

Arcalyst[®]

(rilonacept) For Injection

BREAK FREE FROM FUTURE FLARES

ARCALYST is the first and only FDA-approved therapy to treat recurrent pericarditis and reduce risk of flares in people 12 years and older.

INDICATION

ARCALYST is indicated for the treatment of Recurrent Pericarditis (RP) and reduction in risk of recurrence in adults and pediatric patients 12 years and older.

IMPORTANT SAFETY INFORMATION

- ARCALYST may 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. If you have any signs of an infection, call your doctor right away. Treatment with ARCALYST should be stopped if you get a serious infection. You should not begin treatment with ARCALYST if you have an infection or have infections that keep coming back (chronic infection).

Please see Important Safety Information throughout and full Prescribing Information at ARCALYST.com/PI.

PUT RECURRENT PERICARDITIS IN YOUR PAST

Recurrent pericarditis (RP) is a chronic disease that may need to be treated differently than a *first episode*. Speak with your doctor to find out if ARCALYST is right for you.

This brochure will give you a better understanding of:

- ◆ Different types of pericarditis
- ◆ Pericarditis by the numbers
- ◆ Symptoms of pericarditis
- ◆ Causes of a first episode vs RP
- ◆ The cycle of autoinflammation that drives RP
- ◆ How ARCALYST breaks the cycle of autoinflammation
- ◆ How ARCALYST can help control RP
- ◆ How to take ARCALYST
- ◆ The Kiniksa OneConnect™ support program



Learn more about RP and ARCALYST at ARCALYST.com, and use this QR code to have our newsletter delivered directly to your inbox.



“ I was in pain. I wasn’t able to perform at work... to cook a meal. I received the diagnosis of recurrent pericarditis in February of 2021. Okay...now we can move forward. ”

**Zenda. Business manager, jewelry designer, volunteer.
Prescribed ARCALYST for RP.**

[Watch Zenda tell her story](#)

IMPORTANT SAFETY INFORMATION (continued)

- 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.

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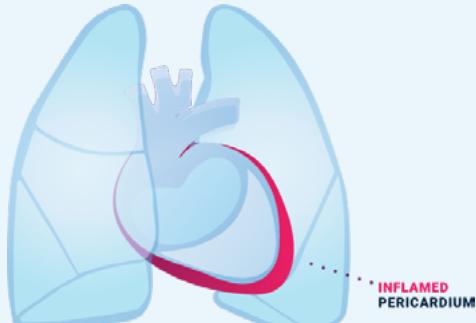
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DIFFERENT TYPES OF PERICARDITIS

WHAT IS PERICARDITIS?

The **pericardium** is a thin membrane that surrounds the heart like a sac. It provides lubrication for the heart, contains it within the chest cavity, and shields it from infection and other types of harm.

Pericarditis is a disease in which that membrane becomes inflamed (in medicine “itis” means “inflamed”). When this happens, the irritated layers of the pericardium rub against each other and can cause a lot of pain.



An episode of pericarditis is often called a flare.

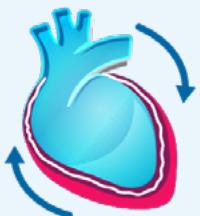
TYPES OF PERICARDITIS INCLUDE A *FIRST OR ONE-TIME EPISODE* AND *RECURRENT PERICARDITIS*.



First or one-time episode of pericarditis

The first episode of pericarditis is often a **single flare** that goes away completely on its own or after treatment.

Average duration: 4 to 6 weeks.



Recurrent pericarditis

Just like it sounds, **RP** is when a pericarditis flare happens again more than 4 weeks after the first one. RP flares can happen repeatedly.

Average disease duration: about 3 years for people who have more than 2 recurrences.

IMPORTANT SAFETY INFORMATION (continued)

- Talk with your doctor about your vaccine history. Ask your doctor whether you should receive any vaccines before you begin treatment with ARCALYST.

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PERICARDITIS BY THE NUMBERS

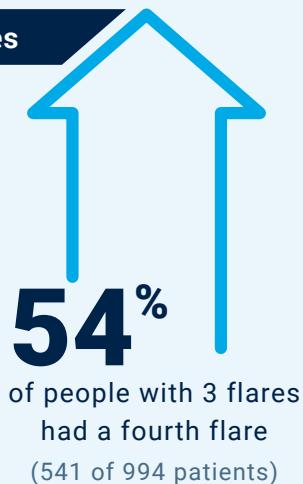
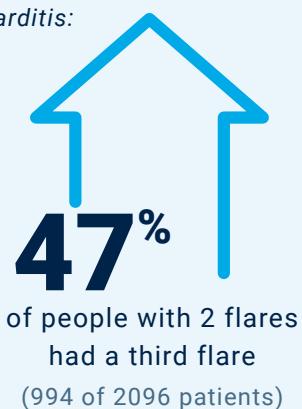


Up to **1 IN 3
PEOPLE**

with a first episode of pericarditis will experience RP within 18 months of their first flare.

