Medicines & Healthcare products Regulatory Agency

MHRA

EAMS 04425/0002 isatuximab

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 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 that manufactures the medicine. This medicine does not yet have a drug license (also called a marketing authorisation). More information about medicines licensing can be found here: http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformationforconsumers/MymedicineFromlaboratorytopharmacyshelf/Licensingmarketingauthorisation/index.htm

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.

Information for the patient:

Isatuximab 20mg/ mL concentrate for solution for infusion

Isatuximab

▼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 start using 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 isatuximab is and what it is used for

What isatuximab is
Isatuximab is an anti-cancer medicine that contains the active substance isatuximab. It belongs to a group of medicines called "monoclonal antibodies". Monoclonal antibodies, such as isatuximab, are proteins that have been designed to recognise and attach themselves to the cancer cells, and help your immune system (the natural defences of your body) destroy the cancer cells.

What is isatuximab used for
For the purpose of this Early Access to Medicines Scheme (EAMS), isatuximab is used together with other medicines called pomalidomide and dexamethasone. The treatment is for patients with multiple myeloma who have received at least 3 previous lines of therapy including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on the last therapy.

If you have any questions on how isatuximab works or why you will be treated with isatuximab, ask your doctor.

2. What you need to know before you use isatuximab

Do not use isatuximab if:
- if you are allergic to isatuximab or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or nurse before using isatuximab and follow all instructions carefully.

Infusion reactions
Tell your doctor or nurse immediately if you have signs of infusion reactions during or after the infusion of isatuximab - see in section 4 for the list of signs of 'Infusion reactions'.

- Before starting a isatuximab infusion, you may be given medicines to reduce infusion reactions (see section 3).
- These reactions can happen during the isatuximab infusion or after the infusion. These reactions are reversible. The hospital staff will monitor you closely during treatment.
- If you get an infusion reaction, your doctor or nurse may decide to give you additional medicines to treat your symptoms and prevent complications, or temporarily stop, slow down, or completely stop the isatuximab infusion.

Decreased fever and low number of white blood cells
Tell your doctor or nurse immediately if you develop fever. Isatuximab can lower the number of white blood cells, which are important in fighting infections.

Blood transfusion
If you need a blood transfusion,

- You will have a blood test first to match your blood type.
- Isatuximab can affect the results of this blood test.
  Tell the person doing the test that you are using isatuximab.

Children and adolescents
Isatuximab is not recommended for use in children and adolescents aged under 18 years. This is because this medicine has not been tested in this age group.

Other medicines and isatuximab
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines you can get without a prescription, and herbal medicines.

Before starting isatuximab, you must also read the package leaflet of all medicines taken together with isatuximab – to find information related to these medicines.

Pregnancy , breast-feeding and contraception
<u>Pregnancy</u>
Ask your doctor, pharmacist or nurse for advice before using isatuximab.
Use of isatuximab is not recommended during pregnancy. If you are pregnant or planning to become pregnant, talk to your doctor about using isatuximab.

For information on pregnancy and other medicinal products that are taken with isatuximab, please look at the package leaflet for these other medicinal products.

<u>Breast-feeding</u>
Ask your doctor, pharmacist or nurse for advice before using isatuximab.

- This is because isatuximab may pass into the breast milk. It is not known how it could affect the baby.
- You and your doctor will decide if the benefit of breastfeeding is greater than the risk to your baby.

Contraception
Women who are using isatuximab and are able to become pregnant must use an effective method of contraception. Use contraception during treatment - and for 5 months after the last dose of isatuximab.

Driving and using machines
Isatuximab is not expected to affect your ability to drive or use machines. If you have any side effects of this medicine, do not drive or use machines. Firsttalk to your doctor, pharmacist or nurse.

3. How to use isatuximab

How much isatuximab is given
The amount of isatuximab you will be given will be calculated based on how much you wiegh. The recommended dose is 10 mg of isatuximab per kilogram of your body weight.

How isatuximab is given
Your doctor or nurse will give you isatuximab into a vein (intravenously) as a drip infusion.

