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 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 before, 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

Tepotinib 225 mg film-coated tablets

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects which you may get. See the end of section 4 for how to report side effects.

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, pharmacist or nurse.
- 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 tepotinib is and what it is used for
2. What you need to know before you take tepotinib
3. How to take tepotinib
4. Possible side effects
5. How to store tepotinib
6. Contents of the pack and other information

1. What tepotinib is and what it is used for

Tepotinib contains the active substance tepotinib which belongs to a group of medicines called protein kinase inhibitors which are used to treat cancer.

Tepotinib is used in adults to treat a type of lung cancer, called non-small cell lung cancer that has certain abnormal changes in the mesenchymal-epithelial transition factor gene (*MET*) and which has spread and/or cannot be removed by surgery.

The changes in the *MET* gene can make an abnormal protein which can lead to uncontrolled cell growth and cancer. By blocking this abnormal protein tepotinib may slow or stop the cancer from growing. It may also help to shrink the cancer.

Your doctor will perform a test to check if your cancer has a change in the *MET* gene to make sure that tepotinib is right for you.

2. What you need to know before you take tepotinib

You must not take tepotinib
If you are allergic to tepotinib or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking tepotinib, if any of the following apply to you:

- if you have or have had any other lung problems.
- if you have or have had liver problems.
- if you are pregnant or plan to become pregnant.
- if you are breastfeeding.

Tell your doctor or pharmacist immediately, if you develop any new or worsening symptoms during treatment (see section 4). Tepotinib may cause sudden breathing difficulties that may be associated with fever and cough

Blood tests
Your doctor will take blood tests before and regularly during treatment with tepotinib. Based on the results, your doctor may decide to interrupt your treatment, reduce your tepotinib dose or stop treatment permanently.

Tepotinib contains lactose
Tepotinib contains 4.15 mg lactose in each tablet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Children and adolescents
Tepotinib is not to be used in children and adolescents under the age of 18 years.

Other medicines and tepotinib
Tell your doctor if you are using, have recently used or might use any other medicines.

The following medicines may affect how well tepotinib works:
- cabamazepine or phenytoin – used to treat seizures or fits
- rifampicin – used to treat tuberculosis (TB).
- St. John's wort – a herbal medicine used to treat depression
- itraconazole – used to treat fungal infections

Tepotinib may affect how well the following medicines work and/or increase side effects of these medicines:
- digoxin – used to treat irregular heart beat or other heart problems
- metformin – used to treat diabetes mellitus

Contraception, pregnancy and breast-feeding
Pregnancy
Do not take tepotinib when you are pregnant, unless advised by your doctor. Tepotinib may harm the unborn baby.

Contraception
You should use an effective method of contraception to avoid becoming pregnant during tepotinib treatment and for at least 1 week after the last dose.

If you are male, you should use barrier contraception to prevent your partner from getting pregnant, whilst you are treated with tepotinib and for at least 1 week after the last dose.

Breast-feeding
Do not breast-feed during treatment with tepotinib and for at least one week after the last dose.

Driving, cycling and using machines
You should take special care when driving and using machines as you may feel unusually tired while taking tepotinib.

3. How to take tepotinib

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The recommended dose is 2 tablets of tepotinib (450 mg) once daily. In case of side effects, your doctor may advise you to reduce the dose to 1 tablet daily or interrupt the treatment for some days or stop treatment permanently.

Swallow the tablets whole, without crushing or chewing. Take the tablets with food or shortly after a meal.

If you take more tepotinib than you should
If you have taken more tepotinib than you should, or if someone else has taken your medicine, contact a doctor or hospital for advice. Medical treatment may be necessary.

If you miss a dose of tepotinib
If you miss a dose of tepotinib, take it as soon as you remember. If your next dose is due within 8 hours, skip the missed dose and take your next dose at your regular time.

If you vomit after taking a dose of tepotinib, take your next dose at your regular time.

If you stop taking tepotinib
Do not stop taking tepotinib unless you have discussed with your doctor or your doctor tells you to stop.

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, although not everybody gets them. The following side effects have been reported with this medicine:

Serious side effects
Contact your doctor immediately for any of the following:
- if you develop any new or worsening symptoms such as sudden breathing difficulties, shortness of breath, cough or fever. These may be symptoms of a serious lung condition (interstitial lung disease) which needs immediate medical attention. This side effect is common (may affect up to 1 in 10 people).
- if you develop yellow discoloration of the skin and eyes (jaundice), darkening of the urine, light-coloured stools (faeces), loss of appetite, nausea or vomiting, pain on the upper right side of your stomach area. These are symptoms and signs of liver problems.

Other side effects
Very common side effects (may affect more than 1 in 10 people)
- Swelling caused by fluid build-up in the body (oedema)
- Nausea
- Diarrhoea
- Abdominal pain
- Constipation
- Vomiting
- Fatigue or tiredness
- Higher than normal blood levels of creatinine
- Reduced protein levels in the blood
- Higher than normal blood levels of a certain liver enzyme (alanine aminotransferase)

Common side effects
- Higher than normal blood levels of certain liver enzymes (aspartate aminotransferase, alkaline phosphatase), amylase or lipase

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. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store tepotinib

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

Store below 25°C. Store all items in original outer packaging, remove only prior to administration.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What tepotinib contains
The active substance is tepotinib. Each tablet contains 225 mg tepotinib (as hydrochloride hydrate)..

The other ingredients are mannitol, colloidal anhydrous silica, crospovidone, magnesium stearate and microcrystalline cellulose in the tablet core and hypromellose, lactose monohydrate, Macrogol, triacetin, red iron oxides (E172) and titanium dioxide in the film-coating.

What tepotinib looks like and contents of the pack
Tepotinib film-coated tablets are white-pink, oval and biconvex with embossment 'M' on one side and plain on the other side. Each pack contains 12 wallets of 14 tablets in Polyamide/ Aluminium/Polyvinyl chloride and Aluminium blister.

Scientific Opinion Holder and manufacturer
Scientific Opinion Holder
Merck Serono Limited
5 New Square
Bedfont Lakes Business Park
Feltham
Middlesex
TW14 8HA

Manufacturer
Merck Healthcare KGaA
Frankfurter Strasse 250
64293 Darmstadt
Germany

This protocol was revised in June 2021

Additional information

You will also be provided with the following item:

- EAMS Informed Consent Form

This item contains key information on potential side effects with tepotinib.

Informed Consent/Assent Form

All patients will have the Early Access to Medicines Scheme explained to them using the Informed Consent Form. All patients will be asked to sign this form and a copy will be given to them to keep.

Patient data to be collected

Patient data collected during the scheme are commonly used for safety surveillance and therefore cannot replace clinical trial data which are used to support a marketing authorisation. These data are required by the MHRA to help verify that the patient's condition complies with the EAMS indication and help identify the side effects and/or other events occurring during and after the EAMS treatment associated with the use of tepotinib. These data include patient's demographics, relevant medical history and prior medications, confirmation of the MET mutation status, ability of the patient to tolerate the EAMS treatment, contraception/pregnancy check, confirmation that the patient has met all eligibility criteria for the EAMS scheme, patient consent form and all side effects.

Contact information

Merck Serono Limited
5 New Square
Bedfont Lakes Business Park
Feltham
Middlesex
TW14 8HA

Contact Details for Medical Information
Telephone: 0208 818 7373
Email: medinfo.uk@merckgroup.com