With each RP flare, the risk of having another flare increases

In a study of 7502 patients with pericarditis:



With each RP flare, the time in between flares decreases.

RP is unpredictable and can last for many years

In a study of people with RP, researchers found that the disease could last (on average) about:*

6 MONTHS
for people who experienced
just 1 recurrence

3 YEARS
for people who experienced
2 or more recurrences

*In this study of 944 people with RP (observed over 10 years), 569 had 1 recurrence, and 375 had 2 or more recurrences.

IMPORTANT SAFETY INFORMATION (continued)

- Medicines that affect the immune system may increase the risk of getting cancer.

Please see Important Safety Information throughout and full Prescribing Information at ARCALYST.com/PI.

SYMPTOMS OF PERICARDITIS

RP may share similar symptoms with a **first or one-time episode** of pericarditis, but **RP may need to be treated differently**.



Main symptom:

Chest pain, which may be so severe that it can be mistaken for a heart attack.

The pain may get worse when breathing in or lying down. The pain tends to get better when sitting up and leaning forward.

Other symptoms include:



Back, neck, or shoulder pain



Low-grade fever



Cough



Overall sense of weakness and fatigue



Shortness of breath when lying down



Anxiety



Heart palpitations



Swelling in the abdomen, legs, or feet

Even though a **first or one-time episode** and **RP** may feel the same, they have different causes. **RP may require different treatment to relieve pain and prevent future flares.**

IMPORTANT SAFETY INFORMATION (continued)

- Stop taking ARCALYST and call your doctor or get emergency care right away if you have any symptoms of an allergic reaction.

Please see Important Safety Information throughout and full Prescribing Information at ARCALYST.com/PI.

CAUSES OF A FIRST EPISODE AND RP

POSSIBLE CAUSES OF A *FIRST OR ONE-TIME EPISODE*

Even though a *first or one-time episode* and **RP** share the same symptoms, **they have different causes**. For this reason, treatments that relieve symptoms in people with a *first episode* may not be able to prevent future flares in people with RP.

There are a number of possible causes for a first or one-time episode:



Heart attack and
heart procedures



Certain
medications



Illnesses



Infection



Injury to the
pericardium



"Idiopathic"
(or unknown)*

*Likely caused by an undiagnosed virus or the body's immune response to a past viral illness.

THE CAUSE OF RECURRENT PERICARDITIS

RP is an autoinflammatory disease, which means **flares are caused by the body's immune system attacking the pericardium**.

Auto - + inflammation

"Self" or automatic

The painful swelling that happens as the body's natural response to injury or infection

Each immune system attack causes inflammation that leads to more immune system response in an ongoing cycle.

