Important Contact Information

My oncologist, infusion clinic, or hospital name

_____

24-hour emergency telephone number

_____

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

SARCLISA ESCENA™ (isatuximab-irfc) Injection for subcutaneous use 1,400 mg/10 mL FOR USE WITH CirCLIQ® On-Body Delivery System

My Patient ID Card

Show this document to healthcare professionals **before** receiving transfusions

I am currently being treated with isatuximab-irfc, a treatment that may affect the results of tests to match my blood type.

Name: _____ Blood type: _____

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).

What is SARCLISA ESCENA?

SARCLISA ESCENA is a prescription medicine used in combination with:

- The medicines pomalidomide and dexamethasone, to treat adults who have received at least 1 prior line of therapy 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 or SARCLISA ESCENA are safe and effective in children.

IMPORTANT SAFETY INFORMATION

Do not receive SARCLISA or SARCLISA ESCENA if you have a severe allergic reaction to isatuximab-irfc or any of the ingredients in SARCLISA or SARCLISA ESCENA (see the list of ingredients in the full Prescribing Information for SARCLISA and SARCLISA ESCENA).

Before you receive SARCLISA or SARCLISA ESCENA, 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 or SARCLISA ESCENA in combination with carfilzomib and dexamethasone for you.
- Have had shingles (herpes zoster).
- Are pregnant or plan to become pregnant. SARCLISA and SARCLISA ESCENA can harm your unborn baby.
  Females who are able to become pregnant:
  – Your healthcare provider will check for pregnancy before you start treatment with SARCLISA or SARCLISA ESCENA.
  – Use an effective birth control (contraception) during treatment and for 5 months after your last dose of SARCLISA or for 7 months after your last dose of SARCLISA ESCENA. 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 or SARCLISA ESCENA.
  Females and males: Before receiving SARCLISA or SARCLISA ESCENA 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 or SARCLISA ESCENA pass into your breast milk. Do not breastfeed during treatment with SARCLISA. Do not breastfeed during treatment with SARCLISA ESCENA and for 7 months after your last dose.

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.

IMPORTANT SAFETY INFORMATION (CONT'D)

How will I receive SARCLISA ESCENA?

- SARCLISA ESCENA will be given to you by your healthcare provider as an injection under the skin (subcutaneous injection) in the stomach area (abdomen). Your healthcare provider will either use the CirCLIQ™ On-Body Injector or a syringe to inject SARCLISA ESCENA. Your healthcare provider will rotate the injection site for each injection, including for other medicines.
- **SARCLISA ESCENA in combination with pomalidomide and dexamethasone, or SARCLISA ESCENA in combination with carfilzomib and dexamethasone** is given in treatment cycles of 28 days (4 weeks).
  - Cycle 1 (28-day cycle), SARCLISA ESCENA is given weekly.
  - Cycle 2 and beyond (28-day cycles), SARCLISA ESCENA is given every 2 weeks.
- **SARCLISA ESCENA in combination with bortezomib, lenalidomide, and dexamethasone** is given in treatment cycles of 28 days (4 weeks).
  - Cycle 1 (28-day cycle), SARCLISA ESCENA is given weekly.
  - Cycles 2 to 12 (28-day cycles), SARCLISA ESCENA is given every 2 weeks.
  - Cycles 13 and beyond, SARCLISA ESCENA 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 injection of SARCLISA ESCENA, to help reduce the risk and severity of allergic reactions, for at least Cycle 1 of treatment.
- 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.
- **Change 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, or legs

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

What are the possible side effects of SARCLISA ESCENA?

