

sanofi

UNDERSTANDING YOUR TREATMENT

SARCLISA® ▼ (ISATUXIMAB)

Us +
You™

This information booklet has been produced by Sanofi for patients prescribed isatuximab in combination with pomalidomide and dexamethasone (Pd). Note: Sarclisa is the brand name for 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 that you may get. See yellowcard.mhra.gov.uk for how to report side effects.

For further information on isatuximab in combination with pomalidomide and dexamethasone, please read the Patient Information Leaflet (PIL) which can be found at: <https://www.medicines.org.uk/emc/files/pil.11535.pdf>. Last accessed May 2023

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WHO IS THIS GUIDE FOR?

This booklet is for patients with relapsed and refractory multiple myeloma (MM) who have been prescribed isatuximab in combination with pomalidomide and dexamethasone (Pd), and their families and carers.

It provides information about your treatment with isatuximab in combination with Pd, how it is used and what to expect during treatment. If you have any questions after reading this booklet, please speak to your healthcare team.

Other sources of information that you may find useful have also been provided in this booklet (see page 22).

YOUR PATIENT CARD

When you were prescribed isatuximab in combination with Pd, your doctor or nurse should have provided you with a patient card. This card contains important safety information about your treatment that your doctors and nurses, or other healthcare providers, need to be aware of during, and after, your treatment with isatuximab in combination with Pd.

You need to carry your patient card with you at all times, and until 6 months after your last infusion of isatuximab.

If you have not yet received your patient card, or are unsure about how to use it, speak to your healthcare team.

WHAT IS ISATUXIMAB?

Isatuximab in combination with Pd is used to treat patients with relapsed and refractory MM who have had at least two treatments for MM, including lenalidomide and a proteasome inhibitor, whose MM has returned or stopped responding to treatment.

Isatuximab in combination with Pd is not recommended for use in children and adolescents aged under 18 years.



**A TARGETED
MONOCLONAL
ANTIBODY, A TYPE OF
IMMUNOTHERAPY.**

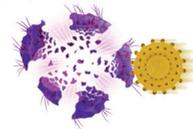
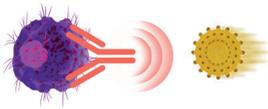
ISATUXIMAB: TARGETED MONOCLONAL ANTIBODY THERAPY

ISATUXIMAB CAN HELP STOP THE SPREAD OF MM

It is a treatment called a monoclonal antibody, a type of immunotherapy, that works with your body's immune system. Isatuximab is able to 'find and bind' to myeloma cells to help control and limit your MM from progressing.

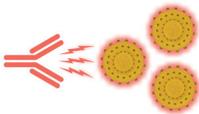
ISATUXIMAB WORKS TO HELP STOP THE SPREAD OF MM IN 3 WAYS

FINDS AND BINDS



Isatuximab can find and bind to myeloma cells, exposing them for elimination by your immune system.

BOOSTS YOUR IMMUNE SYSTEM



Isatuximab can help boost your immune system, making it harder for myeloma cells to survive.

DIRECTLY KILLS



Along with engaging your immune system, Isatuximab can also kill myeloma cells directly.



Isatuximab



Immune system cells

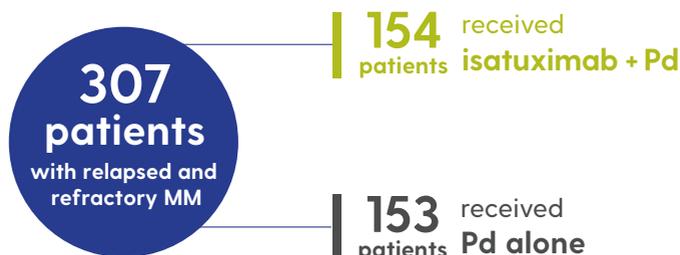


Myeloma cell

HOW WAS ISATUXIMAB STUDIED?

ISATUXIMAB GIVEN IN COMBINATION WITH Pd WAS APPROVED BASED ON A LARGE PHASE 3 STUDY

In this study, patients were given isatuximab together with Pd and compared to patients who were given Pd alone. Patients in the trial had relapsed and refractory multiple myeloma (MM) and had received at least two prior lines of treatment for MM, including lenalidomide and a medicine called a proteasome inhibitor (PI).



