SARCLISA®
(isatuximab-irfc)
Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

# DOSING AND ADMINISTRATION GUIDE

## Indication

SARCLISA (isatuximab-irfc) is indicated:

- In combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least 2 prior therapies including lenalidomide and a proteasome inhibitor
- In combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy
- In combination with bortezomib, lenalidomide, and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are not eligible for autologous stem cell transplant (ASCT)

## Important Safety Information

### CONTRAINDICATIONS

SARCLISA is contraindicated in patients with severe hypersensitivity to isatuximab-irfc or to any of its excipients.

### WARNINGS AND PRECAUTIONS

**Infusion-Related Reactions**

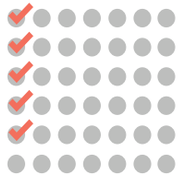
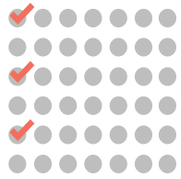
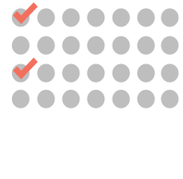
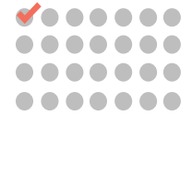
Serious infusion-related reactions (IRRs), including life-threatening anaphylactic reactions, have occurred with SARCLISA treatment. Severe signs and symptoms include cardiac arrest, hypertension, hypotension, bronchospasm, dyspnea, angioedema, and swelling.

**Please see Important Safety Information throughout, and accompanying full Prescribing Information.**

# SARCLISA Dosing Schedule in Combination With VRd[1]

**The recommended dose of SARCLISA is 10 mg/kg administered as an IV infusion at a fixed infusion volume of 250 mL in combination with VRd.**

## Dosing frequency for SARCLISA transitions to once monthly*

| INDUCTION PHASE (6-WEEK CYCLES)† | | CONTINUOUS PHASE (4-WEEK CYCLES)‡ | |
|---|---|---|---|
| CYCLE 1 | CYCLES 2-4 | CYCLES 5-17 | CYCLE 18 AND BEYOND |
| WEEKLY | ONCE EVERY 2 WEEKS | ONCE EVERY 2 WEEKS | ONCE EVERY 4 WEEKS |
|  |  |  |  |
| **5** doses | **3** doses every cycle | **2** doses every cycle | **1** dose every cycle |

For additional dosing instructions for combination agents administered with SARCLISA, refer to the respective manufacturer's Prescribing Information.

*Initiates after cycle 17.
†Induction phase cycles=42 days each.
‡Continuous phase cycles=28 days each.

IV=intravenous; VRd=bortezomib, lenalidomide, dexamethasone.

## Important Safety Information (cont'd)

**Infusion-Related Reactions (cont'd)**

In clinical trials (ICARIA-MM, IKEMA, and IMROZ), in patients treated with SARCLISA (N=592), infusion-related reactions occurred in 206 patients (35%). Among these 206 patients, 92% experienced infusion-related reactions during the first infusion and 12% after the first cycle.

The most common symptoms (≥5%) of an infusion-related reaction included dyspnea and cough. Grade 1 infusion-related reactions were reported in 6% of patients, grade 2 in 28%, and grade 3 or 4 in 1.2%. Anaphylactic reactions occurred in less than 1% of patients. The total incidence of SARCLISA infusion interruptions was less than 1% and the incidence of patients with at least one SARCLISA infusion interruption due to infusion-related reactions was 26%. The median time to first SARCLISA infusion interruption was 61 minutes (range 4 to 240 minutes). SARCLISA was discontinued in 1% of patients due to infusion-related reactions. To decrease the risk and severity of IRRs, premedicate patients prior to SARCLISA infusion with acetaminophen, $H_2$ antagonists, diphenhydramine or equivalent, and dexamethasone.

Monitor vital signs frequently during the entire SARCLISA infusion. For patients with grade ≥2 reactions, interrupt SARCLISA infusion and provide appropriate medical management. For patients with grade 2 or grade 3 reactions, if symptoms improve to grade ≤1, restart SARCLISA infusion at half of the initial infusion rate, with supportive care as needed, and closely monitor patients.

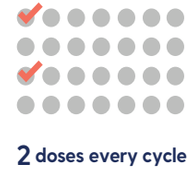


# SARCLISA Dosing Schedule in Combination With Kd or Pd[1]

**The recommended dose of SARCLISA is 10 mg/kg administered as an IV infusion at a fixed infusion volume of 250 mL in combination with either Kd or Pd.**

## Dosing frequency for SARCLISA decreases after cycle 1

**WEEKLY DOSING TRANSITIONS TO EVERY OTHER WEEK AFTER THE FIRST CYCLE**

| CYCLE 1 | CYCLE 2 AND BEYOND |
|---|---|
| WEEKLY | ONCE EVERY 2 WEEKS |
|  |  |
| **4** doses | **2** doses every cycle |

On days where both SARCLISA and carfilzomib are administered, administer dexamethasone first, followed by SARCLISA infusion, then followed by carfilzomib infusion.

For additional dosing instructions for combination agents administered with SARCLISA, refer to the respective manufacturer's Prescribing Information.

- **Continue the SARCLISA regimen until disease progression or unacceptable toxicity**
- The dosing schedule must be carefully followed. If a patient misses a planned dose, administer the infusion as soon as possible and adjust the dosing schedule to maintain the necessary treatment interval
- **See page 8** for information about administration adjustments

Kd=carfilzomib and dexamethasone; Pd=pomalidomide and dexamethasone.

## Important Safety Information (cont'd)

**Infusion-Related Reactions (cont'd)**

If symptoms do not recur after 30 minutes, the infusion rate may be increased to the initial rate, and then increased incrementally. In case symptoms do not improve to grade ≤1 after interruption of SARCLISA infusion, persist or worsen despite appropriate medications, or require hospitalization, permanently discontinue SARCLISA and institute appropriate management. Permanently discontinue SARCLISA if an anaphylactic reaction or life-threatening (grade 4) IRR occurs and institute appropriate management.

