SARCLISA®
(isatuximab)

This Risk Minimization Measure Is Approved by SFDA

IMPORTANT INFORMATION

SARCLISA (ISATUXIMAB)

IS ASSOCIATED WITH RISK OF INTERFERENCE FOR BLOOD TYPING

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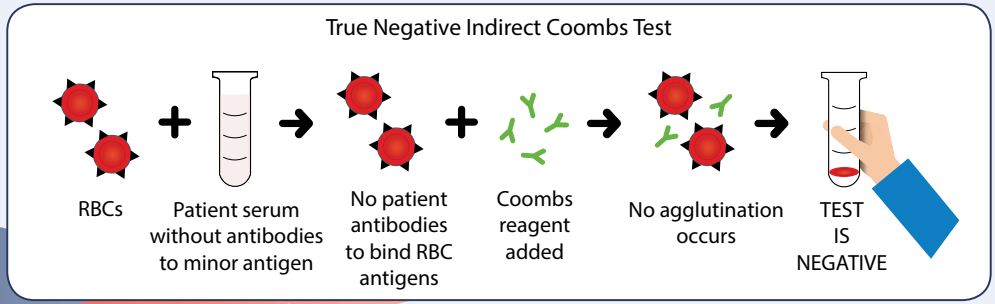
Healthcare Professionals and
Blood Banks Brochure

WARNING FOR BLOOD BANKS

- Isatuximab is bound to CD38 on red blood cells (RBCs) and may mask the detection of antibodies to minor antigens in the patient's serum. Thus, isatuximab may interfere with routine blood compatibility tests with **potential false positive reactions in indirect antiglobulin tests (indirect Coombs Tests).**
- This interference is limited to the minor blood groups and does not affect the determination of a patient's ABO and Rh blood type.
- Isatuximab interference mitigation methods include treating reagent RBCs with dithiothreitol (DTT) to disrupt isatuximab binding or other locally validated methods. Since the Kell Blood group system is also sensitive to DTT treatment, Kell-negative units should be supplied after ruling out or identifying alloantibodies using DTT-treated RBCs.
- If an emergency transfusion is required, you can give non-cross-matched ABO/Rh-compatible RBCs as per local blood bank practices.



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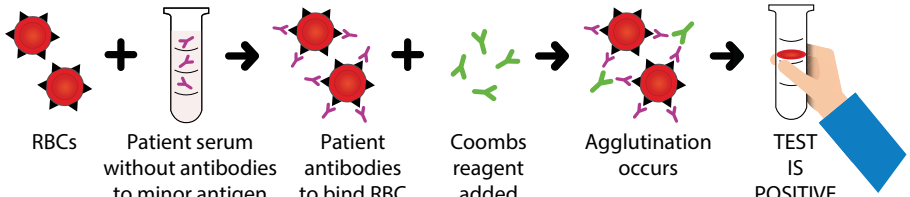
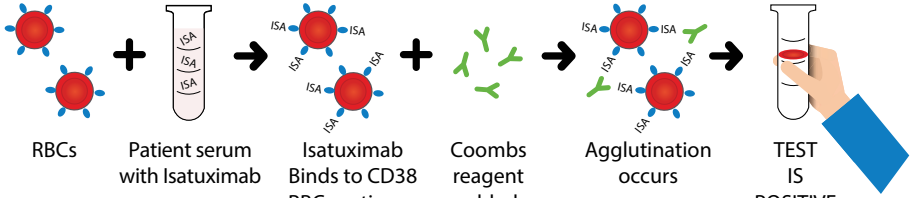
True Positive Indirect Coombs Test



Indirect Coombs Test From an Isatuximab-Treated Patient



ISA = Isatuximab = Coombs reagent = CD38 receptor = Red Blood Cells = Antibodies to minor antigen

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WARNING FOR HEALTHCARE PROFESSIONALS

Appropriate Measures to Manage Isatuximab Interference and Avoid Possible Resulting Adverse Clinical Consequences

- Conduct blood type and screen tests on your patient prior to the first infusion of isatuximab.
- Consider phenotyping prior to starting isatuximab treatment as per local practice.
- Give your patient the latest version of the **Patient Card.**
- If treatment with isatuximab has already started, inform the blood bank that the patient is receiving isatuximab.
- In the event of a planned transfusion, please notify blood transfusion centers about the risk of interference with indirect antiglobulin tests.
- There is currently no available information with regards to how long the interference with the indirect Coombs test may persist after the last infusion of isatuximab. Based on the half-life of isatuximab, it is anticipated that isatuximab mediated positive indirect Coombs test may persist for approximately 6 months after the last infusion. Therefore, please advise your patient to carry the Patient Card at all times and until 6 months after the last dose of isatuximab.
- It is important you always advise your patient to consult the Patient Information Leaflet (PIL) for further information on isatuximab.

For additional information on isatuximab refer to SARCLISA Summary of Product Characteristics (SPC).

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REPORTING OF SUSPECTED ADVERSE REACTIONS

Healthcare professionals are asked to continue to report any suspected adverse drug reactions (ADRs) to Saudi Food and Drug Authority (SFDA) and SANOFI via the following:

Saudi Food and Drug Authority 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)

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FOR TIMELY TRANSFUSIONS

REMINDER FOR HEALTHCARE PROFESSIONALS

- Conduct blood type and screen tests on your patient prior to the first infusion of isatuximab. Inform the blood bank that your patient has been treated with isatuximab which may interfere with indirect antiglobulin tests (indirect coombs tests).

- Verify standing orders for transfusions to determine if your patient received isatuximab within the last year.

- In the event of a planned transfusion, notify blood transfusion centers about the risk of interference with indirect antiglobulin tests.

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- Give your patient a Patient Card to be carried at all time and until 6 months after the last dose of isatuximab. Provide your patient's pre-isatuximab compatibility profile, if available, to the blood bank.

- Ask your patient to tell their other healthcare professionals that they have received isatuximab, particularly before a transfusion, and to show them their Patient Card.

REMINDER FOR BLOOD BANKS

- Identify the blood sample of your patient as containing isatuximab.

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