THE GOALS OF THE STUDY

The main goal of the isatuximab in combination with Pd study was to measure the amount of time a patient lives with MM without it worsening or returning. This is commonly referred to as **progression-free survival**.

Another goal was to measure how many patients **responded positively to treatment**. A positive response to treatment means a decrease in the number of myeloma cells in the bone marrow.

❗ WHAT IS A PHASE 3 STUDY?

Treatments for cancer are often approved based on Phase 3 clinical studies. Generally, Phase 3 studies in cancer:

- Have a large number of patients
- Compare the safety and effectiveness of the new treatment to a current standard treatment
- Measure survival or progression-free survival

For further information on isatuximab in combination with pomalidomide and dexamethasone, please read the Patient Information Leaflet (PIL) which can be found at: <https://www.medicines.org.uk/emc/files/pil.11535.pdf>

ISATUXIMAB IN COMBINATION WITH PD WAS STUDIED IN A WIDE RANGE OF PATIENTS WITH RELAPSED AND REFRACTORY MM

ABOUT PATIENTS IN THE ISATUXIMAB IN COMBINATION WITH PD STUDY



48% were female, 52% were male, and 60% were 65 years of age or older



56% had previously received a stem cell transplant and 44% had not



Nearly everyone in the trial stopped responding to their previous line of treatment

SOME PATIENTS IN THE STUDY HAD OTHER MEDICAL CONDITIONS IN ADDITION TO RELAPSED AND REFRACTORY MM



11% had a history of asthma or chronic obstructive pulmonary disease (COPD)



36% had impaired kidney function

Talk to your doctor or nurse specialist to learn more about the goals of treatment and the range of patients with MM included in the Phase 3 study for isatuximab in combination with Pd.

YOUR TREATMENT WITH ISATUXIMAB

ISATUXIMAB IS GIVEN BY AN INTRAVENOUS (IV) INFUSION

Isatuximab is given in four-week treatment periods, called cycles:

- For the first cycle, you will receive isatuximab once a week
- After the first cycle, you will receive isatuximab once every two weeks

YOU RECEIVE FEWER INFUSIONS AFTER THE FIRST TREATMENT CYCLE



CYCLE 1 (WEEKS 1-4)
ONCE A WEEK



CYCLE 2 AND BEYOND (WEEK 5 ONWARDS)
ONCE EVERY TWO WEEKS

THE SCHEDULE FOR OTHER MEDICINES GIVEN WITH ISATUXIMAB:*

- Pomalidomide is a tablet, which you take once a day on days one to 21 of every four-week cycle
- Dexamethasone is taken once a week as a tablet or it may be given intravenously
- Talk to your healthcare team about how isatuximab is given together with pomalidomide and dexamethasone

In order for isatuximab to work properly, it's important that you receive treatment at the right time. If you miss an infusion, call your healthcare team to reschedule your appointment as soon as possible.

*For information about pomalidomide and dexamethasone, please refer to the Patient Information Leaflet (PIL) for each product. These can be found at: <https://www.medicines.org.uk/emc/>

INFUSION TIMES MAY GET SHORTER AS TREATMENT CONTINUES

ESTIMATED INFUSION TIMES FOR ISATUXIMAB

First infusion



Second infusion



Following infusions



Because isatuximab is given as an IV infusion, something called an infusion reaction can occur. Infusion reactions can happen during or after a isatuximab infusion. Infusion times may need to be longer if you experience an infusion reaction while receiving isatuximab.

- Infusion reactions are reversible, and you will be monitored during your treatment by a healthcare team
- You may be given medicines before your isatuximab infusion to help prevent or reduce possible infusion reactions
- See page 18 for information about the signs of an infusion reaction and tell your healthcare team immediately if you feel unwell during or after a isatuximab infusion

In the clinical study, nearly all of the patients who had infusion reactions experienced them during their first isatuximab infusion. These reactions resolved on the same day in most patients.[†]

[†]In the study, three patients also had infusion reactions at their second infusion and two patients had infusion reactions at their fourth infusion.

