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 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

Pemigatinib 4.5 mg tablets
Pemigatinib 9 mg tablets
Pemigatinib 13.5 mg tablets

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 pemigatinib is and what it is used for

Pemigatinib belongs to a group of medicines called tyrosine kinase inhibitors. It blocks the action of a protein in the cell called fibroblast growth factor receptor 1, 2 and 3 (FGFR1-3), As a result, pemigatinib can block the growth of cancer cells that have an abnormal form of this protein.

Pemigatinib is used to treat adults with **bile duct cancer** (also known as cholangiocarcinoma) if:
- The cancer cells have a defect in the FGFR2 protein and
- The cancer has spread to other parts of the body or cannot be removed by surgery and
- Treatment with other medicines is no longer working.

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

You must not be given pemigatinib if you are:
- allergic to pemigatinib or any of the other ingredients of this medicine (listed in section 6)
- using St John's wort:

Warnings and precautions
Talk to your doctor or pharmacist before taking pemigatinib if you have:
- increased phosphate levels in the blood
- vision or eye problems
- severely reduced liver function
- severely reduced kidney function
- cancer cells that have spread into the brain or spinal cord

Your doctor or nurse will arrange full eye examinations with an eye specialist:
- before starting treatment with pemigatinib
- every 2 months for the first 6 months of treatment
- then every 3 months or immediately if any visual symptoms occur, including flashes of light, visual disturbances or dark spots

Tell your doctor straight away if you notice any change in your vision.

You should also use lubricating or hydrating eye drops or gels, as needed, to help prevent or treat dry eyes.

Children and adolescents
Pemigatinib should not be given to children or adolescents under 18 years. It is not known whether it is safe and effective in this age group.

Other medicines and pemigatinib
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Particularly, inform your doctor if you are taking any of the following medicines so that the doctor can decide upon any necessary changes:
- **St John's wort:** a medicine to treat depression
  You must not take St John's wort during treatment with pemigatinib.
- **itraconazole:** a medicine to treat fungal infections
- **rifampicin:** a medicine to treat tuberculosis or certain other infections
- **carbamazepine, phenytoin, phenobarbital, primidone:** medicines to treat epilepsy
- **bosentan:** a medicine to treat high blood pressure in the lungs, and certain skin hardening or abscesses
- **efavirenz, etravirine:** medicines to treat HIV infection
- **cyclophosphamide, ifosfamide:** medicines to treat cancer
- **methadone:** a medicine to treat severe pain or to counter opioid addiction
- **digoxin:** a medicine to treat heart weakness and irregular heartbeat

- **dabigatran:** a medicine to inhibit blood clotting
- **colchicine:** a medicine to treat gout attacks

Avoid eating grapefruit or drinking grapefruit juice while using this medication.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- **Pregnancy**

Pemigatinib may harm your unborn baby and should not be used during pregnancy. Tell your doctor or nurse straight away if you are pregnant or think that you may be pregnant. A pregnancy test should be performed before starting treatment with pemigatinib.

- **Contraception**

Females who can become pregnant
You should not become pregnant during treatment with pemigatinib. You should have a negative pregnancy test before you start treatment with pemigatinib. You must use effective contraception during treatment and for at least 1 week after the last dose of pemigatinib. An example of effective contraception is the combination of hormonal contraception plus a barrier method, such as condoms. Talk to your doctor or nurse about appropriate contraception.

Males with female partners who can become pregnant
You must use effective contraception during treatment and for at least 1 week after the last dose of pemigatinib.

- **Breast-feeding**

Do not breast-feed during treatment with pemigatinib and for at least 1 week after the last dose.

Driving, cycling and using machines

Pemigatinib can cause side effects such as fatigue or visual disturbances. Do not drive or operate machinery if this happens.

3. How pemigatinib is given

Pemigatinib treatment should be started by a doctor who is experienced in the treatment of bile duct cancer. Always take pemigatinib exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Method of use
Swallow the tablet whole with one glass of water at the same time every day. Pemigatinib may be taken with food or between meals. Do not crush, chew, split or dissolve the tablets.

Duration of use
Take pemigatinib for as long as it is prescribed by your doctor.

If you take more pemigatinib than you should
Tell your doctor if this occurs.

How much pemigatinib is given
The recommended dose is 1 tablet containing 13.5 mg pemigatinib taken once daily for 14 days, followed by 7 days without taking pemigatinib.
Treatment is continued in intervals with 14 days of pemigatinib taken once daily, followed by 7 days off therapy, as shown on the blister foil. Your doctor will adjust the dose or discontinue treatment if needed.

