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.

December 2015
MHRA

Information for the patient:

Information for the Patient

Osimertinib(AZD9291) 40 mg tablets
Osimertinib(AZD9291) 80 mg tablets

Read all of this leaflet carefully before you start taking 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. Do not pass it on to 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 osimertinib is and what it is used for

Osimertinib is a medicine used which is being used in the Early Access to Medicines Scheme to treat a type of lung cancer. It belongs to the protein kinase inhibitor class of anticancer medicines.

Osimertinib is used to treat adults with a type of lung cancer called 'non-small cell lung cancer.' It is used when:
- You test positive for a 'T790M mutation' – see 'How osimertinib works.'
- Your cancer is advanced and is worsening despite previous treatments, including a medicine which worked to block 'EGFR' (Epidermal Growth Factor Receptor).

How osimertinib works
- A test has shown that your cancer is linked to a specific change in the EGFR gene called 'T790M.' This is known as a T790M mutation.
- Because of this T790M mutation, medicines that block EGFR may no longer work.
- Osimertinib affects T790M and may help to slow or stop your lung cancer growing. It may also help to shrink the tumour.

If you have any questions about how this medicine works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take osimertinib

Do not take osimertinib if:
- you are allergic (hypersensitive) to osimertinib or any of the other ingredients of this medicine (listed in section 6).
- you are taking St. John's wort (Hypericum perforatum).

If you are not sure, talk to your doctor, pharmacist or nurse before taking osimertinib.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking osimertinib if:
- you have suffered from inflammation of your lungs (a condition called 'interstitial lung disease').
- you have ever had heart problems - your doctor may want keep a close eye on you.

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

Tell your doctor straight away while taking this medicine if:
- you have sudden difficulty in breathing together with a cough or fever. See 'Serious side effects' in section 4 for more information.

Children and adolescents
Osimertinib has not been studied in children or adolescents. Do not give this medicine to children or adolescents under the age of 18 years.

Other medicines and osimertinib
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes herbal medicines and medicines obtained without a prescription. This is because osimertinib can affect the way some other medicines work. Also some other medicines can affect the way osimertinib works.

Tell your doctor before taking osimertinib if you are taking any of the following medicines:

The following medicines may reduce how well osimertinib works:
- Phenytoin, carbamazepine or phenobarbital – used for seizures or fits.
- Rifabutin or rifampicin – used for tuberculosis (TB).
- St. John's wort (Hypericum perforatum) – an herbal medicine used for depression.

Osimertinib may affect how well the following medicine works and/or increase side effects of these medicines:

- Warfarin – used for blood clots.
- Phenytoin and S-mephenytoin – used for seizures or fits.
- Alfentanil, fentanyl and other painkillers used for operations.
- Rosuvastatin - used to lower cholesterol.
- Oral hormonal contraceptive pill– used to prevent pregnancy.
- Bosentan – used for high blood pressure in the lungs.
- Efavirenz and etravirine – used to treat HIV infections/AIDS.
- Modafinil – used for sleep disorders.

If you are taking any of the medicines listed above, tell your doctor before taking osimertinib. Your doctor will discuss appropriate treatment options with you.

Pregnancy – information for women

- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. If you do become pregnant during treatment, tell your doctor straight away. Your doctor will decide with you whether you should carry on taking osimertinib.
- You should not become pregnant while taking this medicine. If you are able to become pregnant, you must use effective contraception. See 'Contraception - information for women and men' below.
- If you plan to become pregnant after taking the last dose of this medicine, ask your doctor for advice. This is because some medicine may remain in your body (see advice on contraception below).

Pregnancy – information for men

- If your partner becomes pregnant while you are taking this medicine, tell your doctor straight away.

Contraception – information for women and men

You must use effective contraception during treatment.

- Osimertinib may interfere with how well oral hormonal contraceptives work. Discuss with your doctor the most appropriate methods of contraception.
- Osimertinib may pass into semen. Therefore, it is important that men also use effective contraception.

You must also do this after completing treatment with osimertinib:

- **Women** – keep using contraception for 2 months after.
- **Men** – keep using contraception for 4 months after.

Breast-feeding

Do not breast-feed while taking this medicine. This is because it is not known if there is a risk to your baby.

