ISATUXIMAB

PATIENT CARD

DEAR PATIENT RECEIVING SARCLISA (ISATUXIMAB)

- Provide this card to healthcare providers before blood transfusion.
- Keep this card with you at all times and until at least 6 months after the last dose of isatuximab.
- .You can help by reporting any side effects you may get. If you notice any side effects, talk to your doctor or pharmacist. You can also report side effects directly at http://www.medicinesauthority.gov.mt/adrportal and sent by email to ostlicensing.medicinesauthority@gov.mtAdverse . Side effects should also be reported to SANOFI PharmaocovigilanceMalta@sanofi.com
- By reporting side effects, you can help provide more information on the safety of this medicine.

For further information on isatuximab, you can consult the Package Leaflet (PL).

WARNING FOR HEALTHCARE PROVIDERS

- Please note this patient is receiving treatment with SARCLISA (isatuximab).
- This patient card contains important safety information that you need to be aware of before, during, and after treatment with isatuximab.
- Treatment with isatuximab binds to CD38 on red blood cells (RBCs) and is associated with a Risk of Interference with blood typing (positive indirect Coombs Test), which may persist for at least 6 months after the last isatuximab infusion.
- To avoid potential problems with RBC transfusion, you should perform blood type and screen tests prior to the first infusion of isatuximab. Phenotyping may be considered as per local practice.
- If treatment with isatuximab has already started and in the event of a planned transfusion, you should notify the blood bank that the patient is receiving isatuximab and its risk of Interference with Indirect Antiglobulin Tests.
- For additional information on isatuximab, please refer to the Summary of Product Characteristics (SmPC).

MY INFORMATION

Patient's name:

Patient's date of birth (DD / MMM / YYYY) : _____/ _____/ _____

Patient's phone:

Emergency contact (name):

Emergency contact (phone):

MY TREATMENT DETAILS

Please complete this section or ask your doctor to do it.

Isatuximab recommended dose of 10 mg/kg and dosing schedule As per indication

Start date (DD / MMM / YYYY): _____/ _____/ _____

End date NA (DD / MMM / YYYY): _____/ _____/ _____

MY BLOOD RESULTS

Before starting isatuximab, the results of my blood test collected on: _____/ _____/ _____ (DD / MMM / YYYY)

were:

Blood type: A B AB O Rh+ Rh-

The result of my indirect antiglobulin test (indirect Coombs test) was:

Negative Positive for the following antibodies:

MY DOCTOR'S INFORMATION

In case of emergency, or if you find this card, please contact my doctor using the details below.

Doctor's name:

Doctor's phone:

Global version#3 dated Ap 2025, approved by MMA on 27 May 2025 https://medicinesauthority.gov.mt/rmm

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