How often isatuximab is given
Isatuximab is used in treatment cycles of 28 days (4 weeks). It is given together with two other medicines called “pomalidomide” and “dexamethasone”.
- In cycle 1: isatuximab is given once a week on days 1, 8, 15 and 22
- In cycle 2 and beyond: isatuximab is given every 2 weeks on day 1 and 15

Your doctor will continue to treat you with isatuximab as long as you benefit from it and tolerate the possible side effects.

Medicines given before isatuximab
You must have the following medicines before infusion of isatuximab. This is to help reduce your chances of getting possible infusion reactions:
- medicines to reduce allergic reactions (anti-histamine)
- medicines to reduce inflammation (corticosteroids)
- medicines to reduce pain and fever

If you miss a dose of isatuximab
It is very important that you go to all your appointmentss to make sure your treatment works. If you miss any appointments, call your doctor or nurse as soon as possible to reschedule your appointment.

Your doctor or nurse will decide how your treatment should be continued.

If you are given more isatuximab than you should
Isatuximab will be given to you by your doctor or nurse. If you are accidentally given too much (an overdose), your doctor will treat and monitor your side effects.

If you stop using isatuximab
Do not stop your treatment with isatuximab unless you have discussed that with your doctor.

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.

Your doctor will discuss the side effects of isatuximab with you and will explain the possible risks and benefits of your treatment with isatuximab.

The hospital staff will monitor your condition closely during treatment. Tell them immediately if you notice any of the effects below.

Infusion reactions - Very common (may affect more than 1 in 10 people):

Tell your doctor or nurse immediately if you have signs of infusion reaction during or after the infusion of isatuximab.

The most common signs of infusion reaction include:

- feeling short of breath
- cough
- chills
- nausea

The most common severe signs of infusion reaction include:

- high blood pressure (hypertension)
- feeling short of breath

You may also have other symptoms may occur as well during the infusion. Your doctor or nurse may decide to temporarily stop, slow down, or completely stop the isatuximab infusion. They mayalso decide to give you additional medicines to treat your symptoms and prevent complications.

Other side effects

Talk to your doctor, pharmacist or nurse immediately if you have any of the side effects listed below

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

- lower number of red blood cells (anaemia)
- lower number of some white blood cells (neutrophils or lymphocytes which are important in fighting infection)
- lower number of blood platelets (thrombocytopenia)-tell your doctor or nurse if you have any unusual bruising or bleeding.
- infection of the lungs (pneumonia)
- infection of the airways (such as nose, sinuses or throat)
- diarrhoea
- bronchitis
- feeling short of breath
- nausea
- fever with a severe decrease in some white blood cells (febrile neutropenia) (see section 2 for further details)
- vomiting

Common (may affect up to1 in 10 people):

- decreased appetite
- weight loss

If any of the above apply to you, or you are not sure, talk to your doctor, pharmacist or nurse immediately.

5. How to store isatuximab

Isatuximab will be stored at the hospital or clinic.

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 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.

Medicines should not be disposed of via wastewater. Your doctor, pharmacist or nurse will throw away any medicines that are no longer being used. These measures will help protect the environment.

6. Contents of the pack and other information

What isatuximab contains

- The active substance of isatuximab is isatuximab.
- One mL of concentrate contains 20 mg of isatuximab.
- Each vial of concentrate contains 100 mg or 500 mg of isatuximab.
- The other ingredients (excipients) are sucrose, histidine hydrochoride monohydrate, histidine, polysorbate 80, and Water for injection.

What isatuximab looks like and contents of the pack

Isatuximab is a concentrate for solution for infusion and is a colourless to slightly yellow liquid, essentially free of visible particles. Isatuximab is supplied as a carton pack containing 1 glass vial.

Scientific Opinion Holder

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Additional information:

Before treatment starts, you will have the scheme explained to you using the **Informed Consent Form**. You will be asked to sign this document and will be given a copy to keep.

You will also be issued with a Patient Alert Card. This is a wallet-card sized and must be carried with you at all times until 6 months after you have discontinued your isatuximab treatment. It alerts any other healthcare professional that may treat you that you are receiving isatuximab through an early access scheme, and provides information about your healthcare professional out of hours contact details and the Company's contact information.

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