ABOUT YOUR ISATUXIMAB INFUSIONS

MATCHING YOUR BLOOD TYPE



Your doctor may order a test to match your blood type in case you need a blood transfusion during treatment. Isatuximab may affect the results of this test, so your blood type should be matched before you start treatment.

BEFORE YOUR ISATUXIMAB INFUSION



Infusion reactions can happen during or after an infusion of isatuximab. Before each infusion, you may receive other medicines to help reduce your chances of having infusion reactions.

These include:

- Antihistamines to reduce allergic reactions
- Corticosteroids to reduce inflammation
- Medicines to reduce pain and fever

Tell your doctor or nurse right away if you feel unwell during or after an infusion of isatuximab.

If you do not experience an infusion reaction during or after your first four infusions of isatuximab, your doctor may reconsider your need to continue receiving these medicines.

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



PREPARING FOR YOUR INFUSIONS

PLAN AHEAD TO HELP MAKE YOUR EXPERIENCE MORE COMFORTABLE



Eat a healthy meal before your appointment – you may want to avoid fried or spicy foods. You may also want to bring a snack in case you get hungry during your infusion.



It's important to stay hydrated during your infusion. Make sure to drink plenty of fluids before your appointment and bring something with you to drink.



Wear comfortable clothing and consider bringing a blanket, pillow, or anything else that would help you feel at ease.



Take along a book, tablet, music, or anything to help pass the time.



Consider bringing this guide with you, including a list of questions you may have for your healthcare team.



**BEFORE
YOU RECEIVE
ISATUXIMAB**

You must not be given isatuximab if you are allergic to it or any of the other ingredients of this medicine (listed on the next page).

OTHER MEDICINES

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

PREGNANCY AND BREASTFEEDING

Treatment with isatuximab is not recommended during pregnancy. If you are pregnant or planning to become pregnant, talk to your doctor about receiving isatuximab.

Women who are receiving 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.

If you are currently breastfeeding, talk to your doctor, pharmacist, or nurse before receiving isatuximab:

- This is because isatuximab may pass into 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

DRIVING AND USING MACHINES

While isatuximab has no or a negligible effect on your ability to drive or use machines, isatuximab is used with other medicines that may affect your ability to perform these activities. Please refer to the package leaflets from the other medicines you take with isatuximab or discuss with your doctor or pharmacist.

WHAT ISATUXIMAB CONTAINS

Isatuximab is the active ingredient. The other ingredients are sucrose, histidine hydrochloride monohydrate, histidine, polysorbate 80, and water for injections. Tell your doctor or nurse if you know you are allergic to any of these ingredients.

BEFORE YOU RECEIVE ISATUXIMAB (cont'd)

POSSIBLE SIDE EFFECTS OF ISATUXIMAB

Like all medicines, isatuximab can cause side effects, although not everybody gets them. Your healthcare team will discuss the side effects of isatuximab with you and will explain the possible risks and benefits of your treatment with isatuximab.

Your condition will be monitored closely during treatment. Tell a healthcare professional immediately if you notice any of the following side effects.

INFUSION REACTIONS

Infusion reactions are common (around 4/10 patients had infusion reactions in the clinical study) and can happen during or after an infusion of isatuximab.

Infusion reactions are reversible, and you will be monitored closely during treatment by a healthcare professional.

Before your infusion, you may be given medicines to reduce the possibility of having an infusion reaction (see page 12 for more information).

THE MOST COMMON SIGNS OF AN INFUSION REACTION ARE:

- Chills
- Cough
- Feeling short of breath
- Nausea

SEVERE SIGNS OF AN INFUSION REACTION ARE:

- Feeling short of breath
- High blood pressure
- Serious allergic reaction (anaphylactic reaction affecting up to 1 in 100 people) with breathing difficulty and swelling of the face, mouth, throat, lips or tongue

Tell your doctor or nurse immediately if you feel unwell during or after an infusion of isatuximab. If you have an infusion reaction or other side effects during an infusion, your doctor or nurse may decide to slow down, temporarily stop, or completely stop the infusion. They may also give you additional medicines to treat your symptoms and prevent complications.

