

**Arcalyst**<sup>®</sup>  
(rilonacept) For Injection

**NOW FDA APPROVED**

# Take control of your recurrent pericarditis

A once-weekly treatment for people 12 years and older

## INDICATION

ARCALYST is used to treat Recurrent Pericarditis and reduce the risk of recurrence in adults and children 12 years and older.

Please see Important Safety Information throughout and [Product Information](#).



**NOW FDA APPROVED**

# ARCALYST (rilonacept) doesn't just treat recurrent pericarditis. It reduces the risk of future flares.

Recurrent pericarditis can be a painful and debilitating disease. If you are experiencing repeat flares, it may be time to talk to your healthcare provider about ARCALYST—the first and only FDA-approved treatment for people living with recurrent pericarditis who are 12 years and older.

## IMPORTANT SAFETY INFORMATION

ARCALYST can affect your immune system and can lower the ability of your immune system to fight infections. Serious infections, including life-threatening infections and death, have happened in patients taking ARCALYST. You should not begin ARCALYST if you have an infection or have infections that keep coming back. After starting ARCALYST, if you get an infection or show any sign of an infection including a fever, cough, flu-like symptoms, or have any open sores on your body, call your doctor right away. Treatment with ARCALYST should be stopped if you get a serious infection.

Please see **Important Safety Information** throughout and **Product Information**.



## A guide to help you better understand treatment.

### Why ARCALYST?

Learn about recurrent pericarditis, what causes repeat episodes, and how reducing the risk of future flares is possible with ARCALYST.

### Taking control

Discover how ARCALYST is designed to treat recurrent pericarditis. See the powerful results from the clinical study.

### Using ARCALYST

Understand how a once-weekly injection of ARCALYST can provide effective treatment for recurrent pericarditis.

### Kiniksa One Connect™

Find personalized one-on-one support throughout your entire treatment experience.



#### WHY ARCALYST?

## Taking control of recurrent pericarditis by reducing the risk of future flares

Pericarditis is inflammation of the pericardium, a fluid-filled sac that wraps around the heart and expands and contracts as the heart beats. Recurrent pericarditis occurs after an initial flare where symptoms last for a few days or weeks, go away for a period of at least 4 to 6 weeks, and then return again.

### IMPORTANT SAFETY INFORMATION

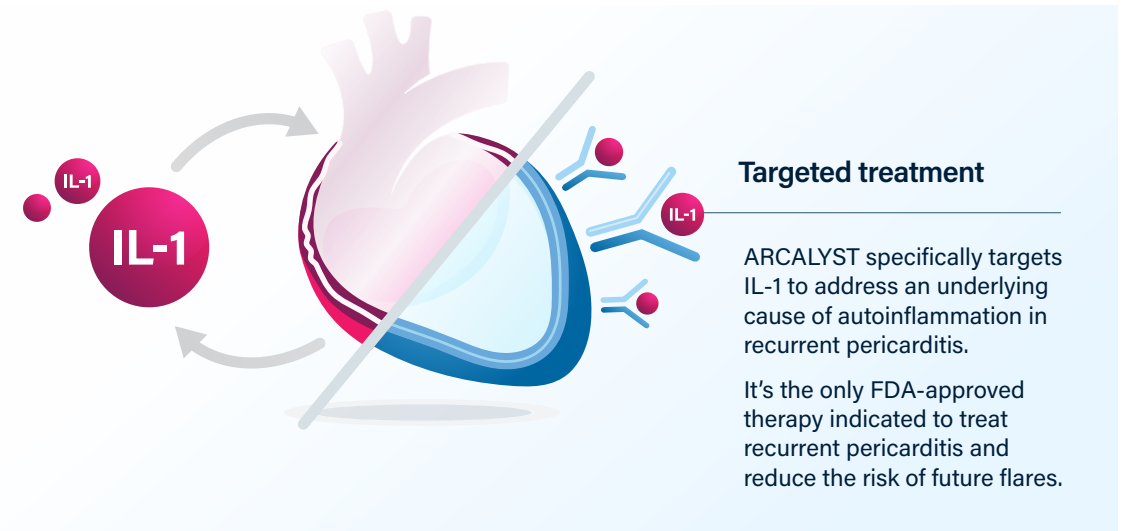
While taking ARCALYST, do not take other medicines that block interleukin-1, such as Kineret® (anakinra), or medicines that block tumor necrosis factor, such as Enbrel® (etanercept), Humira® (adalimumab), or Remicade® (infliximab), as this may increase your risk of getting a serious infection.