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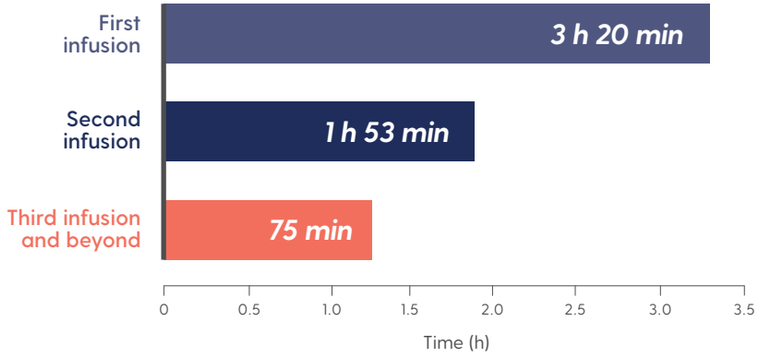
# Infusion Duration for SARCLISA Can Be Decreased Over Time[1]

## Infusion time can be decreased to 75 minutes by the third infusion*

Incremental escalation of the infusion rate should be considered only in the absence of IRRs.[1,2]




## Administering SARCLISA

**Prepare the solution for infusion using an aseptic technique[1]**

- Administer the infusion solution by IV infusion using an IV tubing infusion set (in PE, PVC with or without DEHP, PBD, or PU) with a 0.22-micron in-line filter (PES, PSU, or nylon)
- The infusion solution should be administered for a period of time that will depend on the infusion rate (see the table on the next page)
- Use prepared SARCLISA infusion solution within 48 hours when stored refrigerated at 36°F to 46°F (2°C to 8°C), followed by 8 hours (including the infusion time) at room temperature
- Do not administer SARCLISA infusion solution concomitantly in the same IV line with other agents
- **See page 8** for information about administration adjustments

*Premedication should be used prior to SARCLISA infusion with the following medications to reduce the risk and severity of IRRs: dexamethasone 40 mg orally or IV (or 20 mg orally or IV for patients ≥75 years of age), acetaminophen 650 mg to 1000 mg orally (or equivalent), diphenhydramine 25 mg to 50 mg orally or IV (or equivalent; the IV route is preferred for at least the first 4 infusions).[1]

DEHP=di-(2-ethylhexyl) phthalate; IRR=infusion-related reaction; PBD=polybutadiene; PE=polyethylene; PES=polyethersulfone; PSU=polysulfone; PU=polyurethane; PVC=polyvinyl chloride.

# Infusion Times for SARCLISA[1,2]

## 250-mL fixed infusion volume

| | FIRST INFUSION | SECOND INFUSION | SUBSEQUENT INFUSIONS |
|---|---|---|---|
| **Dilution volume** | | | |
| | 250 mL | 250 mL | 250 mL |
| **Initial rate** | | | |
| | 25 mL/h | 50 mL/h | 200 mL/h |
| **Absence of IRR** | | | |
| | 60 min | 30 min | – |
| **Rate increment** | | | |
| | 25 mL/h every 30 min | 50 mL/h for 30 min, then increase by 100 mL/h | – |
| **Maximum rate** | | | |
| | 150 mL/h | 200 mL/h | 200 mL/h |
| **Total time (if no rate adjustments)** | | | |
| | **3 h 20 min** | **1 h 53 min** | **75 min** |

SARCLISA should be administered by a healthcare professional with immediate access to emergency equipment and appropriate medical support to manage IRRs if they occur.[1]

## Important Safety Information (cont'd)

### Infections

SARCLISA can cause severe, life-threatening, or fatal infections. In patients who received SARCLISA at the recommended dose in ICARIA-MM, IKEMA, and IMROZ (N=592), serious infections, including opportunistic infections, occurred in 46%, grade 3 or 4 infections occurred in 43%, and fatal infections occurred in 4.7%. The most common serious infection reported was pneumonia (32%).

Monitor patients for signs and symptoms of infection prior to and during treatment with SARCLISA and treat appropriately. Administer prophylactic antimicrobials according to guidelines.

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# Premedication[1]

Recommended premedication agents should be administered 15 to 60 minutes prior to starting an infusion of SARCLISA. The following premedication agents should be used to reduce the risk and severity of IRRs:

| Dexamethasone | Acetaminophen |
|---|---|
| **SARCLISA + Kd:** 20 mg (IV on the days of SARCLISA and/or carfilzomib infusions, and orally on the other days)<br>**SARCLISA + Pd:** 40 mg orally or IV (or 20 mg orally or IV for patients ≥75 years of age)<br>**SARCLISA + VRd:** 20 mg (IV on the days of SARCLISA infusions, and orally on the other days) | 650 mg to 1000 mg orally<br>**or**<br>equivalent |

| $H_2$ antagonist | Diphenhydramine |
|---|---|
| Institution-preferred agent | 25 mg to 50 mg orally **or** IV (**or** equivalent). The IV route is preferred for at least the first 4 infusions |

The above recommended dose of dexamethasone (orally or IV) corresponds to the total dose to be administered only once before infusion as part of the premedication and of the backbone treatment, before SARCLISA and carfilzomib, SARCLISA and pomalidomide, or SARCLISA, bortezomib, and lenalidomide administration.

**Recommended antimicrobial prophylaxis**
Initiate antibacterial and antiviral prophylaxis (such as herpes zoster prophylaxis) if needed based on standard guidelines.

**No post-infusion medications are required for SARCLISA**

# Preparing SARCLISA[1]

The dose (mg) of SARCLISA concentrate should be calculated based on patient weight, which should be measured prior to each cycle so that the dose can be adjusted accordingly. More than one SARCLISA vial may be necessary to reach the required dose for the patient.

## Calculating the dose of SARCLISA, an example:

| Patient weight (kg) | | Recommended dose | | Required dose |
|---|---|---|---|---|
| 80 kg | × | 10 mg/kg | = | **800 mg** |

SARCLISA is available in 100 mg/5 mL and 500 mg/25 mL vials.

**SARCLISA infusion solution should be prepared under aseptic conditions.**

- Inspect vials of SARCLISA concentrate before dilution to ensure they do not contain any particles and are not discolored
- The infusion bag must be made of PO, PE, PP, PVC with DEHP, or EVA
- The volume of diluent equal to the required volume of SARCLISA concentrate should be removed from a 250-mL sodium chloride solution for injection or dextrose 5% solution diluent bag
- The appropriate volume of SARCLISA concentrate should be withdrawn from the SARCLISA vial and diluted in the 250-mL infusion bag with sodium chloride 0.9% solution for injection or dextrose 5% solution
- Gently homogenize the diluted solution by inverting the bag. Do not shake

EVA=ethyl vinyl acetate; PO=polyolefins; PP=polypropylene.

