Abbreviated Prescribing Information

Gulf Countries(UAE-KW-QA-OM):

Name and Presentation: SARCLISA 20mg/mL concentrate for solution for infusion. Each vial contains 100 mg of isatuximab in 5 mL of concentrate (100 mg/5mL) or 500 mg of isatuximab in 25 mL of concentrate (500 mg/25mL). Isatuximab is an immunoglobulin G1 (IgG1) monoclonal antibody (mAb).
Therapeutic indications:
- in combination with pomalidomide and dexamethasone, for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies including lenalidomide and a roteasome inhibitor and have demonstrated disease progression on the last therapy.
- in combination with carfilzomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.
Dosage and administration: SARCLISA should be administered by a healthcare professional, in an environment where resuscitation facilities are available. Premedication should be used 15-60 minutes prior to SARCLISA infusion with the following medicinal products to reduce the risk and severity of infusion reactions: Dexamethasone 40 mg oral or intravenous, 20 mg for patients ≥75 years of age, Acetaminophen or oral proton pump inhibitors, Diphenhydramine. The recommended dose of SARCLISA is 10 mg/kg body weight administered as an intravenous infusion in combination with pomalidomide and dexamethasone (Isa-Pd) or in combination with carfilzomib and dexamethasone (Isa-Kd) (isatuximab regimen). Dosing schedule: cycle 1: days 1, 8, 15 and 22 (weekly), cycle 2 and beyond: days 1, 15 (every 2 weeks). Each treatment cycle consists of a 28-day period.
Method of administration: SARCLISA is for intravenous use. For details on preparation and infusion rate see full SmPC.
Contraindications: Hypersensitivity to the active substance or to any of the excipients. See full SmPC for full list of excipients.
Warnings and precautions: Infusion reactions, mostly mild or moderate, have been observed in 38.2% of patients treated with SARCLISA in ICARIA-MM, and in 45.8% of patients treated with Isa-Kd in IKEMA. In ICARIAMM, all infusion reactions started during the first SARCLISA infusion and resolved on the same day in 98% of the infusions. The most common symptoms of an infusion reaction included dyspnoea, cough, chills and nausea.
The most common severe signs and symptoms included hypertension, dyspnoea, and bronchospasm. In IKEMA, the infusion reactions occurred on the infusion day in 99.2% of episodes. In patients treated with Isa-Kd, 94.4% of those experiencing an IR experienced it during the first cycle of treatment.
All infusion reactions resolved. The most common symptoms of an infusion reaction included cough, dyspnoea, nasal congestion, vomiting and nausea. The most common severe signs and symptoms included hypertension and dyspnoea. To decrease the risk and severity of infusion reactions, patients should be pre-medicated prior to SARCLISA infusion with acetaminophen, diphenhydramine or equivalent; dexamethasone is to be used as both premedication and anti-myeloma treatment. Vital signs should be frequently monitored during the entire SARCLISA infusion.
When required, interrupt SARCLISA infusion and provide appropriate medical and supportive measures. In case symptoms do not improve to grade ≤1 after interruption of SARCLISA infusion, persist or worsen despite appropriate medicinal products, require hospitalization or are life-threatening, permanently discontinue SARCLISA and institute appropriate management. Most of the grade 3-4 neutropenia have been reported as laboratory abnormalities.

In patients treated with Isa-Pd, neutropenia occurred as a laboratory abnormality in 96.1% of patients and as an adverse reaction (1) in 46.7% of patients, with Grade 3-4 neutropenia reported as a laboratory abnormality in 84.9% of patients and as an adverse reaction in 45.4% of patients. Neutropenic complications have been observed in 30.3% of patients, including 11.8% of febrile neutropenia and 25.0% of neutropenic infections.
In patients treated with Isa-Kd, neutropenia occurred as a laboratory abnormality in 54.8% of patients and as an adverse reaction (1) in 4.5% of patients, with Grade 3-4 neutropenia reported as a laboratory abnormality in 19.2% of patients (with 17.5% Grade 3 and 1.7% Grade 4) and as an adverse reaction in 4.0% of patients.
Neutropenic complications have been observed in 2.8% of patients, including 1.1% of febrile neutropenia and 1.7% of neutropenic infections Complete blood cell counts should be monitored periodically during treatment. Patients with neutropenia should be monitored for signs of infection. No dose reductions of SARCLISA are recommended. SARCLISA dose delays and the use of colony-stimulating factors (e.g. G-CSF) should be considered to mitigate the risk of neutropenia.
A higher incidence of infections including grade ≥ 3 infections, mainly pneumonia, upper respiratory tract infection and bronchitis, occurred with SARCLISA. Patients receiving SARCLISA should be closely monitored for signs of infection and appropriate standard therapy instituted. Physicians should carefully evaluate patients before and during treatment as per International MyelomaWorking Group (IMWG) guidelines for occurrence of second primary malignancies (SPM) and treatment should be initiated as indicated. Isatuximab binds to CD38 on red blood cells (RBCs) and may result in a false positive indirect antiglobulin test (indirect Coombs test).
There is currently no available information with regards to how long the interference may persist. Based on the half-life of isatuximab, it may persist for approximately 6 months after the last infusion of SARCLISA. Patient should have blood type and screen tests performed prior to the first infusion of Isatuximab and should be monitored for theoretical risk of haemolysis. For details in tests interference see full SmPC.
Drug interactions: Isatuximab has no impact on the pharmacokinetics of pomalidomide or carfilzomib and vice versa. Isatuximab may interfere with serological testing and with Serum Protein Electrophoresis and
Immunofixation assays.Abbreviated Prescribing Information :**Fertility, pregnancy and lactation:** Women of childbearing potential treated with isatuximab should use effective contraception during treatment and for 5 months after cessation of treatment. The use of isatuximab in pregnant women is not recommended since there are no available data.**Undesirable effects:** Observed in clinical trials: Infections/infestations: very common: pneumonia, upper respiratory tract infection, bronchitis. Neoplasms benign, malignant and unspecified: common: skin squamous cell carcinoma. Blood/lymphatic system disorders: very common: neutropenia, febrile neutropenia. Metabolism and nutrition disorders: common: decreased appetite and shingles. Cardiac disorders: common: atrial fibrillation. Respiratory, thoracic and mediastinal disorders: very common: dyspnoea. Gastrointestinal disorders: very common: diarrhea, nausea, vomiting. Investigations: common: weight decreased. Injury, poisoning and procedural complications: very common: infusion reaction.**Legal classification:** Prescription Only Medicine.**Marketing authorization holder:** Sanofi Winthrop Industrie, 82 Avenue Raspail, 94250 Gentilly, France **Abbreviated Prescribing Information based on the EU SmPC dated March 2023.**

Before prescribing always refer to your full local prescribing information see the full Summary of Product Characteristics

KSA :

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Therapeutic indications:
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- in combination with carfilzomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.
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complications have been observed in 30.3% of patients, including 11.8% of febrile neutropenia and 25.0% of neutropenic infections.
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