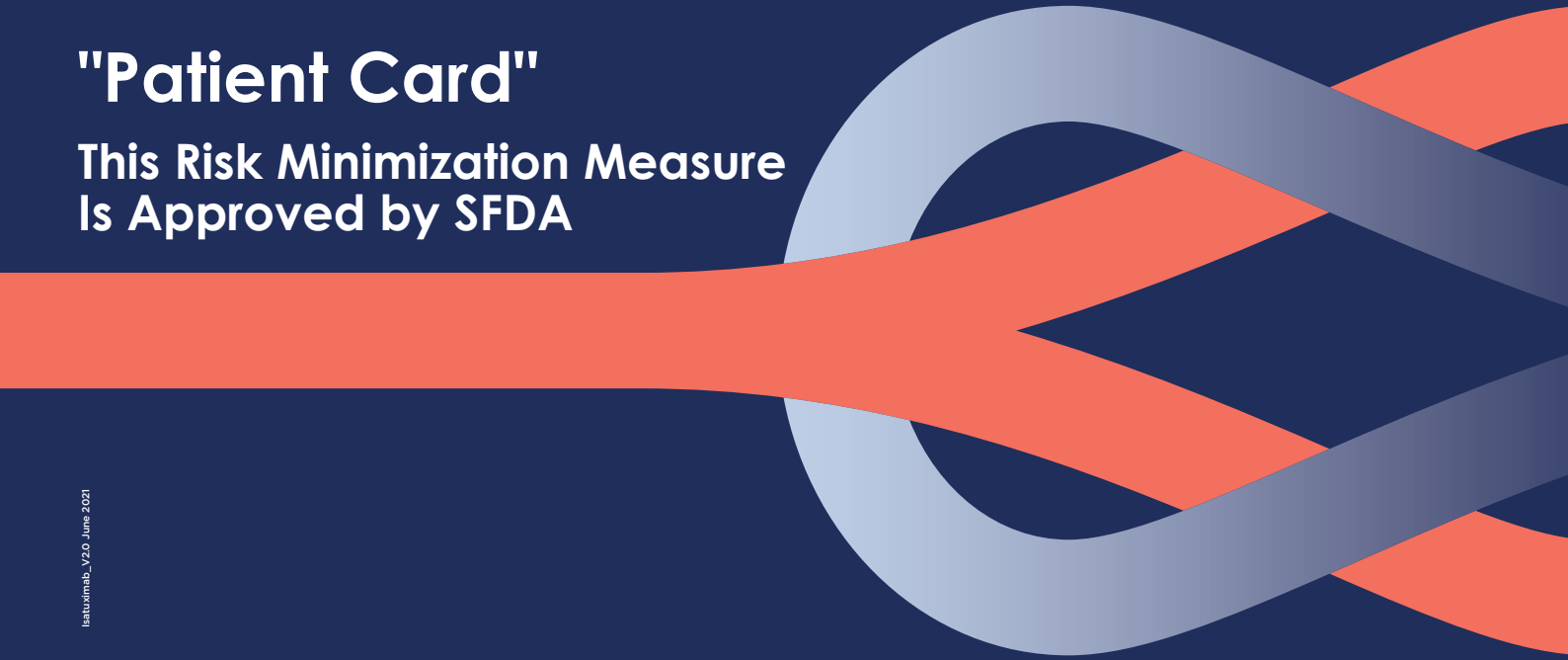
SARCLISA®
(isatuximab)

"Patient Card"

This Risk Minimization Measure Is Approved by SFDA



Isatuximab_V2.0 June 2021

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:

Cycle 1:
Treatment is once a week on Days 1,8,15 & 22

Cycle 2 and beyond:
Treatment is once every 2 weeks on Days 1&15

Start Date (DD / MMM / YYYY):

NA

End Date (DD / MMM / YYYY):

It is important to record the end date of your treatment because SARCLISA may interfere with indirect antiglobulin test (indirect Coombs test) for approximately 6 months after the last infusion.

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:

Isatuximab_V2.0 June 2021

PATIENT CARD

Dear Patient Receiving SARCLISA (Isatuximab)

- Isatuximab may interfere with the blood typing (indirect Coombs test) during the treatment and may persist for approximately 6 months after the last infusion.
- Provide this card to healthcare providers before blood transfusion.
- Keep this card with you at all times and until 6 months after the last dose of isatuximab.
- If you notice any side effects, talk to your doctor or pharmacist. Side effects should be reported to SANOFI or to the Saudi food drug authority on:

In case of any drug-related adverse events, please contact: The National Pharmacovigilance Center (NPC)
Fax: +966-11-205-7662
Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa/
For SANOFI Pharmacovigilance center, please contact: +966-544-284-797
E-mail: Ksa_pharmacovigilance@sanofi.com
For extra copies please contact (+966564095207)

- For further information on isatuximab, you can consult the patient information leaflet

Isatuximab_V2.0 June 2021

WARNING FOR HEALTHCARE PROVIDERS

- Please note that 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 risk of interference with blood typing (Positive Indirect Coombs Test), which may persist for approximately 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 blood typing tests.
- For additional information on isatuximab, please refer to the SARCLISA Summary of Product Characteristics(SPC)

Isatuximab_V2.0 June 2021

For Medical Information, please contact: +966-12-6693318
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Isatuximab_V2.0 June 2021