## Important Safety Information (cont'd)

**Neutropenia**

SARCLISA may cause neutropenia.

In clinical trials (ICARIA-MM, IKEMA, and IMROZ), in patients treated with SARCLISA (N=592), neutropenia based on laboratory values occurred in 81%, with grade 3 or 4 occurring in 52%. Neutropenic infections occurred in 12% of patients, with grade 3 or 4 in 4.9%, and febrile neutropenia in 4%.

Monitor complete blood cell counts periodically during treatment. If needed, use antibacterial and antiviral prophylaxis during treatment. Monitor patients with neutropenia for signs of infection. In case of grade 4 neutropenia, delay SARCLISA dose until neutrophil count recovery to at least 1 x $10^9$/L, and provide supportive care with growth factors, according to institutional guidelines. No dose reductions of SARCLISA are recommended.

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# Administration Adjustments for SARCLISA[1]

No dose reduction of SARCLISA is recommended. Administration adjustments should be made if patients experience IRRs.

For other medicinal products that are administered with SARCLISA, see the respective manufacturer's Prescribing Information.

## IRRs

- In patients necessitating an intervention (grade ≥2, moderate IRRs), a temporary interruption of the infusion should be considered and additional symptomatic medicinal products can be administered
- For patients with grade 2 or grade 3 reactions, if symptoms improve to grade ≤1, SARCLISA infusion may be resumed at half of the initial infusion rate under close monitoring and supportive care, as needed
- If symptoms do not recur after 30 minutes, the infusion rate may be increased to the initial rate and then increased incrementally, as shown in the table on page 5
- Permanently discontinue treatment with SARCLISA and administer additional supportive therapy as needed if symptoms:
  - Do not improve to grade ≤1 after interruption of SARCLISA infusion
  - Persist or worsen despite administration of appropriate medicinal products
  - Require hospitalization or are life-threatening

## Neutropenia

- Monitor complete blood cell counts periodically during treatment
- Consider the use of antibacterial and antiviral prophylaxis during treatment
- Monitor patients with neutropenia for signs of infection
- If grade 4 neutropenia occurs, delay SARCLISA dose until neutrophil count recovery to at least 1 x $10^9$/L, and provide supportive care with growth factors, according to institutional guidelines

## Important Safety Information (cont'd)

**Second Primary Malignancies**

The incidence of second primary malignancies, during treatment and post-treatment, is increased in patients treated with SARCLISA-containing regimens. In clinical trials (ICARIA-MM, IKEMA, and IMROZ), in patients treated with SARCLISA (N=592), second primary malignancies occurred in 71 patients (12%).

In ICARIA-MM, at a median follow-up time of 52 months, second primary malignancies occurred in 7% of patients treated with SARCLISA, pomalidomide, and dexamethasone (Isa-Pd) and in 2% of patients treated with Pd.

In IKEMA study, at a median follow-up time of 57 months, second primary malignancies occurred in 10% of patients treated with SARCLISA, carfilzomib, and dexamethasone (Isa-Kd) and in 8% of patients treated with Kd.



# Storage and Handling[1]

SARCLISA injection is a clear to slightly opalescent, colorless to slightly yellow solution, essentially free of visible particulates, supplied as follows:

- One 100 mg/5 mL (20 mg/mL) single-dose vial in a carton: NDC 0024-0654-01
- One 500 mg/25 mL (20 mg/mL) single-dose vial in a carton: NDC 0024-0656-01

## Storage requirements

- Store SARCLISA in a refrigerator at 36°F to 46°F (2°C to 8°C) in the original carton to protect from light
- Do not freeze
- Do not shake

## Handling and disposal

Discard all unused portions of SARCLISA solution. All materials that have been utilized for dilution and administration should be disposed of according to standard procedures.

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# Adverse Reactions for SARCLISA + VRd

## Adverse reactions (≥20%) in patients receiving SARCLISA + VRd[1]

| | SARCLISA + VRd (n=263) | | VRd (n=181) | |
|---|---|---|---|---|
| **Adverse reactions** | **All grades** | **Grade 3 or 4** | **All grades** | **Grade 3 or 4** |
| **Infections and infestations** | | | | |
| *Upper respiratory tract infection*[a] | **65%** | **4.6%** | 57%[b] | 6% |
| *Pneumonia*[c] | **45%**[d] | **26%** | 31%[e] | 19% |
| *COVID-19*[f] | **22%** | **0.8%** | 17%[g] | 1.7% |
| **General disorders and administration site conditions** | | | | |
| *Fatigue*[h] | **55%** | **11%** | 50% | 9% |
| *Peripheral edema* | **33%** | **0%** | 33% | 1.1% |
| *IRR* | **24%** | **0.4%** | 1.1% | 0% |
| **Gastrointestinal disorders** | | | | |
| *Diarrhea* | **55%** | **8%** | 49% | 8% |
| *Constipation* | **36%** | **2.3%** | 41% | 1.7% |
| **Nervous system disorders** | | | | |
| *Peripheral sensory neuropathy* | **54%** | **7%** | 61% | 6% |
| **Eye disorders** | | | | |
| *Cataract* | **38%** | **16%** | 25% | 11% |
| **Musculoskeletal and connective tissue disorders** | | | | |
| *Musculoskeletal pain*[a] | **38%** | **4.2%** | 33% | 3.3% |
| **Skin and subcutaneous tissue disorders** | | | | |
| *Rash*[i] | **32%** | **5%** | 34% | 5% |
| **Psychiatric disorders** | | | | |
| *Insomnia* | **22%** | **3.8%** | 24% | 2.2% |

- SARCLISA + VRd demonstrated lower rates of peripheral neuropathy than VRd alone: 54% vs 61% (all grades), and comparable rates of grade ≥3 peripheral neuropathy vs VRd alone (7% vs 6%)

The IMROZ trial was conducted from December 2017 to September 26, 2023 (date of the interim analysis), during the COVID-19 pandemic.[3]