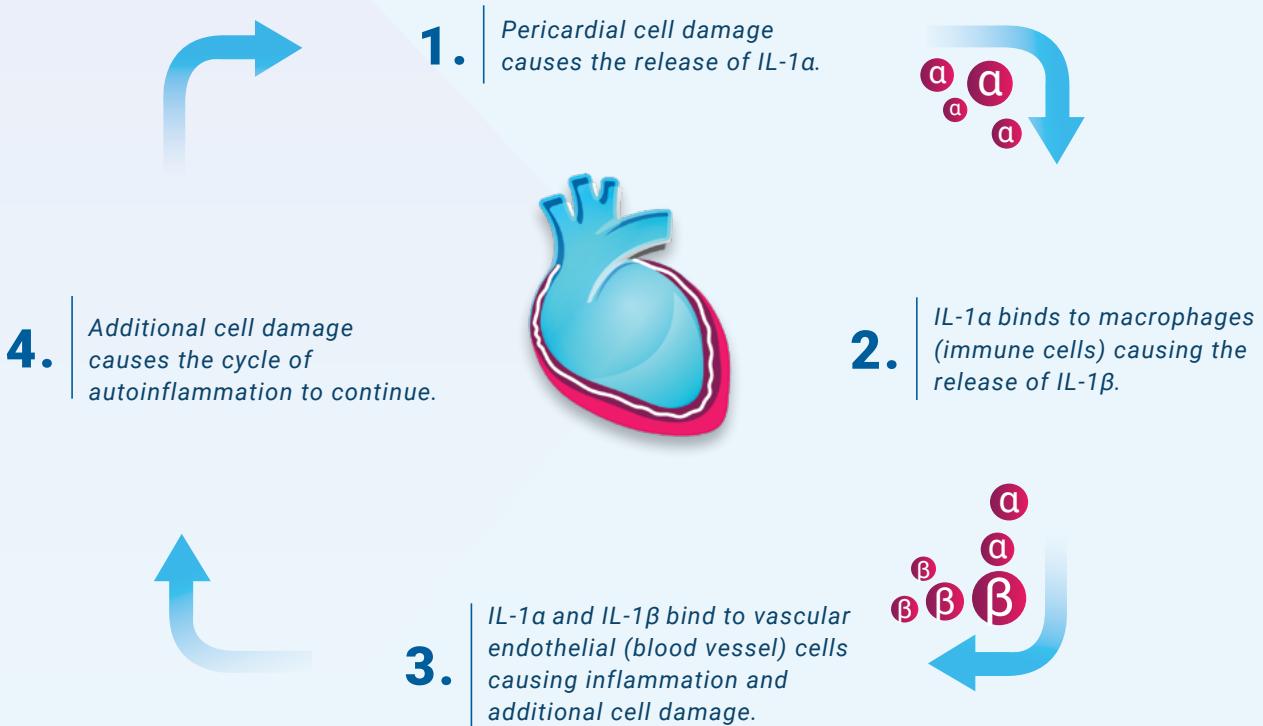
IMPORTANT SAFETY INFORMATION (continued)

• Your doctor will do blood tests to check for changes in your blood cholesterol and triglycerides.

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UNDERSTANDING THE CYCLE OF AUTOINFLAMMATION THAT DRIVES RP

RP occurs when proteins called **IL-1 α** and **IL-1 β** signal the immune system to attack the pericardium. Each attack causes inflammation that leads to more attacks in an ongoing cycle of autoinflammation.



IL-1 α , interleukin-1 α ; IL-1 β , interleukin-1 β .

IMPORTANT SAFETY INFORMATION (continued)

- In patients with recurrent pericarditis, common side effects include injection-site reactions, which may include pain, redness, swelling, itching, bruising, lumps, inflammation, skin rash, blisters, warmth, and bleeding at the injection site, and upper respiratory tract infections.

Please see Important Safety Information throughout and full Prescribing Information at ARCALYST.com/PI.

IMAGINE A FUTURE FREE FROM FLARES: TREATMENT WITH ARCALYST CAN HELP BREAK THE ONGOING CYCLE OF RP

“What helped me was learning as much as I could. Asking [my doctor] questions about the effects of [ARCALYST].**”**

—Zenda. Business manager, jewelry designer, volunteer.
Prescribed ARCALYST for RP.

[Watch Zenda tell her story](#)



“What I like about ARCALYST is that it's once a week, and I can do it at home. I don't need to go to a doctor's office. And I can be independent and do it myself.**”**

—Cathy. Wife, mother, fitness instructor.
Prescribed ARCALYST for RP.

[Watch Cathy tell her story](#)



“I work with Jasmin [at the Kiniksa OneConnect™ program] who is just great to work with. She helped me navigate all of the insurance...[and] have ARCALYST shipped directly to my home.**”**

—Warren. Husband, father, motorcycle enthusiast.
Prescribed ARCALYST for RP.

[Watch Warren tell his story](#)



IMPORTANT SAFETY INFORMATION (continued)

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UNDERSTANDING HOW ARCALYST BREAKS THE CYCLE OF AUTOINFLAMMATION IN RP

ARCALYST is the first and only FDA-approved therapy to treat RP and reduce risk of flares in people 12 years and older. ARCALYST works by specifically targeting the IL-1–driven cycle of autoinflammation.

By blocking IL-1 signaling,
ARCALYST breaks the
cycle of RP
to treat and
prevent flares

1. Pericardial cell damage causes the release of IL-1 α .



4. Additional cell damage causes the cycle of autoinflammation to continue.



2. IL-1 α binds to macrophages (immune cells) causing the release of IL-1 β .



ARCALYST
traps IL-1 α
and IL-1 β ,
blocking
IL-1 signaling

3. IL-1 α and IL-1 β bind to vascular endothelial (blood vessel) cells causing inflammation and additional cell damage.

IMPORTANT SAFETY INFORMATION (continued)

- 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.

