

## TREATMENT GUIDE

Your treatment. Your questions answered.

### INDICATIONS

KINERET<sup>®</sup> (anakinra) is a prescription medicine called an interleukin-1 receptor antagonist (IL-1Ra) used to:

**RA:** Reduce the signs and symptoms and slow the damage of moderate to severe active rheumatoid arthritis (RA) in people aged 18 years and older when 1 or more other drugs for RA have not worked

**NOMID:** Treat people with a form of Cryopyrin-Associated Periodic Syndromes (CAPS) called Neonatal-Onset Multisystem Inflammatory Disease (NOMID)

**DIRA:** Treat people with Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

KINERET is not for children with Juvenile Rheumatoid Arthritis.

#### **IMPORTANT SAFETY INFORMATION**

#### Do not take KINERET if you are allergic to:

- Proteins made from bacteria called E. coli. Ask your healthcare provider if you are not sure
- Anakinra or any of the ingredients in KINERET. See the end of the patient leaflet for a complete list of ingredients in KINERET

WHAT YOU NEED TO KNOW ABOUT KINERET® (anakinra)



"We advocated for our child. We did whatever we felt was necessary. And we never gave up."

- Sam, father of Quinn who is a NOMID patient on KINERET

This represents one patient's experience. Individual results may vary.

# What should I know about KINERET<sup>®</sup> (anakinra)?

### KINERET is injected daily under the skin

- > KINERET should be injected around the same time every day
- > If you miss a KINERET injection and are unsure when to take your next one, contact your healthcare provider for guidance
- > Even if you have used an injectable drug before, you may need some training and practice before you feel confident administering KINERET

### KINERET blocks a protein called interleukin-1 (IL-1)

- > Your doctor may have prescribed KINERET because he/she thinks your symptoms may be caused by IL-1
- > IL-1 is a protein in the body that causes inflammation

### The FDA evaluated the benefits and safety of KINERET and approved it for the treatment of RA, NOMID, and DIRA

- > People who use KINERET often have some skin reactions where they inject. Most injection site reactions are mild, happen early during treatment, and last about 14 to 28 days
- > Young patients taking KINERET to treat NOMID or DIRA can experience side effects, but in clinical trials most side effects were mild and no patient had to stop treatment because of side effects

### **IMPORTANT SAFETY INFORMATION** (cont'd)

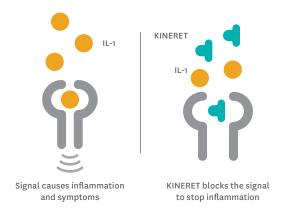
### Before starting KINERET, tell your healthcare provider if you:

- Have an infection, a history of infections that keep coming back, or other problems that can increase your risk of infections
- Are scheduled to receive any vaccines. People using KINERET should not receive live vaccines
- $\cdot$  Have kidney problems
- Are pregnant or plan to become pregnant. It is not known if KINERET will harm your unborn baby
- Are breastfeeding or plan to breastfeed. It is not known if KINERET passes into your breast milk. You and your healthcare provider should decide if you will use KINERET or breastfeed

### How does KINERET work?

### KINERET reduces inflammation by blocking IL-1

- > The IL-1 protein plays an important role in NOMID, DIRA, and in some cases of RA
- > IL-1 binds to receptors on cells throughout the body to send a signal that can cause inflammation



### Inflammatory symptoms caused by IL-1 include:



### Stay the course

When it comes to treatment with KINERET it's important to stay the course. It can take time for you to notice an improvement in your symptoms, but staying consistent with the injections is essential.

### **IMPORTANT SAFETY INFORMATION** (cont'd)

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

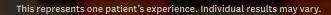
### HOW TO USE

# KINERET<sup>®</sup> (anakinra)

### "

I made a commitment to seeing it through...at this point, it's part of my routine.

– Megan, an RA patient on KINERET



### How is KINERET<sup>®</sup> (anakinra) supplied?

KINERET is supplied in single-use, prefilled, graduated glass syringes



- > Each graduated syringe contains 100 mg of KINERET solution
- > KINERET is dispensed in a 7-day pack
- > Use the KINERET prefilled syringe that matches the day of the week until all 7 syringes are used



### Kineret >>>>> ON TRACK

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If you need extra injection supplies (sharps containers, needle clippers, swabs and wipes) just **call Kineret ON TRACK™ at 866.547.0644**, 8 AM to 8 PM EST, Monday through Friday.