[a]Includes other related terms.[1]
[b]Includes 1 patient (0.6%) with fatal upper respiratory tract infection.[1]
[c]Pneumonia includes atypical pneumonia, bronchopulmonary aspergillosis, COVID-19 pneumonia, lower respiratory tract infection, *Pneumocystis jirovecii* pneumonia, pneumonia, pneumonia aspiration, pneumonia bacterial, pneumonia influenzal, pneumonia klebsiella, pneumonia legionella, pneumonia parainfluenzae viral, pneumonia pneumococcal, pneumonia pseudomonal, pneumonia respiratory syncytial viral, pneumonia viral, pulmonary sepsis.[1]
[d]Includes 14 patients (5%) with fatal pneumonia.[1]
[e]Includes 4 patients (2.2%) with fatal pneumonia.[1]
[f]COVID-19 includes COVID-19 infections other than COVID-19 pneumonia.[1]
[g]Includes 2 patients (1.1%) with fatal COVID-19.[1]
[h]Fatigue includes fatigue, asthenia, or malaise.[1]
[i]Rash includes dermatitis, dermatitis acneiform, dermatitis allergic, dermatitis atopic, dermatitis exfoliative generalized, drug eruption, rash, rash erythematous, rash macular, rash maculopapular, rash pruritic, rash pustular, skin exfoliation, skin hyperpigmentation, skin lesion, skin reaction, and toxic skin eruption.[1]

## Serious adverse reactions[1,3]

- Serious adverse reactions occurred in 71% of patients receiving SARCLISA + VRd
  - The serious adverse reaction in >5% of patients who received SARCLISA + VRd was pneumonia (30%)
- Fatal adverse reactions (grade 5 TEAEs) were reported in 11% of patients with SARCLISA + VRd (that occurring in more than 1% of patients was pneumonia [5%]) vs 5.5% of patients with VRd alone

# Additional Safety Data for SARCLISA + VRd

## Hematology laboratory abnormalities in patients receiving SARCLISA + VRd vs VRd alone[1]

| | SARCLISA + VRd (n=263) | | VRd (n=181) | |
|---|---|---|---|---|
| **Laboratory parameter** | **All grades** | **Grade 3-4** | **All grades** | **Grade 3-4** |
| *Decreased hemoglobin* | **99%** | **17%** | 98% | 16% |
| *Decreased leukocytes* | **97%** | **32%** | 88% | 17% |
| *Decreased lymphocytes* | **95%** | **60%** | 92% | 53% |
| *Decreased platelets* | **95%** | **30%** | 85% | 28% |
| *Decreased neutrophils* | **87%** | **54%** | 80% | 37% |

The denominator used to calculate the rate is based on the number of patients with a baseline value and at least one post-baseline value.

Monitor patients for signs and symptoms of infection prior to and during treatment with SARCLISA and treat appropriately. Administer prophylactic antimicrobials according to guidelines.

**Permanent discontinuations due to adverse events were similar across arms: 23% for SARCLISA + VRd and 26% for VRd alone.[1,3]**

## Median treatment duration[1]

The median treatment duration was 53 months (range: 0.5 to 69) with SARCLISA + VRd (n=263) vs 31 months (range: 0.6 to 67) with VRd alone (n=181).

TEAE=treatment-emergent adverse event.

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SAFETY INFORMATION

# Adverse Reactions for SARCLISA + Kd

## Adverse reactions (≥10%) in patients receiving SARCLISA + Kd with a difference between arms of ≥5% compared with Kd alone[1]

| | SARCLISA + Kd (n=177) | | | Kd (n=122) | | |
|---|---|---|---|---|---|---|
| **Adverse reactions** | **All grades** | **Grade 3** | **Grade 4** | **All grades** | **Grade 3** | **Grade 4** |
| **General disorders and administration site conditions** | | | | | | |
| *IRR*[a] | **46%** | **0.6%** | **0%** | 3.3% | 0% | 0% |
| *Fatigue*[b] | **42%** | **5%** | **0%** | 32% | 3.3% | 0% |
| **Infections** | | | | | | |
| *Upper respiratory tract infection*[c] | **67%** | **9%** | **0%** | 57% | 7% | 0% |
| *Pneumonia*[d] | **36%** | **19%** | **3.4%** | 30% | 15% | 2.5% |
| *Bronchitis*[e] | **24%** | **2.3%** | **0%** | 13% | 0.8% | 0% |
| **Vascular disorders** | | | | | | |
| *Hypertension*[f] | **37%** | **20%** | **0.6%** | 32% | 18% | 1.6% |
| **Respiratory, thoracic, and mediastinal disorders** | | | | | | |
| *Dyspnea*[g] | **29%** | **5%** | **0%** | 24% | 0.8% | 0% |
| *Cough*[h] | **23%** | **0%** | **0%** | 15% | 0% | 0% |
| **Gastrointestinal disorders** | | | | | | |
| *Diarrhea* | **36%** | **2.8%** | **0%** | 29% | 2.5% | 0% |
| *Vomiting* | **15%** | **1.1%** | **0%** | 9% | 0.8% | 0% |

[a]IRR includes IRR, cytokine release syndrome, and hypersensitivity.
[b]Fatigue includes fatigue and asthenia.
[c]Upper respiratory tract infection includes acute sinusitis, chronic sinusitis, H1N1 influenza, H3N2 influenza, influenza, laryngitis, laryngitis viral, nasal herpes, nasopharyngitis, pharyngitis, pharyngotonsillitis, respiratory syncytial virus infection, rhinitis, sinusitis, sinusitis bacterial, tonsillitis, tracheitis, upper respiratory tract infection, viral rhinitis, respiratory tract infection, respiratory tract infection viral, influenza-like illness, parainfluenzae virus infection, respiratory tract infection bacterial, and viral upper respiratory tract infection.
[d]Pneumonia includes atypical pneumonia, lower respiratory tract infection, lower respiratory tract infection viral, *Pneumocystis jirovecii* pneumonia, pneumonia, pneumonia influenzal, pneumonia legionella, pneumonia pneumococcal, pneumonia respiratory syncytial viral, pneumonia streptococcal, pneumonia viral, pulmonary sepsis, and pulmonary tuberculosis.
[e]Bronchitis includes bronchitis, bronchitis viral, respiratory syncytial virus bronchitis, bronchitis chronic, and tracheobronchitis.
[f]Hypertension includes hypertension, blood pressure increased, and hypertensive crisis.
[g]Dyspnea includes dyspnea and dyspnea exertional.
[h]Cough includes cough, productive cough, and allergic cough.