Please see Important Safety Information throughout and [Product Information](#).

## Recurrent pericarditis may be driven by uncontrolled autoinflammation.

Think of the pericardium as a water balloon that protects the heart, and when it is inflamed, it becomes thicker than usual. This causes the heart to rub against the pericardium, which causes chest pain and other symptoms. This event is commonly described as an episode or a flare.

Recurring flares may be driven by interleukin-1 (IL-1), a protein produced by your body that causes a continuous cycle of autoinflammation in the pericardium.





#### TAKING CONTROL

## Proving powerful results through the clinical study of ARCALYST (rilonacept)

ARCALYST was studied in 61 people who were diagnosed with recurrent pericarditis and experiencing at least a third flare. Some people were given ARCALYST and others were given placebo. The results were then compared in order to understand how effective ARCALYST was at reducing the risk of future flares and providing symptom relief.

### IMPORTANT SAFETY INFORMATION

Before starting ARCALYST, tell your doctor if you think you have an infection, are being treated for an infection, have signs of an infection, have any open sores, have a history of infections that keep coming back, have asthma, have diabetes or an immune system problem, have tuberculosis or have been in contact with someone who has had tuberculosis, have or have had HIV, hepatitis B or hepatitis C, or take other medicines that affect your immune system.

Please see **Important Safety Information throughout and [Product Information](#)**.

ARCALYST goes beyond symptom relief and reduces the risk of future flares.

#### REDUCED RISK

**96%** reduction in risk of recurrent pericarditis episodes

ARCALYST was proven to **significantly reduce the risk of future flares**. In the ARCALYST study, 23 of 31 patients (74.2%) who took placebo had a recurrence compared with 2 of 30 patients (6.7%) who took ARCALYST.

## ARCALYST helps relieve the pain and other symptoms of pericarditis.

### RELIEF OF SYMPTOMS

**97%** of patients experienced rapid treatment response  
On average, treatment response was about 5 days.

During the study, people were asked to rate their pain based on a rating scale called the Numerical Rating Scale.

- Most people **experienced pain reduction within 5 days** of starting ARCALYST

Clinicians also assessed the levels of C-reactive protein (CRP). This is a protein that is detected in the body when inflammation is present.

- Most people achieved **CRP normalization within 7 days** of starting ARCALYST

## People experienced more pain-free days with ARCALYST.

### LESS PAIN AND FEWER TREATMENTS

**92%** of days with minimal or no pericarditis pain  
Compared to 40% of days for patients who were on placebo.

#### In the study of ARCALYST:

- ARCALYST **significantly reduced the pain** that is associated with recurrent pericarditis
- All patients were able to **stop taking steroids** and switched to ARCALYST only

### IMPORTANT SAFETY INFORMATION

Before you begin treatment with ARCALYST, talk with your healthcare provider about your vaccine history. Ask your healthcare provider whether you should receive any vaccines, including the pneumonia vaccine and flu vaccine, before you begin treatment with ARCALYST.

Please see Important Safety Information throughout and [Product Information](#).



## USING ARCALYST

# Understanding how to use ARCALYST (rilonacept)

ARCALYST is a once-weekly self-administered subcutaneous injection, which means it is an “under the skin” injection you give to yourself. The following pages will help you become familiar with the administration and dosing of ARCALYST. Once you are prescribed ARCALYST, you will be given complete information and support every step of the way.