LOW NUMBER OF WHITE BLOOD CELLS

Isatuximab can lower the number of white blood cells in your body, which are important in fighting infections. Tell your doctor or nurse immediately if you develop a fever, as it may be a sign of infection.

RISK OF NEW CANCERS

New cancers have occurred in patients during treatment with isatuximab in combination with Pd. Your doctor or nurse will be able to discuss this risk with you before starting treatment and will monitor you for new cancers during your treatment.

TUMOUR LYSIS SYNDROME

A fast breakdown of cancer cells (tumour lysis syndrome) may occur. Symptoms may include irregular heartbeat, seizures (fits), confusion, muscle cramps, or decrease in urine output. Contact your doctor immediately if you experience any of these symptoms.

VERY COMMON SIDE EFFECTS

(may affect **more than** 1/10 patients)



Neutropenia

(lower number of some white blood cells, which are important in fighting infection)

Febrile neutropenia

(fever with a severe decrease in some white blood cells)

Anaemia

(lower number of red blood cells)

Thrombocytopenia

(lower number of blood platelets – tell your doctor or nurse if you have any unusual bruising or bleeding)



Dyspnoea

(feeling short of breath)



Pneumonia

(infection of the lungs)

Upper respiratory tract infection

(infection of the airways, such as nose, sinuses or throat)

Bronchitis



Nausea (feeling sick)

Vomiting

Diarrhoea



Infusion reaction

COMMON SIDE EFFECTS

(may affect **up to** 1/10 patients)



Decreased appetite

Weight loss



Skin squamous cell carcinoma

(a type of skin cancer)



Atrial fibrillation

(irregular heartbeat)



Herpes zoster

(shingles)

If you get any side effects, talk to your doctor, nurse or other members of your healthcare team. This includes any possible side effects not listed here.

**WHEN IT COMES TO
YOUR HEALTH, YOUR
VOICE MATTERS**

YOUR DOCTOR OR NURSE MAY KNOW WHAT'S BEST FOR YOUR HEALTH, HOWEVER ONLY YOU KNOW HOW YOU FEEL

Your doctor and nurse are the most important resource you have for information and guidance throughout your treatment journey. But, you play an important role in your care too. That's why it can be helpful to stay in regular contact with your healthcare team.

- Try keeping a journal to write down how you feel, especially in between treatments and appointments. This information can help your doctor or nurse provide you with the best care
- You may also have questions. Don't hesitate to ask your healthcare team about anything you are uncertain about or want to understand better

QUESTIONS YOU MAY WANT TO ASK YOUR DOCTOR

- How long will I receive treatment with isatuximab in combination with Pd?
- How will I know if my treatment is working?
- Are there follow-up tests after I begin treatment?
- How does isatuximab work with the other medicines I receive?
- What side effects should I be aware of?
- If I have side effects, what can be done about them?
- Can I exercise while I'm receiving treatment?
- Can I continue to work while I receive treatment?
- Can I travel while I receive treatment?

You may find it helpful to take notes at your next appointment. There is a notes section at the end of this booklet for you to use if you would like.

FURTHER ADVICE, HELP AND SUPPORT

RESOURCES

Please visit our dedicated isatuximab patient website via:

www.sanofioncology.co.uk/en/patients/isatuximab



INFORMATION AND PRACTICAL SUPPORT FOR PATIENTS WITH MM, AND THEIR FAMILIES AND FRIENDS CAN BE PROVIDED BY SPECIALIST ORGANISATIONS, SUCH AS MYELOMA UK.

MYELOMA UK:

Myeloma UK is the only organisation in the UK dealing exclusively with myeloma. Through their website you can find accessible information about myeloma, access to help and support for patients and carers, information about MM support groups and discussion forums.

<https://www.myeloma.org.uk>

PATIENT INFORMATION LEAFLET:

For further information on isatuximab in combination with pomalidomide and dexamethasone, please read the patient information leaflet via:

<https://www.medicines.org.uk/emc/files/pil.11535.pdf>

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If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.