# Additional Safety Data for SARCLISA + Kd

## Hematology laboratory abnormalities in patients receiving SARCLISA + Kd vs Kd alone[1]

| | SARCLISA + Kd (n=177) | | | Kd (n=122) | | |
|---|---|---|---|---|---|---|
| **Laboratory parameter** | **All grades** | **Grade 3** | **Grade 4** | **All grades** | **Grade 3** | **Grade 4** |
| *Hemoglobin decreased* | **99%** | **22%** | **0%** | 99% | 20% | 0% |
| *Lymphocytes decreased* | **94%** | **52%** | **17%** | 95% | 43% | 14% |
| *Platelets decreased* | **94%** | **19%** | **11%** | 88% | 16% | 8% |
| *Neutrophils decreased* | **55%** | **18%** | **1.7%** | 43% | 7% | 0.8% |

The denominator used to calculate the percentages was based on the safety population.

Complete blood cell counts should be monitored periodically during treatment. Patients with neutropenia should be monitored for signs of infection. In case of infection, appropriate standard therapy should be instituted. Antibacterial and antiviral prophylaxis can be considered during treatment.

## Serious adverse reactions[1,2]

- Serious adverse reactions occurred in 59% of patients receiving SARCLISA + Kd
  - The most frequent serious adverse reactions in >5% of patients who received SARCLISA + Kd were pneumonia (25%) and upper respiratory tract infections (9%)
- Fatal adverse reactions occurred in 3.4% of patients receiving SARCLISA + Kd (those occurring in >1% of patients were pneumonia in 1.7% and cardiac failure in 1.1% of patients) vs 3.3% in the Kd arm

## Permanent treatment discontinuation due to adverse reactions (grades 1 to 4)[1,2]

| SARCLISA + Kd | Kd |
|---|---|
| **8%** | **14%** |

- The most frequent adverse reactions requiring permanent discontinuation were infections (2.8%, SARCLISA + Kd; 4.9%, Kd)
- Dosage interruptions due to an adverse reaction occurred in 33% of patients who received SARCLISA. The most frequent adverse reaction requiring dosage interruption was IRR (30%)

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# Adverse Reactions for SARCLISA + Pd

## Adverse reactions (≥10%) in patients receiving SARCLISA + Pd with a difference between arms of ≥5% compared with Pd alone[1]

| | SARCLISA + Pd (n=152) | | | Pd (n=149) | | |
|---|---|---|---|---|---|---|
| **Adverse reactions** | **All grades** | **Grade 3** | **Grade 4** | **All grades** | **Grade 3** | **Grade 4** |
| **General disorders and administration site conditions** | | | | | | |
| *IRR*[a] | **38%** | **1.3%** | **1.3%** | 0% | 0% | 0% |
| **Infections** | | | | | | |
| *Upper respiratory tract infection*[b] | **57%** | **9%** | **0%** | 42% | 3.4% | 0% |
| *Pneumonia*[c] | **31%** | **22%** | **3.3%** | 23% | 16% | 2.7% |
| **Blood and lymphatic system disorders** | | | | | | |
| *Febrile neutropenia* | **12%** | **11%** | **1.3%** | 2% | 1.3% | 0.7% |
| **Respiratory, thoracic, and mediastinal disorders** | | | | | | |
| *Dyspnea*[d] | **17%** | **5%** | **0%** | 12% | 1.3% | 0% |
| **Gastrointestinal disorders** | | | | | | |
| *Diarrhea* | **26%** | **2%** | **0%** | 19% | 0.7% | 0% |
| *Nausea* | **15%** | **0%** | **0%** | 9% | 0% | 0% |
| *Vomiting* | **12%** | **1.3%** | **0%** | 3.4% | 0% | 0% |

[a]IRR includes IRR, cytokine release syndrome, and drug hypersensitivity.
[b]Upper respiratory tract infection includes bronchiolitis, bronchitis, bronchitis viral, chronic sinusitis, fungal pharyngitis, influenza-like illness, laryngitis, nasopharyngitis, parainfluenzae virus infection, pharyngitis, respiratory tract infection, respiratory tract infection viral, rhinitis, sinusitis, tracheitis, upper respiratory tract infection, and upper respiratory tract infection bacterial.
[c]Pneumonia includes atypical pneumonia, bronchopulmonary aspergillosis, pneumonia, pneumonia haemophilus, pneumonia influenzal, pneumonia pneumococcal, pneumonia streptococcal, pneumonia viral, candida pneumonia, pneumonia bacterial, haemophilus infection, lung infection, pneumonia fungal, and *Pneumocystis jirovecii* pneumonia.
[d]Dyspnea includes dyspnea, dyspnea exertional, and dyspnea at rest.

# Additional Safety Data for SARCLISA + Pd

## Hematology laboratory abnormalities in patients receiving SARCLISA + Pd vs Pd alone[1]

| | SARCLISA + Pd (n=152) | | | Pd (n=149) | | |
|---|---|---|---|---|---|---|
| **Laboratory parameter** | **All grades** | **Grade 3** | **Grade 4** | **All grades** | **Grade 3** | **Grade 4** |
| *Hemoglobin decreased* | **99%** | **32%** | **0%** | 97% | 28% | 0% |
| *Neutrophils decreased* | **96%** | **24%** | **61%** | 92% | 38% | 31% |
| *Lymphocytes decreased* | **92%** | **42%** | **13%** | 92% | 35% | 8% |
| *Platelets decreased* | **84%** | **14%** | **16%** | 79% | 9% | 15% |

The denominator used to calculate the percentages was based on the safety population.

Complete blood cell counts should be monitored periodically during treatment. Patients with neutropenia should be monitored for signs of infection. In case of infection, appropriate standard therapy should be instituted. Antibacterial and antiviral prophylaxis can be considered during treatment.