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TAKE CONTROL WITH ARCALYST

IN THE CLINICAL TRIAL, ARCALYST DELIVERED PROVEN, POWERFUL RESULTS

PROVEN FLARE PREVENTION

96%
vs placebo

REDUCTION IN RISK OF FLARES WHILE ON TREATMENT

- ♦ **2 of 30 participants taking ARCALYST had a flare.** In both cases, the flare happened **during a temporary interruption** (1 to 3 weekly doses) in ARCALYST treatment
- ♦ **23 of 31 participants taking placebo had a flare.** In every case, the flare went away after they were given ARCALYST

ARCALYST was studied in people diagnosed with RP who were experiencing at least a second recurrence. Reduced pain and inflammation and time to transition to ARCALYST alone were evaluated in 86 participants taking ARCALYST. Risk of recurrence and days with minimal or no pain were subsequently evaluated in 61 participants, 30 of whom continued taking ARCALYST compared with 31 who were switched to placebo.



“[ARCALYST] was certainly worth a try for me... after just a few days, I started seeing a difference. And I would say within about a month I was pretty much back to normal and I have been since then. I haven't had a single flare.* **”**

Warren. Husband, father, motorcycle enthusiast. Prescribed ARCALYST for RP.
[Watch Warren tell his story](#)

*After 3 years of continuous ARCALYST therapy, Warren discontinued treatment and experienced a flare. He restarted ARCALYST and has been flare-free since then.

IMPORTANT SAFETY INFORMATION (continued)

- Talk with your doctor about your vaccine history. Ask your doctor whether you should receive any vaccines before you begin treatment with ARCALYST.

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FREEDOM FROM PAIN AND STEROIDS

RAPID RELIEF

97%

OF PARTICIPANTS ACHIEVED PAIN RELIEF AND INFLAMMATION RESOLUTION, MOST AFTER THE FIRST DOSE*†‡

- ◆ Average time to pain relief was 5 days
- ◆ Average time to inflammation resolution was 7 days

*Participants rated their pain based on the Numerical Rating Scale.

†Inflammation was measured by levels of C-reactive protein (CRP), which may be elevated when inflammation is present.

‡Pain relief was defined as ≤2 on a 0-10 pain scale and normal CRP levels were defined as ≤0.5 mg/dL.

MORE PAIN-FREE DAYS

Participants reported

92%

OF DAYS WITH MINIMAL OR NO PAIN WHILE TAKING ARCALYST

Participants taking placebo reported only 40% of days with minimal or no pain.

FREEDOM FROM STEROIDS

100%

OF PARTICIPANTS TAKING STEROIDS SUCCESSFULLY TRANSITIONED TO ARCALYST ALONE

Of the 86 participants, 41 were taking steroids when the trial began.

All 41 transitioned off them completely soon after starting ARCALYST.

- ◆ Average time to transition to ARCALYST alone from traditional therapies, including NSAIDs, colchicine, or corticosteroids (alone or in combination) was only 7.9 weeks

NSAIDs, nonsteroidal anti-inflammatory drugs.

ARCALYST prevents RP flares only while taken as prescribed. Even if you feel better, speak with your doctor before stopping ARCALYST.

IMPORTANT SAFETY INFORMATION (continued)

- Medicines that affect the immune system may increase the risk of getting cancer.

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LONG-TERM PREVENTION

The ARCALYST clinical trial included a long-term extension (LTE) of up to 2 years.

- Given the opportunity to remain in the trial for up to an additional 24 months of ARCALYST treatment, **99% (74 of 75)** of eligible participants chose to continue treatment in the LTE

WHILE ON TREATMENT IN THE LTE, ARCALYST CONTINUED TO DELIVER POWERFUL RESULTS:

98%

REDUCTION IN RISK OF FLARES IN THOSE WHO CONTINUED TREATMENT VS THOSE WHO SUSPENDED TREATMENT

In participants who continued in the LTE more than 18 months after their last flare:

- 3% (**1 of 33**) of those who continued taking ARCALYST had a flare. This occurred during a temporary interruption (4 weeks) in ARCALYST treatment
- 75% (**6 of 8**) who suspended ARCALYST treatment for observation had a flare following discontinuation

These results are consistent with risk reduction seen in the previous period of the trial.

52 of the 74 participants remained on treatment for 18 months after their last flare. Of these participants, 33 continued treatment with open-label ARCALYST, 8 suspended treatment and remained in the trial for observation, and 11 exited the trial.

ARCALYST may be used for the duration of your disease.

RP is an unpredictable disease. For some people it can last months. For others it can last years. While certain treatments used for first (or one-time) episodes may not be appropriate for long-term use, **ARCALYST may be used until the cycle of autoinflammation has resolved.**

IMPORTANT SAFETY INFORMATION (continued)

- Stop taking ARCALYST and call your doctor or get emergency care right away if you have any symptoms of an allergic reaction.

