *(vomiting)*
Inflammation of liver *(hepatitis)*	• feeling sick *(nausea)*, being sick *(vomiting)* • loss of appetite • pain on the right side of the abdomen (stomach) • yellowing of the skin or the whites of the eyes • dark-coloured urine • bleeding or bruising more easily than normal
Inflammation of hormone glands *(especially thyroid, pituitary, adrenal, pancreas)*	• rapid heartbeat • weight loss or weight gain • increased sweating • hair loss • feeling cold • constipation • abdominal pain • deeper voice • muscle aches • dizziness or fainting • headache that will not go away or unusual headache

Symptoms of serious side effects (continued)

Conditions	**Possible symptoms**
Type 1 diabetes, including diabetic ketoacidosis (acid in the blood produced from diabetes)	• feeling more hungry or thirsty than usual • needing to urinate more often including at night • weight loss • feeling sick *(nausea)*, being sick *(vomiting)* • stomach pain • feeling tired • unusual sleepiness • having difficulty thinking clearly • breath that smells sweet or fruity

	• deep or fast breathing
Inflammation of kidneys *(nephritis)*	• changes in amount or colour of urine • swelling of the ankles • loss of appetite • blood in the urine
Inflammation of skin	• rash, itching, , peeling, or skin sores • ulcers in the mouth, nose, throat, or genital area
Inflammation of heart muscle *(myocarditis)*	• trouble breathing • dizziness or fainting • fever • chest pain and chest tightness • flu like symptoms
Inflammation of brain and nervous system *(myasthenic syndrome/myasthenia gravis, Guillain-Barré syndrome, encephalitis)*	• neck stiffness • headache • fever, chills • vomiting • eye sensitivity to light • weakness of eye muscles, drooping eyelids • dry eyes and blurred vision • difficulty swallowing, dry mouth • impaired speech • confusion and sleepiness • dizziness • pricking or pins and needles sensations in the hands and feet • aching muscles • difficulty walking or lifting objects • abnormal heart beat/rate or blood pressure
Inflammation of spinal cord *(myelitis)*	• 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
Inflammation of eyes	• changes in eyesight
Inflammation of other organs	• severe or persistent muscle or joint pains • severe muscle weakness • swollen or cold hands or feet • feeling tired

Infusion-related reactions

Some people may have allergic-like reactions when they receive an infusion. These usually develop within minutes or hours but may develop up to 24 hours after treatment.

Symptoms include:
- shortness of breath or wheezing
- itching or rash
- flushing
- dizziness
- chills or shaking
- fever

- drop in blood pressure (feeling like passing out)

Solid organ transplant rejection and other complications, including graft-versus-host disease (GvHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic). These complications can be serious and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with dostarlimab. Your healthcare professionals will monitor you for these complications.

➔ **Seek medical attention immediately** if you think you may be having a reaction.

Other side effects

The following side effects have been reported with dostarlimab when given in combination with platinum-containing chemotherapy.

Very common side effects - (may affect **more than 1 in 10** people):

- underactive thyroid gland
- skin rash
- dry skin
- high temperature; fever
- increased liver enzyme levels in the blood.

➔ **Check the table** above for symptoms of possible serious side effects.

Common side effects - (may affect **up to 1 in 10** people):

- overactive thyroid gland
- decreased secretion of adrenal hormones
- inflammation of the lung
- inflammation of the lining of the bowel *(colon).*

➔ **Check the table** above for symptoms of possible serious side effects.

Uncommon side effects - (may affect **up to 1 in 100** people):

- inflammation of the thyroid gland
- Type 1 diabetes or diabetic complications
- a condition in which the muscles become weak and there is a rapid fatigue of the muscles *(myasthenic syndrome)*
- inflammation of the heart muscle
- inflammation of the pancreas
- inflammation of the stomach
- inflammation of the blood vessels in the food pipe, stomach, or bowel
- inflammation of the eye
- inflammation of the joints
- inflammation of the muscles
- inflammation throughout the body.

➔ **Check the table** above for symptoms of possible serious side effects

The following side effects have been reported with dostarlimab alone:

Very common side effects - (may affect **more than 1 in 10** people):

- decrease in the number of red blood cells *(anaemia);*
- reduced thyroid gland activity *(hypothyroidism)*;
- diarrhoea; feeling sick *(nausea)*; being sick *(vomiting);*

- skin redness or rash; blistering of the skin or mucous membranes; itchy skin;
- high temperature; fever;
- increased liver enzyme levels in the blood.
- Joint pain

➔ **Check the table** above for symptoms of possible serious side effects.