## IMPORTANT SAFETY INFORMATION

ARCALYST can cause serious side effects: Medicines that affect the immune system may increase the risk of getting cancer. Stop taking ARCALYST and call your doctor or get emergency care right away if you have any symptoms of an allergic reaction (eg, rash, swollen face, trouble breathing). Your doctor will do blood tests to check for changes in your blood cholesterol and triglycerides.

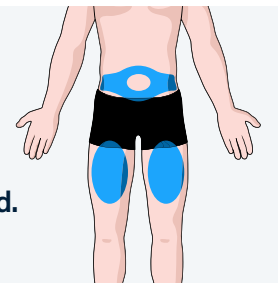
**Please see Important Safety Information throughout and [Product Information](#).**

## Common side effects.

After taking ARCALYST for recurrent pericarditis, some people experienced side effects. The most common side effects include:

- Injection-site reactions
- Upper respiratory tract infections
- Joint and muscle aches

**You should change (rotate) the injection site each time you inject ARCALYST. Changing injection sites helps to prevent irritation and allows the medicine to be completely absorbed.**



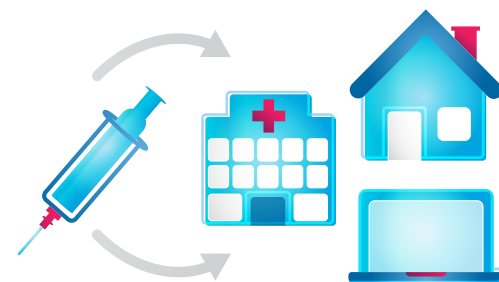
Please report side effects by contacting Kiniksa Pharmaceuticals toll-free at 1-833-546-4572 and select option 3 or contact FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

## ARCALYST is a once-weekly self-administered subcutaneous injection.

**Self-administered** means you give the injection to yourself.

**Subcutaneous** means "under the skin."

Your first injection of ARCALYST will be given with the help of a healthcare provider in the doctor's office or with support from an ARCALYST Nurse Educator.



**Do not try to give yourself ARCALYST injections until you are sure that you understand how to prepare and inject your dose.**

### IMPORTANT SAFETY INFORMATION

Common side effects of ARCALYST include injection-site reactions, upper respiratory tract infections, and joint and muscle aches.

Please see Important Safety Information throughout and [Product Information](#).

## The recommended dose for recurrent pericarditis is shown below.

It is important to use ARCALYST exactly as prescribed by your healthcare provider.

ADULTS (18 years and older)	ADOLESCENTS (12 to 17 years)
<p><b>Starter doses:</b> <b>320 mg</b> given as two 2-mL injections of 160 mg each</p>	<p><b>Starter doses:</b> <b>4.4 mg/kg</b> given as 1 or 2 injections, up to a maximum of 320 mg (up to 2 mL)</p>
<p><b>Weekly maintenance dose:</b> <b>160 mg</b> given as a once-weekly 2-mL injection</p>	<p><b>Weekly maintenance dose:</b> <b>2.2 mg/kg</b> given as a once-weekly injection, up to a maximum of 160 mg (up to 2 mL)</p>

After your first injection of ARCALYST, you will self-administer a once-weekly injection.



Scan code to watch the full injection training video or visit [ARCALYST.com/training](https://www.arcalyst.com/training).









**Your personalized  
treatment support  
starts here**

## We're here to help

We understand that starting a new treatment can be challenging, which is why the Kiniksa One Connect program was created—to help make support simple.

From injection training to understanding your insurance coverage and more—your dedicated Patient Access Lead is here for you with personalized one-on-one support each step of the way.



**1-833-KINIKSA** (1-833-546-4572)  
Monday-Friday (8 AM-8 PM ET)

Learn more at [ARCALYST.com](https://www.arcalyst.com)



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(riloncept) For Injection