## Serious adverse reactions[1,2]

- Serious adverse reactions occurred in 62% of patients receiving SARCLISA + Pd
  - Serious adverse reactions in >5% of patients who received SARCLISA + Pd included pneumonia (26%), upper respiratory tract infection (7%), and febrile neutropenia (7%)
- Fatal adverse reactions occurred in 11% of patients receiving SARCLISA + Pd (those that occurred in >1% of patients were pneumonia and other infections [3%]) vs 11% in the Pd arm

## Permanent treatment discontinuation due to adverse reactions (grades 1 to 4)[1,2]

| SARCLISA + Pd | Pd |
|---|---|
| **7%** | **12%** |

- Dosage interruptions due to an adverse reaction occurred in 31% of patients who received SARCLISA + Pd[1]
  - Discontinuations from treatment due to infection were reported in 2.6% of patients receiving SARCLISA + Pd vs 5% of patients receiving Pd alone
  - The most frequent adverse reaction requiring dosage interruption was IRR (28%)

**The addition of SARCLISA to Pd**
did not increase treatment discontinuations due to adverse reactions vs Pd alone[1,2]

**Please see Important Safety Information throughout, and accompanying full Prescribing Information.**

SARCLISA®
(isatuximab-irfc)
Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

# Additional Safety Information With SARCLISA[1]

## IRRs

### Incidence and timing of IRRs

Across 3 clinical trials, **IRRs occurred** in 35% of patients receiving SARCLISA (n=206/592). Among these patients, 92% experienced IRRs during the first infusion and 12% experienced them after the first cycle

**Grade 1 IRRs** were reported in 6% of patients receiving SARCLISA, grade 2 in 28%, and grade 3 or 4 in 1.2% across the 3 clinical trials

### Symptoms of IRRs

**The most common symptoms** (≥5%) of an IRR across the 3 clinical trials included dyspnea and cough

– Anaphylactic reactions occurred in <1% of patients across the 3 clinical trials

**Serious IRRs**, including life-threatening anaphylactic reactions, have occurred with SARCLISA treatment. Severe signs and symptoms included cardiac arrest, hypertension, hypotension, bronchospasm, dyspnea, angioedema, and swelling

### Infusion interruption and discontinuation due to IRRs

**Infusion interruption** of SARCLISA occurred in <1% of patients across the 3 clinical trials; of these patients, 26% experienced interruptions due to IRRs

**SARCLISA alone was discontinued** due to IRRs in 1% of patients across the 3 clinical trials

# Additional Safety Information With SARCLISA (cont'd)

## Managing IRRs[1,4]

- To decrease the risk and severity of IRRs, premedicate patients prior to SARCLISA infusion with acetaminophen, $H_2$ antagonists, diphenhydramine or equivalent, and dexamethasone
- Monitor vital signs frequently during the entire SARCLISA infusion

| | | |
|---|---|---|
| *Grade 1 IRRs* | No interruption or intervention is indicated. | |
| *Grade 2-3 IRRs* | Interrupt SARCLISA infusion and provide appropriate medical management. | **If symptoms improve to grade ≤1**, restart SARCLISA infusion at half of the initial infusion rate, with supportive care as needed, and closely monitor patients.<br>• If symptoms do not recur after 30 minutes, the infusion rate may be increased to the initial rate, and then increased incrementally, as shown in the infusion rate table on page 5 |
| | | **If symptoms do not improve to grade ≤1** after interruption of SARCLISA infusion, persist or worsen despite appropriate medications, or require hospitalization, permanently discontinue SARCLISA and institute appropriate management. |
| *Grade 4 IRRs* | Permanently discontinue SARCLISA and institute appropriate management. | |

## Defining IRR grades[4]

| | |
|---|---|
| *Grade 1* | Mild transient reaction. |
| *Grade 2* | Therapy or infusion interruption indicated, but IRR responds promptly to symptomatic treatment (eg, antihistamines, NSAIDs, narcotics, IV fluids); prophylactic medications indicated for ≤24 hours. |
| *Grade 3* | Prolonged (ie, not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of symptoms following initial improvement; hospitalization indicated for clinical sequelae. |
| *Grade 4* | Life-threatening consequences; urgent intervention indicated. |

NSAID=nonsteroidal anti-inflammatory drug.

**Please see Important Safety Information throughout, and accompanying full Prescribing Information.**

SARCLISA® (isatuximab-irfc)
Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

# Additional Safety Information With SARCLISA (cont'd)[1]

## Infections

- SARCLISA can cause severe, life-threatening, or fatal infections. In patients who received SARCLISA at the recommended dose in ICARIA-MM, IKEMA, and IMROZ (N=592), serious infections, including opportunistic infections, occurred in 46%, grade 3 or 4 infections occurred in 43%, and fatal infections occurred in 4.7%. The most common type of serious infection reported was pneumonia (32%)
- Monitor patients for signs and symptoms of infection prior to and during treatment with SARCLISA and treat appropriately. Administer prophylactic antimicrobials according to guidelines

## Neutropenia

- Monitor complete blood cell counts periodically during treatment
- Consider the use of antibacterial and antiviral prophylaxis during treatment
- Monitor patients with neutropenia for signs of infection
- If grade 4 neutropenia occurs, delay SARCLISA dose until neutrophil count recovery to at least 1 x $10^9$/L, and provide supportive care with growth factors, according to institutional guidelines

## Cardiac failure in the IKEMA trial**†

- In IKEMA, cardiac failure was reported in 7% of patients in the SARCLISA + Kd group (grade ≥3, 4%) and in 7% of patients in the Kd group (grade ≥3, 4.1%)
- In IKEMA, serious cardiac failure was observed in 4% of patients in the SARCLISA + Kd group and in 3.3% of patients in the Kd group

*Cardiac failure included cardiac failure, cardiac failure congestive, cardiac failure acute, cardiac failure chronic, left ventricular failure, and pulmonary edema.
†See the current Prescribing Information for carfilzomib for more information.



# Additional Safety Information With SARCLISA (cont'd)[1]

## Second primary malignancies

- Monitor patients for the development of second primary malignancies
- The incidence of second primary malignancies is increased in patients treated with regimens that contain SARCLISA
  - The overall incidence of second primary malignancies in all SARCLISA-exposed patients was 12%
  - In the IMROZ trial, at a median follow-up time of 60 months, second primary malignancies occurred in 16% of patients in the SARCLISA + VRd arm and in 9% of patients in the VRd arm
  - In the IKEMA trial, at a median follow-up time of 57 months, second primary malignancies occurred in 10% of patients in the SARCLISA + Kd arm and in 8% of patients in the Kd arm
  - In ICARIA-MM, at a median follow-up time of 52 months, second primary malignancies occurred in 7% of patients in the SARCLISA + Pd arm and in 2% of patients in the Pd arm
- The most common (≥1%) second primary malignancies in ICARIA-MM, IKEMA, and IMROZ (N=592) included skin cancers (7% with SARCLISA-containing regimens and 3.1% with comparative regimens) and solid tumors other than skin cancer (4.6% with SARCLISA-containing regimens and 2.9% with comparative regimens). Patients with non-melanoma skin cancer continued treatment after resection of the skin cancer, except 2 patients in the SARCLISA + VRd arm and 1 patient in the VRd arm of the IMROZ study

## Dose modifications

Dose delay may be required to allow for recovery of blood counts in the event of hematological toxicity. For dosing instructions for combination agents administered with SARCLISA, refer to the respective manufacturer's Prescribing Information.