SARCLISA ESCENA can cause serious side effects, including:

- **Allergic reactions.** SARCLISA ESCENA can cause severe or life-threatening allergic reactions throughout the body (systemic administration reactions). Your healthcare provider may stop your injection and not complete it or completely stop treatment with SARCLISA ESCENA if you have an allergic reaction. Tell your healthcare provider or get medical help right away if you develop any of the following signs and symptoms of an allergic reaction including:
  - shortness of breath, wheezing, or trouble breathing
  - swelling of the face, mouth, throat, or tongue
  - throat tightness
  - heart beating faster than usual
  - dizziness
  - lightheadedness or fainting
  - headache
  - cough
  - skin rash or itching
  - nausea
  - runny or stuffy nose
  - chills
- **Injection site reactions** can happen at or near the SARCLISA ESCENA injection site. Symptoms of these local skin reactions include redness, swelling, and pain. Tell your healthcare provider if you develop injection site reactions during treatment with SARCLISA ESCENA.
- **Decreased white blood cell counts.** Decreased white blood cell counts are common and can be severe during treatment with SARCLISA ESCENA. If fever occurs, this may be a sign that you have an infection. Your healthcare provider will check your blood cell counts during treatment with SARCLISA ESCENA and may prescribe 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 ESCENA.**

Blood transfusion management for people treated with SARCLISA ESCENA™ (isatuximab-irfc) and SARCLISA® (isatuximab-irfc)

Dear healthcare professional,

SARCLISA ESCENA™ (isatuximab-irfc) and SARCLISA® (isatuximab-irfc) bind 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 isatuximab-irfc infusion. If treatment with isatuximab-irfc has begun prior to the patient having blood type and screen tests conducted or phenotyping considered, blood compatibility testing can be resolved using dithiothreitol-treated RBCs. In clinical trials, ABO/RhD blood typing was not affected by treatment with isatuximab-irfc. If an emergency transfusion is required, non–cross-matched ABO/RhD-compatible RBCs can be given as per local blood bank practices. For more information, consult the prescribing physician and visit **sarclisahcp.com** for the full Prescribing Information.

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IMPORTANT SAFETY INFORMATION (CONT'D)

What are the possible side effects of SARCLISA ESCENA?

- **Infections.** SARCLISA ESCENA can cause infections that are severe, life-threatening, or that can lead to death. Your healthcare provider will monitor you for signs and symptoms of infection before and during treatment with SARCLISA ESCENA. 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 ESCENA. **Tell your healthcare provider right away if you develop a fever or any signs or symptoms of infection during treatment with SARCLISA ESCENA.**
- **Risk of new cancers.** New cancers have happened in people during treatment with SARCLISA ESCENA. Your healthcare provider will monitor you for new cancers during treatment with SARCLISA ESCENA.
- **Change in blood tests.** SARCLISA ESCENA may affect the results of blood tests to match your blood type for at least 6 months after your last injection of SARCLISA ESCENA. Your healthcare provider will do blood tests to match your blood type before you start treatment with SARCLISA ESCENA. **Tell all of your healthcare providers that you are being treated with SARCLISA ESCENA before receiving blood transfusions.**

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

- upper respiratory tract infection
- lung infection (pneumonia)
- tiredness
- muscle and joint pain
- diarrhea
- trouble sleeping
- COVID-19
- constipation
- swelling of the hands, legs, ankles, and feet

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

- upper respiratory tract infection
- muscle and joint pain
- lung infection (pneumonia)
- high blood pressure
- COVID-19
- trouble sleeping
- diarrhea
- fever

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

- tingling or numbness of the arms or legs
- constipation
- diarrhea
- tiredness
- muscle and joint pain
- upper respiratory tract infection
- reaction at the injection site
- trouble sleeping
- nausea and vomiting
- skin rash
- skin redness
- swelling throughout the body (edema)
- COVID-19
- back pain
- low blood pressure
- lung infection (pneumonia)
- bronchitis
- muscle spasm
- weight decreased
- flu
- urinary tract infection
- fever
- abdominal pain

The most common abnormal blood test results during treatment with SARCLISA ESCENA combination therapies include:

- decreased white blood cell counts
- decreased red blood cell counts
- decreased platelet counts

Heart failure can happen during treatment with SARCLISA ESCENA 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 of the possible side effects of SARCLISA ESCENA. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see, full Prescribing Information for SARCLISA, full Prescribing Information for SARCLISA ESCENA, Patient Information for SARCLISA, and Patient Information for SARCLISA ESCENA.

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