SARCLISA® **Rx Only**
(isatuximab-irfc) injection, for intravenous use

Patient Information
SARCLISA® (sar-cli-sa)
(isatuximab-irfc)
injection

SARCLISA is used together with two or three other combinations of medicines: either pomalidomide and dexamethasone, or carfilzomib and dexamethasone, or bortezomib, lenalidomide, and dexamethasone. You should also read the Medication Guide that comes with pomalidomide and lenalidomide. You can ask your healthcare provider or pharmacist for information about carfilzomib and dexamethasone.

What is SARCLISA?
SARCLISA is a prescription medicine used in combination with:
- the medicines pomalidomide and dexamethasone, to treat adults who have received at least 2 prior therapies including lenalidomide and a proteasome inhibitor to treat multiple myeloma.
- the medicines carfilzomib and dexamethasone, to treat adults with multiple myeloma who have already received 1 to 3 lines of treatment and they did not work or are no longer working.
- the medicines bortezomib, lenalidomide and dexamethasone, to treat adults with newly diagnosed multiple myeloma who cannot receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant).

It is not known if SARCLISA is safe and effective in children.

Do not receive SARCLISA if you have a severe allergic reaction to isatuximab-irfc or any of the ingredients in SARCLISA. See the end of this leaflet for complete list of ingredients in SARCLISA.

Before receiving SARCLISA, tell your healthcare provider about all of your medical conditions, including if you:
- have an infection.
- have heart problems, if your healthcare provider prescribes SARCLISA in combination with carfilzomib and dexamethasone for you.
- have had shingles (herpes zoster).
- are pregnant or plan to become pregnant. SARCLISA can harm your unborn baby.
  - Females who are able to become pregnant should use an effective method of birth control during treatment and for 5 months after your last dose of SARCLISA. Talk to your healthcare provider about birth control methods that you can use during this time.
  - Tell your healthcare provider right away if you think you are pregnant or become pregnant during treatment with SARCLISA.
  - Before receiving SARCLISA in combination with either pomalidomide or lenalidomide, females and males must agree to the instructions in the pomalidomide or lenalidomide REMS programs. The pomalidomide and lenalidomide REMS programs have specific requirements about birth control, pregnancy testing, blood donation, and sperm donation that you need to know. Talk to your healthcare provider to learn more about pomalidomide or lenalidomide.
- are breastfeeding or plan to breastfeed. It is not known if SARCLISA passes into your breast milk. Do not breastfeed during treatment with SARCLISA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive SARCLISA?
- SARCLISA will be given to you by your healthcare provider by intravenous (IV) infusion into your vein.
- **SARCLISA in combination with pomalidomide and dexamethasone, or SARCLISA in combination with carfilzomib and dexamethasone** is given in treatment cycles of 28 days (4 weeks).
  - Cycle 1 (28-day cycle), SARCLISA is given weekly.
  - Cycle 2 and beyond (28-day cycles), SARCLISA is given every 2 weeks.
- **SARCLISA in combination with bortezomib, lenalidomide, and dexamethasone** is given in treatment cycles of 42 days (6 weeks) from cycle 1 to 4 and in treatment cycles of 28 days (4 weeks) from cycle 5.
  - Cycle 1 (42-day cycle), SARCLISA is given weekly (Days 1, 8, 15, 22, and 29).
  - Cycles 2 to 4 (42-day cycles), SARCLISA is given every 2 weeks (Days 1, 15, and 29).
  - Cycles 5 to 17 (28-day cycles), SARCLISA is given every 2 weeks (Days 1 and 15).
  - Cycles 18 and beyond (28-day cycles), SARCLISA is given every 4 weeks.
- Your healthcare provider will decide how many treatments you will receive.
- Your healthcare provider will give you medicines before each infusion of SARCLISA, to help reduce the risk of infusion reactions (make them less frequent and severe).
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

What are the possible side effects of SARCLISA?
SARCLISA may cause serious side effects including:
- **Infusion reactions.** Infusion reactions are common with SARCLISA and can sometimes be severe or life threatening.
  - Your healthcare provider will prescribe medicines before each infusion of SARCLISA to help decrease your risk for infusion reactions or to help make any infusion reaction less severe. You will be monitored for infusion reactions during each infusion of SARCLISA.
  - Your healthcare provider may slow down or stop your infusion, or completely stop treatment with SARCLISA if you have an infusion reaction.

