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

Risankizumab 300 mg concentrate for solution for infusion

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side-effects 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.
- 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 risankizumab is and what it is used for:

For the purpose of the Early Access to Medicines Scheme (EAMS), risankizumab is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant or contraindicated to tumour necrosis factor-alpha (TNFα) antagonist therapies, vedolizumab and ustekinumab and for the treatment of adolescent patients aged 16 to 17 years with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant or contraindicated to TNFα antagonist therapies.

How risankizumab works

This medicine works by stopping a protein in the body called ‘IL-23’, which causes inflammation.

Crohn’s disease is an inflammatory disease of the digestive tract. If you have active Crohn’s disease you will first be given other medicines. If these medicines do not work well enough, you will be given risankizumab to treat your Crohn’s disease.

Risankizumab reduces the inflammation and can therefore help to reduce the signs and symptoms of your disease.

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

You should not be given risankizumab

- if you are allergic to risankizumab or any of the other ingredients of this medicine (listed in section 6).
- if you have an infection, including active tuberculosis, which your doctor thinks is important.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before and during the use of risankizumab

- if you currently have an infection or if you have an infection that keeps coming back.

- if you have tuberculosis (TB).
- if you have recently received or plan to receive an immunisation (vaccine). You should not be given certain types of vaccines while using risankizumab.

It is important that your doctor or nurse keep a record of the batch number of your risankizumab.
Every time you get a new pack of risankizumab, your doctor or nurse must note down the date and the batch number (which is on the packaging after "Lot").

Allergic reactions
Tell your doctor or seek medical help immediately if you notice any signs of an allergic reaction while you are taking risankizumab such as

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

Children and adolescents
Risankizumab is not recommended for children and adolescents under 16 years of age. This is because risankizumab has not been studied in this age group.

Other medicines and risankizumab
Tell your doctor, pharmacist or nurse

- if you are using, have recently used or might use any other medicines.
- if you have recently had or are going to have a vaccination. You should not be given certain types of vaccines while using risankizumab.

If you are not sure, talk to your doctor, pharmacist or nurse before and during the use of risankizumab.

Pregnancy, breast-feeding and contraception
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. This is because it is not known how this medicine will affect the baby.

If you are a woman who can become pregnant, you should use contraception while using this medicine and for at least 21 weeks after your last dose of risankizumab.

If you are breast-feeding or are planning to breast-feed, talk to your doctor before using this medicine.

Driving, cycling and using machines
Risankizumab is not likely to affect your driving and use of machines.

Risankizumab contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

- **How risankizumab will be given**

You will begin treatment with risankizumab with a starting dose which will be given by your doctor or nurse through a drip in your arm (intravenous infusion).

Starting doses

	How much?	**When?**
Starting doses	600 mg (2 x 300 mg)	When your doctor tells you
	600 mg (2 x 300 mg)	4 weeks after 1st dose
	600 mg (2 x 300 mg)	4 weeks after 2nd dose

Afterwards, you will receive risankizumab as an injection under your skin. See treatment protocol information for patients for risankizumab 90 mg solution for injection in pre-filled syringe.

Maintenance doses

	How much?	**When?**
1st maintenance dose	360 mg (4 x 90 mg)	4 weeks after the last starting dose (at Week 12)

Further doses	360 mg (4 x 90 mg)	Every 8 weeks, starting after the 1st maintenance dose

If you forget to use risankizumab
If you forget or miss the appointment for any of your doses, contact your doctor to reschedule your appointment as soon as you remember.

If you stop using risankizumab
Do not stop using risankizumab without talking to your doctor first. If you stop treatment, your symptoms may come back.

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

- **Possible side effects**

Like all medicines, risankizumab can cause side effects, although not everybody gets them.

Serious side effects
Talk to your doctor or get medical help immediately if you have symptoms of a serious infection such as
- fever, flu-like symptoms, night sweats
- feeling tired or short of breath, cough which will not go away
- warm, red and painful skin, or a painful skin rash with blisters

Your doctor will decide if you can keep using risankizumab.

