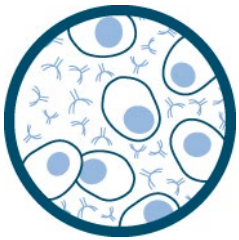


ISATUXIMAB

IMPORTANT INFORMATION

# SARCLISA (ISATUXIMAB) IS ASSOCIATED WITH RISK OF INTERFERENCE FOR BLOOD TYPING

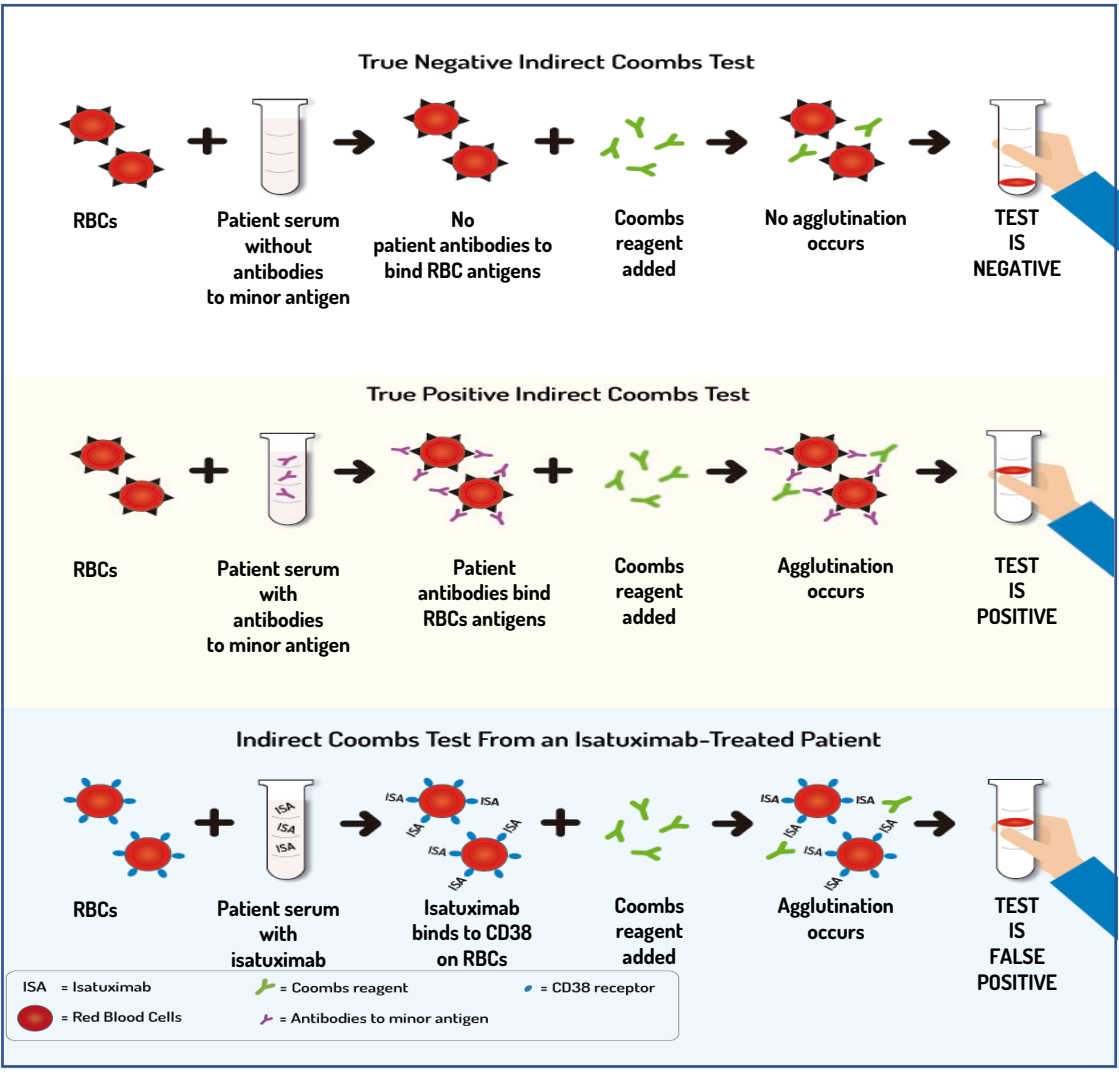
## HEALTHCARE PROFESSIONALS AND BLOOD BANKS BROCHURE

Global version#3 dated Feb 2024, Approved by MMA on 14/11/2024

sanofi

# WARNING FOR BLOOD BANKS

- Isatuximab binds to CD38 on red blood cells (RBC) and may result in a false positive indirect antiglobulin test (indirect Coomb test). 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.



# 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.
- The interference with the indirect Coombs test may persist for at least 6 months after the last infusion. Therefore, please advise your patient to carry the Patient Card at all times and until at least 6 months after the last dose of isatuximab.
- It is important you always advise your patient to consult the Package Leaflet (PL) for further information on isatuximab.

## REPORTING OF SUSPECTED ADVERSE REACTIONS

Isatuximab is subject to additional monitoring of its benefit/risk balance. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system: Report Form can be downloaded from http://www.medicinesauthority.gov.mt/adrportal and sent by email to postlicensing.medicinesauthority@gov.mtAdverse

Or to sanofi: PharmaocovigilanceMalta@sanofi.com

## ADDITIONAL RESOURCES

For additional information on isatuximab, please refer to the Summary of Product Characteristics (SmPC) or contact SANOFI by using one of the following methods:

- **Phone:** +39 02 39394275
- **Email:** Informazioni.medicoscientifiche@sanofi.com

# 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 interferes 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.

Give your patient a Patient Card to be carried at all times and until at least 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 BLANKS

Identify the blood sample of your patient as containing isatuximab.