### How is KINERET stored?



KINERET is stored in a refrigerator between **36°F and 46°F** (2°C and 8°C)



**DO NOT** freeze or shake KINERET



You can keep KINERET at room temperature for up to **12 hours** 

If KINERET is left unrefrigerated for more than 12 hours, **it should be discarded** 



Keep KINERET in its original carton and **away from light** 

#### **IMPORTANT SAFETY INFORMATION** (cont'd)

KINERET and other medicines may affect each other and cause serious

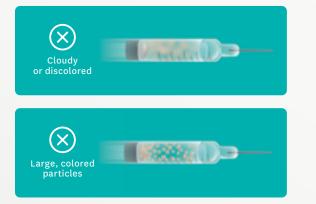
**side effects.** Especially, tell your healthcare provider if you take certain other medicines that affect your immune system called Tumor Necrosis Factor (TNF) blockers. Ask your healthcare provider for a list of these medicines if you are not sure. Know the medications you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new prescription.

### **IMPORTANT SAFETY INFORMATION** (cont'd) KINERET may cause serious side effects, including:

**Serious infections.** KINERET may lower your ability to fight infections. During treatment with KINERET, call your healthcare provider right away if you get an infection, have any sign of an infection including a fever or chills, or have any open sores on your body. You may get an infection if you receive live vaccines while you use KINERET. You should not receive live vaccines while you use KINERET

### Preparing your injection

- 1 Set up a clean and flat workspace such as a table
- **2** Take 1 KINERET<sup>®</sup> (anakinra) prefilled syringe out of the refrigerator
- 3 Check the expiration date
- 4 Wait for 30 minutes to let the solution come to room temperature
- **5** Ensure that the liquid in the syringe is clear and colorless (a few small bubbles are not a problem)





### **KINERET** Injection Training Video

Press play to watch a step-by-step video on how to administer your KINERET injection



If you are administering KINERET to a baby or child, you may need to prepare a dose that is smaller than 100 mg.

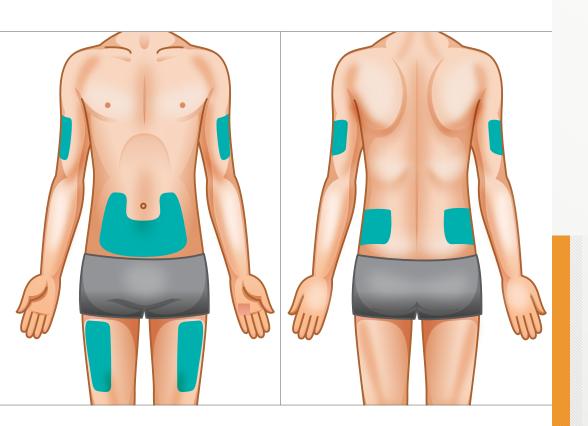
Please see the "Using KINERET for Your Child" section to learn how.

#### **IMPORTANT SAFETY INFORMATION** (cont'd)

**Serious allergic reactions.** Stop using KINERET, call your healthcare provider, and get emergency help right away if you have any of these symptoms of a serious allergic reaction: swelling of your face, lips, mouth, or tongue; trouble breathing; wheezing; severe itching; skin rash, redness, or swelling outside of the injection site area; dizziness or fainting; fast heartbeat or pounding in your chest (tachycardia); or sweating. People with DIRA may have an increased risk of allergic reactions, especially in the first several weeks

### Select your injection site

### 1 Choose an injection site



2 Be sure to choose a new site each time you inject KINERET<sup>®</sup> (anakinra)

- Do not inject an area that is tender, red, bruised, or hard
- 🗙 Avoid areas with scars or stretch marks
- Do not inject close to a vein that you can see under the surface of the skin
- 3 Clean your injection site with an alcohol swab and let the area dry

### Kineret >>>>> ON TRACK

You can use the journal included in your KINERET Welcome Kit to track your injections. If you have questions about injection site rotation, or would like to request a new injection site tracker journal, **call Kineret ON TRACK<sup>™</sup> at 866.547.0644,** 8 AM to 8 PM EST, Monday through Friday, to reach one of our KINERET trained nurses.