**No dose reduction** of SARCLISA is recommended

**Please see Important Safety Information throughout, and accompanying full Prescribing Information.**

SARCLISA®
(isatuximab-irfc)
Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

## Important Safety Information

### CONTRAINDICATIONS

SARCLISA is contraindicated in patients with severe hypersensitivity to isatuximab-irfc or to any of its excipients.

### WARNINGS AND PRECAUTIONS

**Infusion-Related Reactions**

Serious infusion-related reactions (IRRs), including life-threatening anaphylactic reactions, have occurred with SARCLISA treatment. Severe signs and symptoms include cardiac arrest, hypertension, hypotension, bronchospasm, dyspnea, angioedema, and swelling.

In clinical trials (ICARIA-MM, IKEMA, and IMROZ), in patients treated with SARCLISA (N=592), infusion-related reactions occurred in 206 patients (35%). Among these 206 patients, 92% experienced infusion-related reactions during the first infusion and 12% after the first cycle.

The most common symptoms (≥5%) of an infusion-related reaction included dyspnea and cough. Grade 1 infusion-related reactions were reported in 6% of patients, grade 2 in 28%, and grade 3 or 4 in 1.2%. Anaphylactic reactions occurred in less than 1% of patients. The total incidence of SARCLISA infusion interruptions was less than 1% and the incidence of patients with at least one SARCLISA infusion interruption due to infusion-related reactions was 26%. The median time to first SARCLISA infusion interruption was 61 minutes (range 4 to 240 minutes). SARCLISA was discontinued in 1% of patients due to infusion-related reactions. To decrease the risk and severity of IRRs, premedicate patients prior to SARCLISA infusion with acetaminophen, $H_2$ antagonists, diphenhydramine or equivalent, and dexamethasone.

Monitor vital signs frequently during the entire SARCLISA infusion. For patients with grade ≥2 reactions, interrupt SARCLISA infusion and provide appropriate medical management. For patients with grade 2 or grade 3 reactions, if symptoms improve to grade ≤1, restart SARCLISA infusion at half of the initial infusion rate, with supportive care as needed, and closely monitor patients. If symptoms do not recur after 30 minutes, the infusion rate may be increased to the initial rate, and then increased incrementally. In case symptoms do not improve to grade ≤1 after interruption of SARCLISA infusion, persist or worsen despite appropriate medications, or require hospitalization, permanently discontinue SARCLISA and institute appropriate management. Permanently discontinue SARCLISA if an anaphylactic reaction or life-threatening (grade 4) IRR occurs and institute appropriate management.

**Infections**

SARCLISA can cause severe, life-threatening, or fatal infections. In patients who received SARCLISA at the recommended dose in ICARIA-MM, IKEMA, and IMROZ (N=592), serious infections, including opportunistic infections, occurred in 46%, grade 3 or 4 infections occurred in 43%, and fatal infections occurred in 4.7%. The most common serious infection reported was pneumonia (32%).

Monitor patients for signs and symptoms of infection prior to and during treatment with SARCLISA and treat appropriately. Administer prophylactic antimicrobials according to guidelines.

**Neutropenia**

SARCLISA may cause neutropenia.

In clinical trials (ICARIA-MM, IKEMA, and IMROZ), in patients treated with SARCLISA (N=592), neutropenia based on laboratory values occurred in 81%, with grade 3 or 4 occurring in 52%. Neutropenic infections occurred in 12% of patients, with grade 3 or 4 in 4.9%, and febrile neutropenia in 4%.

Monitor complete blood cell counts periodically during treatment. If needed, use antibacterial and antiviral prophylaxis during treatment. Monitor patients with neutropenia for signs of infection. In case of grade 4 neutropenia, delay SARCLISA dose until neutrophil count recovery to at least 1 x $10^9$/L, and provide supportive care with growth factors, according to institutional guidelines. No dose reductions of SARCLISA are recommended.

**Second Primary Malignancies**

The incidence of second primary malignancies, during treatment and post-treatment, is increased in patients treated with SARCLISA-containing regimens. In clinical trials (ICARIA-MM, IKEMA, and IMROZ), in patients treated with SARCLISA (N=592), second primary malignancies occurred in 71 patients (12%).

In ICARIA-MM, at a median follow-up time of 52 months, second primary malignancies occurred in 7% of patients treated with SARCLISA, pomalidomide, and dexamethasone (Isa-Pd) and in 2% of patients treated with Pd.

In IKEMA study, at a median follow-up time of 57 months, second primary malignancies occurred in 10% of patients treated with SARCLISA, carfilzomib, and dexamethasone (Isa-Kd) and in 8% of patients treated with Kd.

In IMROZ study, at a median follow-up time of 60 months, second primary malignancies occurred in 16% of patients treated with SARCLISA, bortezomib, lenalidomide, and dexamethasone (Isa-VRd) and in 9% of patients treated with VRd.

The most common (≥1%) second primary malignancies in ICARIA-MM, IKEMA, and IMROZ (N=592) included skin cancers (7% with SARCLISA-containing regimens and 3.1% with comparative regimens) and solid tumors other than skin cancer (4.6% with SARCLISA-containing regimens and 2.9% with comparative regimens). Patients with non-melanoma skin cancer continued treatment after resection of the skin cancer, except 2 patients in the Isa-VRd arm and 1 patient in the VRd arm of the IMROZ study. Monitor patients for the development of second primary malignancies.

**Laboratory Test Interference**

*Interference with Serological Testing (Indirect Antiglobulin Test)*

SARCLISA binds to CD38 on red blood cells (RBCs) and may result in a false-positive indirect antiglobulin test (indirect Coombs test). This interference with the indirect Coombs test may persist for approximately 6 months after the last infusion of SARCLISA. The indirect antiglobulin test was positive during Isa-Pd treatment in 68% of the tested patients, and during Isa-Kd treatment in 63% of patients. In patients with a positive indirect antiglobulin test, blood transfusions were administered without evidence of hemolysis. ABO/RhD typing was not affected by SARCLISA treatment.