  Get medical help right away if you develop any of the following symptoms of infusion reaction during or after an infusion of SARCLISA:
  - shortness of breath, wheezing or trouble breathing
  - swelling of the face, mouth, throat, or tongue
  - throat tightness
  - palpitations
  - dizziness, lightheadedness, or fainting
  - headache
  - cough
  - rash or itching
  - nausea
  - runny or stuffy nose
  - chills

- **Infections.** SARCLISA can cause infections that are severe, life-threatening, or that may lead to death. Your healthcare provider will monitor you for signs and symptoms of infection before and during treatment with SARCLISA. Your healthcare provider may prescribe medicines for you to help prevent infections and treat you as needed if you develop an infection during treatment with SARCLISA. **Tell your healthcare provider right away if you develop a fever or any signs or symptoms of infection during treatment with SARCLISA.**
  - **Decreased white blood cell counts.** Decreased white blood cell counts are common with SARCLISA and certain white blood cells can be severely decreased. Fever can occur with low white blood cell counts and may be a sign that you have an infection. Your healthcare provider will check your blood cell counts during treatment with SARCLISA and may prescribe a medicine to help increase your white blood cell counts. **Tell your healthcare provider right away if you develop any fever or symptoms of infection during treatment with SARCLISA.**
- **Risk of new cancers.** New cancers have happened in people during and after treatment with SARCLISA. Your healthcare provider will monitor you for new cancers during treatment with SARCLISA.
- **Changes in blood tests.** SARCLISA may affect the results of blood tests to match your blood type for about 6 months after your last infusion of SARCLISA. Your healthcare provider will do blood tests to match your blood type before you start treatment with SARCLISA. **Tell all of your healthcare providers that you are being treated with SARCLISA before receiving blood transfusions.**

The most common side effects of SARCLISA in combination with pomalidomide and dexamethasone include:

- upper respiratory tract infection
- lung infection (pneumonia)
- diarrhea
- decreased red blood cell count (anemia)
- decreased platelet count (thrombocytopenia)

The most common side effects of SARCLISA in combination with carfilzomib and dexamethasone include:

- upper respiratory tract infection
- tiredness and weakness
- high blood pressure
- diarrhea
- lung infection (pneumonia)
- trouble breathing
- trouble sleeping
- bronchitis
- cough
- back pain
- decreased red blood cell count (anemia)
- decreased platelet count (thrombocytopenia)

The most common side effects of SARCLISA in combination with bortezomib, lenalidomide and dexamethasone include:

- upper respiratory tract infection
- diarrhea
- tiredness and weakness
- tingling or numbness of the arms or legs
- lung infection (pneumonia)
- muscle or bone pain
- clouding of your eye (cataract)
- constipation
- swelling of the hands, legs, ankles and feet
- rash
- trouble sleeping
- COVID-19
- decreased red blood cell count (anemia)
- decreased platelet count (thrombocytopenia)

Heart failure can happen during treatment with SARCLISA in combination with carfilzomib and dexamethasone. **Tell your healthcare provider right away if you develop any of the following symptoms:**

- trouble breathing
- cough
- swelling of your ankles, feet, and legs

These are not all the possible side effects of SARCLISA. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of SARCLISA.
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about SARCLISA that is written for health professionals.

What are the ingredients in SARCLISA?
Active ingredient: isatuximab-irfc
Inactive ingredients: histidine, histidine hydrochloride monohydrate, polysorbate 80, sucrose, and water for injection.
Manufactured by: sanofi-aventis U.S. LLC, Bridgewater, NJ 08807, A SANOFI COMPANY. U.S. License No. 1752.

For more information, go to www.sanofi-aventis.us or call 1-800-633-1610.

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