Other side effects
Talk to your doctor, pharmacist or nurse if you notice any of the following side effects:

Very common: may affect more than 1 in 10 people
- upper respiratory infections with symptoms such as sore throat and stuffy nose

Common: may affect up to 1 in 10 people
- feeling tired
- fungal skin infection
- injection site reactions (such as redness or pain)
- itching
- headache

Uncommon: may affect up to 1 in 100 people
- small raised red bumps on the skin

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. You should also report any side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple AppStore.

- **How to store risankizumab**

Risankizumab 300 mg concentrate for solution for infusion is given in a hospital or clinic and patients should not need to store or handle it.

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 vial label and outer carton after 'EXP'.

Store in a refrigerator (2°C - 8°C). Do not freeze.

Keep the vial in the original carton in order to protect from light.

Do not shake the risankizumab vial. Prolonged vigorous shaking can damage the medicine.

Do not use this medicine if the liquid is cloudy or contains flakes or large particles.

Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment.

- **Contents of the pack and other information**

What risankizumab contains

- The active substance is risankizumab. Each vial contains 300 mg of risankizumab in 3.33 mL solution.
- The other ingredients are succinic acid, disodium succinate hexahydrate, sorbitol, polysorbate 20 and water for injections.

What risankizumab looks like and contents of the pack

Risankizumab is a clear and colourless to slightly yellow liquid in a vial. The liquid may contain tiny white or clear particles.

Each pack contains 1 vial.

Scientific Opinion Holder

AbbVie Ltd
Maidenhead
SL6 4UB
UK

Manufacturer

AbbVie Deutschland GmbH & Co. KG
Knollstrasse, 67061
Ludwigshafen
Germany

This protocol was revised April 2022

Information for the patient

Risankizumab 90 mg solution for injection in pre-filled syringe

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side-effects 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.

- 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.
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How risankizumab works

This medicine works by stopping a protein in the body called 'IL-23', which causes inflammation.

Crohn's disease is an inflammatory disease of the digestive tract. If you have active Crohn's disease you will first be given other medicines. If these medicines do not work well enough, you will be given risankizumab to treat your Crohn's disease.

Risankizumab reduces the inflammation and can therefore help to reduce the signs and symptoms of your disease.

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

You should not be given risankizumab
- if you are allergic to risankizumab or any of the other ingredients of this medicine (listed in section 6).
- if you have an infection, including active tuberculosis, which your doctor thinks is important.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before and during the use of risankizumab
- if you currently have an infection or if you have an infection that keeps coming back.
- if you have tuberculosis (TB).
- if you have recently received or plan to receive an immunisation (vaccine). You should not be given certain types of vaccines while using risankizumab.

It is important that your doctor or nurse keep a record of the batch number of your risankizumab.
Every time you get a new pack of risankizumab, your doctor or nurse must note down the date and the batch number (which is on the packaging after "Lot").

<u>Allergic reactions</u>
Tell your doctor or seek medical help immediately if you notice any signs of an allergic reaction while you are taking risankizumab such as
- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

Children and adolescents
Risankizumab is not recommended for children and adolescents under 16 years of age. This is because

risankizumab has not been studied in this age group.

Other medicines and risankizumab
Tell your doctor, pharmacist or nurse

- if you are using, have recently used or might use any other medicines.
- if you have recently had or are going to have a vaccination. You should not be given certain types of vaccines while using risankizumab.

If you are not sure, talk to your doctor, pharmacist or nurse before and during the use of risankizumab.

Pregnancy, breast-feeding and contraception
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. This is because it is not known how this medicine will affect the baby.

If you are a woman who can become pregnant, you should use contraception while using this medicine and for at least 21 weeks after your last dose of risankizumab.

If you are breast-feeding or are planning to breast-feed, talk to your doctor before using this medicine.

Driving, cycling and using machines
Risankizumab is not likely to affect your driving and use of machines.

Risankizumab contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

3. How risankizumab will be given

You will begin treatment with risankizumab with a starting dose which will be given by your doctor or nurse through a drip in your arm (intravenous infusion).