Driving and using machines

Osimertinib has no or no marked influence on the ability to drive and use machines.

3. How to take osimertinib

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

How much to take

- The recommended dose is one 80 mg tablet each day.
- If necessary, your doctor may reduce your dose to one 40 mg tablet each day.

How to take

- Osimertinib is taken by mouth. Swallow the tablet whole with water. Do not crush, split or chew the tablet.
- Take osimertinib every day at about the same time.
- You can take this medicine with or without food.

If you have trouble swallowing the tablet, you can mix it in water:

- Put the tablet in a glass.
- Add 50 mL (about two-thirds of a tumblerful) of still (non-fizzy) water – do not use any other liquids.
- Stir the water until the tablet breaks up into very small pieces -the tablet will not completely dissolve.
- Drink the liquid straight away.
- To make sure you have taken all of the medicine, rinse the glass thoroughly with another 50 mL of water and drink it.

If you take more osimertinib than you should

If you take more than your normal dose, contact your doctor or nearest hospital straight away.

If you forget to take osimertinib

If you forget a dose, take it as soon as you remember it. However, if it is less than 12 hours until your next dose is due, skip the missed dose. Take your next normal dose at its scheduled time.

If you stop taking osimertinib

Do not stop taking this medicine - talk to your doctor first. It is important to take this medicine every day, for as long as your doctor prescribes it for you.
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.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

Serious side effects

Tell your doctor straight away if you notice the following serious side effect:

- Sudden difficulty in breathing together with a cough or fever - this may be a sign of inflamed lungs (a condition called ‘interstitial lung disease’) and can be fatal in some cases. Your doctor may wish to stop osimertinib if you get this side effect. This side effect is common: it may affect up to 1 in 10 people.

Tell your doctor straight away if you notice the serious side effect listed above.

Other side effects

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

- Diarrhoea - this may come and go during treatment. Tell your doctor if your diarrhoea does not go away or becomes severe.
- Skin and nail problems - signs may include itching, dry skin, rash, redness around the fingernails. This is more likely in areas exposed to the sun. Using moisturisers regularly on your skin and nails can help with this. Tell your doctor if your skin or nail problems get worse.
- Stomatitis - inflammation of the inner lining of the mouth.
- Abnormal decrease in the number of white blood cells (leukocytes or neutrophils).
- Reduction in the number of platelets in the blood.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see the Patient Alert Card). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store osimertinib

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date (EXP) which is stated on the bottle. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- Do not use any pack that is damaged or shows signs of tampering.

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 osimertinib contains

- The active substance is osimertinib (as mesylate).
- Each 40mg film-coated tablet contains 40 mg of osimertinib.
- Each 80 mg film-coated tablet contains 80 mg of osimertinib.
- The other ingredient(s) are mannitol, microcrystalline cellulose, low-substituted hydroxpropyl cellulose, sodium stearyl fumarate, polyvinyl alcohol, titanium dioxide, macrogol 3350, talc, yellow iron oxide, red iron oxide, black iron oxide.

What osimertinib looks like and contents of the pack
Osimertinib 40 mg is supplied as a plain, round, biconvex beige film coated tablet.
Osimertinib 80 mg is supplied as a plain, oval, biconvex beige film coated tablet.

Osimertinib is supplied in a High-density polyethylene (HDPE) bottle with a white polypropylene (PP) child-resistant screw cap, containing 25 tablets.

Scientific Opinion Holder
AstraZeneca UK Ltd

600 Capability Green
Luton
LU1 3LU

For any information about this medicine, please contact the local representative of the Scientific Opinion Holder:

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Additional information:

Before treatment starts, you will have the scheme explained carefully to you by your physician and you will be provided with two documents:

Information for the patient (this document)

Patient Alert Card

You will be given a Patient Alert Card after giving informed consent. This is a credit-card sized card that you must carry at all times. It contains important information on the main symptoms of the most important side effect and highlights the importance of seeking immediate medical attention should they occur. The card also alerts any other healthcare professional that may treat you that you are receiving osimertinib through an early access scheme. It has the details of your own physician and their contact details.

Contact information:
Email: astrazenecaUKMCdrugsafety@astrazeneca.com

Telephone number for AstraZeneca UK Limited: 0800 783 0033