If you miss a dose of pemigatinib
If you miss a dose of pemigatinib by 4 hours or more, or if you vomit after taking pemigatinib, do not take another pemigatinib tablet to make up for the missed dose. Take your next dose of pemigatinib at the scheduled time.

If you stop receiving pemigatinib
Do not stop taking pemigatinib without discussing this with your doctor, as this could reduce the success of therapy.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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 immediately if you have any serious side effects. Side effects of pemigatinib may occur with the following frequencies:

Very common (may affect more than 1 in 10 people):
- low sodium in blood; symptoms include decreased ability to think, headache, nausea, poor balance, confusion, seizures, coma
- blood tests showing increase of creatinine, which can suggest kidney problems; usually raised creatinine does not cause symptoms, but symptoms of kidney problems may include nausea and changes in urination
- high or low phosphate levels seen in blood tests. High phosphate levels are common during treatment with pemigatinib but can also be serious.

Your doctor or nurse will check your blood phosphate levels before and during treatment with pemigatinib. They might advise changes in your diet or prescribe treatment to lower blood phosphate levels.
Tell your doctor, nurse or pharmacist straight away if you develop muscle cramps or numbness or tingling around your mouth.

Common (may affect up to 1 in 10 people)
- fluid build-up under the retina (the light-sensitive layer at the back of the eye)
- inflammation of the cornea (the clear outer layer of the eye)
- reduced vision

Tell your doctor, nurse or pharmacist straight away if you develop any change in your vision during treatment with pemigatinib, including blurred vision, flashes of light or seeing black spots. You may need to see an eye specialist straight away.

Other side effects
May occur with following frequencies**:**
Very common (may affect more than 1 in 10 people)
- taste disturbance
- dry eyes
- nausea
- inflammation of the inner lining of the mouth
- diarrhoea
- constipation
- dry mouth
- skin reactions with redness, swelling and pain on palms of the hands and/or soles of the feet, called hand-foot syndrome
- nail toxicity, including nails separating from the nail bed, nail pain, nail bleeding, breaking of the nails, colour or texture changes in your nails, infected skin around the nail
- hair loss
- dry skin
- joint pain
- fatigue

Common (may affect up to 1 in 10 people)
- eyelash changes including abnormally long eyelashes, ingrown eyelashes
- abnormal hair growth

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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 pemigatinib
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 bottle. The expiry date refers to the last day of that month.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What pemigatinib contains
- The active substance is pemigatinib.
  Each 4.5 mg tablet contains 4.5 mg pemigatinib.
  Each 9 mg tablet contains 9 mg pemigatinib.
  Each 13.5 mg tablet contains 13.5 mg pemigatinib.
- The other ingredients are microcrystalline cellulose, sodium starch glycolate (Type A), magnesium stearate.

What pemigatinib looks like and contents of the pack
Pemigatinib 4.5 mg tablets are round, white to off-white, debossed on one side with “I” and “4.5” on the reverse. The tablet diameter is 5.8 mm.
Pemigatinib 9 mg tablets are oval, white to off-white, debossed on one side with “I” and “9” on the reverse. The tablet size is 10 mm × 5 mm.
Pemigatinib 13.5 mg tablets are round, white to off-white, debossed on one side with “I” and “13.5” on the reverse. The tablet diameter is 8.5 mm.

The tablets are provided in a high density polyethylene bottle with a child-resistant closure. The bottle contains 14 tablets.

Scientific Opinion Holder and manufacturer

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Manufacturer
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Netherlands

This protocol was revised in January 2021

Additional information

Informed Consent/Assent Form

You will have the Early Access to Medicines Scheme (EAMS) explained to you using 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.

Patient Alert Card

Each patient must be given a Patient Alert Card before they start treatment with pemigatinib. The patient must keep this alert card with them at all times during the treatment and for at least 5 months after completing their treatment. The card summarises that they are currently receiving pemigatinib, the important side effects for which they need to seek assistance should they occur, details of the patient's treating physician, out of hours contact details and the company contact details.

Patient data to be collected

Information collected during the scheme will mostly be used for safety surveillance and cannot replace a proper clinical trial to support a marketing authorisation. These data are required by the MHRA to help verify that your condition complies with the EAMS indication and help interpret the side effects and other events occurring during and after the EAMS treatment. These data include your initials, year of birth, gender, information about your cancer, comorbidities, and any medications you may be taking.

Contact information

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You should also report side effects to Incyte Biosciences UK Ltd by emailing the
Incyte Drug Call Centre at eumedinfo@incyte.com or calling 00 800 000 27423. By reporting side effects, you can help provide more information on the safety of this medicine.