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HOW TO TAKE ARCALYST

ARCALYST is a once-weekly, self-administered, subcutaneous (under the skin) injection.



You will receive your first injection at the doctor's office or **with the support of an ARCALYST Clinical Educator**. You will then prepare and self-administer your once-weekly injection.

- ◆ Do not try to give yourself ARCALYST injections until you are sure you understand how to prepare and inject your dose

Step-by-step instructions

In addition to one-on-one training, resources are available at ARCALYST.com with instructions on how to prepare and inject ARCALYST.



[Step-by-step instruction video](#)



[Step-by-step instruction manual](#)



Use this QR code to view the video and/or download the written instructions on how to prepare and inject ARCALYST. Also see the ARCALYST Instructions for Use available at ARCALYST.com/PI.

IMPORTANT SAFETY INFORMATION (continued)

- Your doctor will do blood tests to check for changes in your blood cholesterol and triglycerides.

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“ We offer personalized, one-on-one support to help you get the most from your experience with ARCALYST® (rilonacept). ”

– Kiniksa Patient Access Lead

Once your doctor has prescribed ARCALYST and enrolled you in the **Kiniksa OneConnect™** program, you will be paired with a dedicated Patient Access Lead (PAL) who will provide support and guidance throughout every step of treatment with ARCALYST.

Your Kiniksa OneConnect™ PAL can assist you with:

- ✓ Understanding your insurance coverage and prior authorization (PA) requirements.
- ✓ Cost-saving options if you are eligible.
- ✓ Getting refills on time.
- ✓ Options for injection training.
- ✓ Ongoing education and support.

Getting started: We will help make the start of treatment a seamless experience.

Understanding your insurance coverage

- ✓ Your PAL will guide you through the insurance process by helping explain your coverage and partnering with your doctor's office if a PA is needed.
 - 96% of ARCALYST prescriptions are approved by commercial insurance plans

Injection training

- ✓ Your PAL can work with you to set up one-on-one injection training with an **ARCALYST Clinical Educator**, who will guide you through the injection process, either virtually or in person

Financial assistance: Our programs are designed to help remove barriers to treatment.

Kiniksa Copay Program

- ✓ As little as \$0/month
- If you are eligible, the Kiniksa Copay Assistance Program may be able to help lower your out-of-pocket costs to as little as \$0 per month.*

Patient Assistance Program

- ✓ Financial assistance is also available to eligible patients who don't have insurance or don't have adequate insurance.[†]

*To be eligible for the Kiniksa Copay Assistance Program, you must have commercial insurance, must not have Medicare, Medicaid, or other government insurance, and must meet other eligibility criteria. You also must agree to the rules set forth in the terms and conditions for the program. Please visit kiniksapolicies.com/copay to review additional eligibility criteria.

[†]To be eligible for the Kiniksa Patient Assistance Program, you must meet certain financial eligibility requirements. Please visit kiniksapolicies.com/pap to review additional eligibility criteria.

Treatment support: Our work doesn't end after treatment begins. Your PAL provides support throughout the entire treatment experience.

ARCALYST delivery and refills

- ✓ Your PAL will help you set up ongoing delivery of ARCALYST directly to your door and send reminders when it's time to refill.

ARCALYST product support

- ✓ Your PAL will assist you with product-related questions and provide access to educational tools and resources about your treatment.

Additional resources and support

- ✓ Your PAL will check in with you regularly to make sure you are getting the support you need. If your situation changes (new insurance, change of address, upcoming travel, etc), your PAL can help find ways to avoid treatment interruptions.



For more information on the Kiniksa OneConnect™ support program, use this QR code or visit ARCALYST.com.

SPEAK WITH YOUR DOCTOR TO SEE IF ARCALYST IS RIGHT FOR YOU



Speak with your doctor

Make an appointment to ask questions and discuss treatment with ARCALYST.



Take notes on your symptoms and goals

Record how you are feeling and how your symptoms impact your life.



Research treatments

Search for sites with information about RP and RP treatments. ARCALYST.com is a good place to start.



Write a list of your questions

It can be difficult to remember everything you want to ask during your appointment, so prepare your list of questions in advance and bring them with you.



Have an open, honest, and collaborative conversation with your doctor

Share your experiences and ask questions. Listen to your doctor's recommendations. Collaborate with your doctor to determine if ARCALYST is right for you.



Use this QR code
to download a guide
for planning your next
doctor's visit.

Getting the care you need often starts with
being your own best advocate.

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