Before the first SARCLISA infusion, conduct blood type and screen tests on SARCLISA-treated patients. Consider phenotyping prior to starting SARCLISA treatment. If treatment with SARCLISA has already started, inform the blood bank that the patient is receiving SARCLISA and that SARCLISA interference with blood compatibility testing can be resolved using dithiothreitol-treated RBCs. If an emergency transfusion is required, non-cross-matched ABO/RhD-compatible RBCs can be given as per local blood bank practices.

*Interference with Serum Protein Electrophoresis and Immunofixation Tests*

SARCLISA is an IgG kappa monoclonal antibody that can be incidentally detected on both serum protein electrophoresis and immunofixation assays used for the clinical monitoring of endogenous M-protein. This interference can impact the accuracy of the determination of complete response in some patients with IgG kappa myeloma protein.

**Embryo-Fetal Toxicity**

Based on the mechanism of action, SARCLISA can cause fetal harm when administered to a pregnant woman. SARCLISA may cause fetal immune cell depletion and decreased bone density. Advise pregnant women of the potential risk to a fetus. Advise females with reproductive potential to use an effective method of contraception during treatment with SARCLISA and for 5 months after the last dose. The combination of SARCLISA with pomalidomide or lenalidomide is contraindicated in pregnant women because pomalidomide or lenalidomide may cause birth defects and death of the unborn child. Refer to the pomalidomide or lenalidomide prescribing information on use during pregnancy.

### ADVERSE REACTIONS

In combination with pomalidomide and dexamethasone: The most common adverse reactions (≥20%) were upper respiratory tract infection, infusion-related reactions, pneumonia, and diarrhea. The most common hematology laboratory abnormalities (≥80%) were decreased hemoglobin, decreased neutrophils, decreased lymphocytes, and decreased platelets.

In combination with carfilzomib and dexamethasone: The most common adverse reactions (≥20%) were upper respiratory tract infection, infusion-related reactions, fatigue, hypertension, diarrhea, pneumonia, dyspnea, insomnia, bronchitis, cough, and back pain. The most common hematology laboratory abnormalities (≥80%) were decreased hemoglobin, decreased lymphocytes, and decreased platelets.

In combination with bortezomib, lenalidomide, and dexamethasone: The most common adverse reactions (≥20%) were upper respiratory tract infections, diarrhea, fatigue, peripheral sensory neuropathy, pneumonia, musculoskeletal pain, cataract, constipation, peripheral edema, rash, infusion-related reaction, insomnia, and COVID-19. The most common hematologic laboratory abnormalities (≥80%) were decreased hemoglobin, decreased leukocytes, decreased lymphocytes, decreased platelets, and decreased neutrophils.

Serious adverse reactions occurred in 62% of patients receiving Isa-Pd. Serious adverse reactions in >5% of patients who received Isa-Pd included pneumonia (26%), upper respiratory tract infections (7%), and febrile neutropenia (7%). Fatal adverse reactions occurred in 11% of patients (those that occurred in more than 1% of patients were pneumonia and other infections [3%]).

Serious adverse reactions occurred in 59% of patients receiving Isa-Kd. The most frequent serious adverse reactions in >5% of patients who received Isa-Kd were pneumonia (25%) and upper respiratory tract infections (9%). Adverse reactions with a fatal outcome during treatment were reported in 3.4% of patients in the Isa-Kd group (those occurring in more than 1% of patients were pneumonia occurring in 1.7% and cardiac failure in 1.1% of patients).

Serious adverse reactions occurred in 71% of patients receiving Isa-VRd. The serious adverse reaction in >5% of patients who received Isa-VRd was pneumonia (30%). Fatal adverse reactions occurred in 11% of patients with Isa-VRd (those occurring in more than 1% of patients were pneumonia [5%]).

### USE IN SPECIAL POPULATIONS

Because of the potential for serious adverse reactions in the breastfed child from isatuximab-irfc administered in combination with pomalidomide or lenalidomide and dexamethasone, advise lactating women not to breastfeed during treatment with SARCLISA.

**Please see accompanying full Prescribing Information.**

SARCLISA®
(isatuximab-irfc)
Injection for IV use | 500 mg/25 mL, 100 mg/5 mL

# Guideline Recommendations for Isatuximab-irfc (SARCLISA) Regimens[5]

NCCN CATEGORY 1 PREFERRED

**National Comprehensive Cancer Network® (NCCN®) recommends isatuximab-irfc (SARCLISA), bortezomib, lenalidomide, and dexamethasone as a NCCN Category 1, Preferred Regimen for the treatment of patients with newly diagnosed multiple myeloma who are non-transplant candidates (<80 years old who are not frail)[5]**

NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

NCCN=National Comprehensive Cancer Network® (NCCN®).

Scan to learn more about SARCLISA for **patients with non-transplant NDMM**

## Indication

SARCLISA (isatuximab-irfc) is indicated:

- In combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least 2 prior therapies including lenalidomide and a proteasome inhibitor
- In combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy
- In combination with bortezomib, lenalidomide, and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are not eligible for autologous stem cell transplant (ASCT)

## Important Safety Information

**CONTRAINDICATIONS**

SARCLISA is contraindicated in patients with severe hypersensitivity to isatuximab-irfc or to any of its excipients.

**Please see Important Safety Information throughout, and accompanying full Prescribing Information.**

**References: 1.** SARCLISA. Prescribing information. sanofi-aventis U.S. LLC; 2024. **2.** Data on file. sanofi-aventis U.S. LLC. **3.** Facon T, Dimopoulos MA, Leleu XP, et al; IMROZ Study Group. Isatuximab, bortezomib, lenalidomide, and dexamethasone for multiple myeloma. *N Engl J Med*. Published online June 3, 2024. doi:10.1056/NEJMoa2400712 **4.** US Department of Health and Human Services. *Common Terminology Criteria for Adverse Events (CTCAE) v5.0*. National Cancer Institute; 2017. **5.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Multiple Myeloma V.4.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed September 13, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org.

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SARCLISA® (isatuximab-irfc)
Injection for IV use | 500 mg/25 mL, 100 mg/5 mL