Starting doses

	How much?	**When?**
Starting doses	600 mg (2 x 300 mg)	When your doctor tells you
	600 mg (2 x 300 mg)	4 weeks after 1st dose
	600 mg (2 x 300 mg)	4 weeks after 2nd dose

Afterwards, you will receive risankizumab as an injection under your skin.

Maintenance doses

	How much?	**When?**
1st maintenance dose	360 mg (4 x 90 mg)	4 weeks after the last starting dose (at Week 12)
Further doses	360 mg (4 x 90 mg)	Every 8 weeks, starting after the 1st maintenance dose

If you forget to use risankizumab
If you forget or miss the appointment for any of your doses, contact your doctor to reschedule your appointment as soon as you remember.

If you stop using risankizumab
Do not stop using risankizumab without talking to your doctor first. If you stop treatment, your symptoms may come back.

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, risankizumab can cause side effects, although not everybody gets them.

Serious side effects
Talk to your doctor or get medical help immediately if you have symptoms of a serious infection such as
- fever, flu-like symptoms, night sweats
- feeling tired or short of breath, cough which will not go away
- warm, red and painful skin, or a painful skin rash with blisters

Your doctor will decide if you can keep using risankizumab.

Other side effects
Talk to your doctor, pharmacist or nurse if you notice any of the following side effects:

Very common: may affect more than 1 in 10 people
- upper respiratory infections with symptoms such as sore throat and stuffy nose

Common: may affect up to 1 in 10 people
- feeling tired
- fungal skin infection
- injection site reactions (such as redness or pain)
- itching
- headache

Uncommon: may affect up to 1 in 100 people
- small raised red bumps on the skin

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. You should also report any side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple AppStore.

5. How to store risankizumab

Risankizumab 90 mg solution for injection in pre-filled syringe is given in a hospital or clinic and patients should not need to store or handle it.

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 syringe label and outer carton after 'EXP'.

Store in a refrigerator (2°C - 8°C). Do not freeze.

Keep the pre-filled syringes in the original carton in order to protect from light.

Do not use this medicine if the liquid is cloudy or contains flakes or large particles.

Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment.

6. Contents of the pack and other information

What risankizumab contains
- The active substance is risankizumab. Each pre-filled syringe contains 90 mg of risankizumab in 1 mL solution.
- The other ingredients are succinic acid, disodium succinate hexahydrate, sorbitol, polysorbate 20 and water for injections.

What risankizumab looks like and contents of the pack
Risankizumab is a clear and colourless to slightly yellow liquid in a pre-filled syringe with needle shield. The liquid may contain tiny white or clear particles.

Each pack contains 1 pre-filled syringe.

Scientific Opinion Holder

AbbVie Ltd
Maidenhead
SL6 4UB
UK

Manufacturer

AbbVie Deutschland GmbH & Co. KG
Knollstrasse, 67061
Ludwigshafen
Germany

This protocol was revised April 2022

Additional information

Informed Consent Form

All patients will have the Early Access to Medicine Scheme (EAMS) explained to them by their doctor, using the informed consent form. You will be asked to sign this form and a copy will be given to you to keep.

Patient data to be collected

Patient data collected during the scheme are mostly used for safety surveillance and cannot replace a proper clinical trial to support a marketing authorisation. These data are required by the Medicines and Healthcare products Regulatory Agency (MHRA) to help verify that the patient's 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 patient's initials, year of birth, gender, diagnosis and severity of Crohn's disease based on clinical assessment, previous medical history, dose and duration of previous treatment, comorbidities, and concomitant medications including dose and duration

No other additional data will be collected which relates to you personally.

Contact information

Contact Details for reporting Adverse Events:

Name: Abbvie UK Pharmacovigilance

Telephone: 01628 561092

Email: GBPV@abbvie.com

Contact Details for the EAMS programme (excluding Adverse Event reporting):

Name: Clinigen

Telephone: 01932 824 100

Email: medicineaccess@clinigengroup.com

Contact Details for Medical Information:

Name: Abbvie UK Medical Information

Telephone: 01628 561092

Email: ukmedinfo@abbvie.com