Common side effects - (may affect **up to 1 in 10** people):

- overactive thyroid gland;
- decrease secretion of adrenal hormones *(adrenal insufficiency);*
- inflammation of the lung;
- inflammation of the lining of the bowel *(colon)*;
- inflammation of the pancreas;
- inflammation of the stomach;
- inflammation of the liver;
- muscle pain;
- chills;
- reaction to the infusion;
- hypersensitivity reaction to the infusion.

➔ **Check the table** above for symptoms of possible serious side effects.

Uncommon side effects - (may affect **up to 1 in 100** people):

- inflammation of the brain;
- destruction of red blood cells *(Autoimmune haemolytic anaemia)*;
- inflammation of the pituitary gland, in the base of the brain;
- inflammation of the thyroid gland;
- Type 1 diabetes or diabetic complications *(diabetic ketoacidosis)*;
- inflammation of the food pipe;
- a condition in which the muscles become weak and there is a rapid fatigue of the muscles *(myasthenia syndrome)*;
- inflammation of the heart muscle
- inflammation of the joints;
- inflammation of the muscles;
- inflammation of the eye - the iris (the coloured part of the eye) and the ciliary body (area around the iris);
- inflammation of the kidneys.
- Inflammation throughout the body

➔ **Check the table** above for symptoms of possible serious side effects.

➔ **Contact your doctor or nurse as soon as possible** if you develop any of these symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 dostarlimab

Dostarlimab will be given to you in a hospital or clinic and the healthcare professionals will be responsible for its storage.

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 package in order to protect from light.

If not used immediately, the prepared infusion may be stored for up to 24 hours at 2°C to 8°C or 6 hours at room temperature (up to 25°C) from the time of preparation/dilution until the end of administration.

Do not use if this medicine contains visible particles.

Do not store any unused medicine for reuse. Any unused medicine or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

6. Contents of the pack and other information

What dostarlimab contains

The active substance is dostarlimab.

One vial of 10 mL concentrate for solution for infusion (sterile concentrate) contains 500 mg of dostarlimab.

Each mL of concentrate for solution for infusion contains 50 mg of dostarlimab.

The other ingredients are trisodium citrate dihydrate; citric acid monohydrate; L-arginine hydrochloride; sodium chloride; polysorbate 80; and water for injection (see section 2).

What dostarlimab looks like and contents of the pack

Dostarlimab is a clear to slightly opalescent colourless to yellow solution, essentially free from visible particles.

It is available in cartons containing one glass vial.

Scientific Opinion Holder

GlaxoSmithKline UK Limited

980 Great West Road Brentford

Middlesex TW8 9GS UK

Manufacturer

GlaxoSmithKline (Ireland) Limited

12 Riverwalk

Citywest Business Campus

Dublin 24

Ireland

This protocol was revised in April 2023

EAMS number: 52719/0001

Additional information

The Early Access to Medicines Scheme (EAMS) will be explained to you by your doctor using the information contained in this leaflet and the ***EAMS consent form***. You will be asked to sign this form and a copy will be given to you to keep.

You will also be asked to give permission to have some data collected to help understand dostarlimab treatment within the scheme. Data like your age, details about your endometrial cancer, medical history such as previous treatments or procedures received for the condition, dostarlimab dose (number of infusions, when doses are given), details of any other medicines you are taking for any medical reason and side effects from the EAMS treatment will be collected for safety surveillance. In addition, your information will help to assess whether you are benefitting from the treatment based on information collected as part of routine care for your endometrial cancer.

You will find detailed information about the collection of your data and its use by GSK in the ***EAMS consent form.***

You will also be given an ***EAMS patient card***, which is a wallet-sized card that you should carry at all times and for at least 4 months after your last dose of dostarlimab. It alerts any other healthcare professional that may treat you that you are receiving (or received) dostarlimab through an early access scheme. Your ***EAMS patient card*** summarises the most important side effects for which you or your healthcare professional need to look out for and seek assistance if they occur. The ***EAMS patient card*** also provides you with contact details of your treating doctor, out of hours contact details and company contact details.

Additional data will be collected on health outcome benefit from your treatment with dostarlimab based on your doctor's clinical judgement, as part of your routine cancer care. Collection of this data is voluntary and subject to your consent. The reason for collecting this additional data is to better understand how you are benefiting from your treatment in a real-world setting. You can still receive dostarlimab in this EAMS without giving your consent to the collection to the type of data, however If you agree to the collection you will need to provide a second signature on the Informed Consent Form.

Contact information

Contact information:

Contact details for medical information

Phone: 0800 221 441, Email: ukmedinfo@gsk.com

Contact information for safety reporting

Adverse events must be reported to: OAX37649@gsk.com, phone 0800 221 441 or via fax: 020 8754 7822

Adverse events must also be reported via Yellow Card to: https://yellowcard.mhra.gov.uk