Patient Information **Rx Only**

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

SARCLISA is used in combination with other medicines called pomalidomide and dexamethasone. You should also read the Medication Guide that comes with pomalidomide. You can ask your healthcare provider or pharmacist for information about dexamethasone.

What is SARCLISA?
SARCLISA is a prescription medicine used in combination with pomalidomide and dexamethasone to treat adults who have received at least 2 prior therapies, including lenalidomide and a proteasome inhibitor, to treat multiple myeloma.
It is not known if SARCLISA is safe and effective in children.

Do not receive SARCLISA if you have a history of 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:
- are pregnant or plan to become pregnant. SARCLISA may harm your unborn baby. You should not receive SARCLISA during pregnancy.
  - 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.
- are breastfeeding or plan to breastfeed. It is not known if SARCLISA passes into your breast milk. You should 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 is given in treatment cycles of 28 days (4 weeks), together with the medicines pomalidomide and dexamethasone.
  - In cycle 1, SARCLISA is usually given weekly.
  - Starting in cycle 2, SARCLISA is usually given every 2 weeks.

  Your healthcare provider will decide how long you should receive SARCLISA.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.
- Your healthcare provider will give you medicines before each dose of SARCLISA, to help reduce the risk of infusion reactions (make them less frequent and severe).

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.
  - 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 dose of SARCLISA.
  - Your healthcare provider may slow down or stop your infusion, or completely stop treatment with SARCLISA if you have an infusion reaction.

  Tell your healthcare provider right away if you develop any of the following symptoms of infusion reaction during or within 24 hours after an infusion of SARCLISA:
  - feeling short of breath
  - cough
  - chills
  - nausea
- **Decreased white blood cell counts.** Decreased white blood cell counts are common with SARCLISA and certain white blood cells can be severely decreased. You may have an increased risk of getting certain infections, such as upper and lower respiratory infections.
  Your healthcare provider will check your blood cell counts during treatment with SARCLISA. Your healthcare provider may prescribe an antibiotic or antiviral medicine to help prevent infection, or a medicine to help increase your white blood cell counts during treatment with SARCLISA.
  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 treatment with SARCLISA. Your healthcare provider will monitor you for new cancers during treatment with SARCLISA.
- **Change in blood tests.** SARCLISA can affect the results of blood tests to match your blood type. 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 include:
- lung infection (pneumonia)
- decreased red blood cell counts (anemia)
- upper respiratory tract infection
- decreased platelet counts (thrombocytopenia)
- diarrhea

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.

This Patient Information has been approved by the U.S. Food and Drug Administration. Issued: March 2020

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