For questions about your treatment, read the KINERET Prescribing Information and/or ask your doctor.

#### **IMPORTANT SAFETY INFORMATION** (cont'd)

**Decreased ability of your body to fight infections (immunosuppression).** It is not known if treatment with medicines that cause immunosuppression, like KINERET, affect your risk of getting cancer

#### **IMPORTANT SAFETY INFORMATION** (cont'd)

**Low white blood cell count (neutropenia).** KINERET may cause you to have a lower number of certain white cells (neutrophils). Neutrophils are important in fighting infections. You should have blood tests before starting treatment with KINERET, then monthly for 3 months. After the first 3 months you should have your blood tested every 3 months for up to 1 year

Please <u>click here</u> or go to page 27 for Important Safety Information. Please <u>click here</u> for full Prescribing Information.

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### Giving your injection



#### Hold the syringe barrel and pull the cover straight off the needle

Gently pinch a fold of skin at the cleaned injection site



Hold the syringe like a pencil at a 45- to 90-degree angle to the skin

### **IMPORTANT SAFETY INFORMATION** (cont'd)

### The most common side effects of KINERET include:

• Injection site skin reactions. The symptoms of injection site skin reactions may include: redness, swelling, bruising, itching, and stinging. Most injection site reactions are mild, happen early during treatment, and last about 14 to 28 days. Injection site reactions have been observed less frequently in people with NOMID



Insert the needle into the skin with a quick, dart-like motion

- Slowly push the plunger all the way down to inject KINERET<sup>®</sup> (anakinra)
- When the syringe is empty, pull the needle out of the skin while keeping the needle at the same angle

### **ON TRACK**

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If you have questions or concerns about injecting KINERET, call Kineret ON TRACK<sup>™</sup> at 866.547.0644, 8 AM to 8 PM EST, Monday through Friday, to reach one of our KINERET trained nurses.

For questions about your treatment, read the KINERET Prescribing Information and/or ask your doctor.

### **IMPORTANT SAFETY INFORMATION** (cont'd)

#### The most common side effects of KINERET include: (cont'd)

- RA gets worse with treatment, if you
- Diarrhea
- Joint pain
- Feeling like you have the flu
- already have RA • Headache

Nausea and vomiting

- Sore throat or runny nose
- Sinus infection
- Tell your healthcare provider if you have any side effect that bothers you or does not go away.

Please click here or go to page 27 for Important Safety Information. Please click here for full Prescribing Information.

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Pain in your

stomach area

### After your injection

- Place a cotton ball or gauze over the injection site and press for several seconds
  - Don't use an alcohol wipe—it may sting!
- Put your used syringe in a sharps disposal container right away
- **3** Track your injection site in a diary or on the KINERET Injection Tracker



#### **IMPORTANT SAFETY INFORMATION** (cont'd)

These are not all of the possible side effects of KINERET. For more information ask your healthcare provider or pharmacist. You can also see the Full Prescribing Information for KINERET including Patient Information and Instructions for Use at https://www.kineretrx.com/pdf/Full-Prescribing-Information-English.pdf

To report suspected side effects, contact Sobi North America at 1-866-773-5274 or FDA at 1-800-FDA-1088

# Understanding injection site reactions

- > Skin reactions are the most common side effect with KINERET<sup>®</sup> (anakinra) and may appear as redness, swelling, bruising, itching, or stinging at the injection site<sup>1</sup>
- > Injection site skin reactions are most common during the first month of treatment and usually last about 14 to 28 days<sup>1</sup>

### Tips to help address injection site reactions:

- Cool the site with a cold compress or the enclosed ice pack for a few minutes, both before and after the injection
- Oon't skip the warm-up step of bringing KINERET to room temperature
- Apply hydrocortisone or an antihistamine cream to your injection site
- Rotate sites to avoid soreness. A diary or the KINERET Injection Tracker can help keep track of sites
- Don't inject into skin that is red, bruised, tender, or hard

Please <u>click here</u> or go to page 27 for Important Safety Information. Please <u>click here</u> for full Prescribing Information.

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### WHAT TO KNOW

### ABOUT USING

KINERET<sup>®</sup> (anakinra)

### FOR YOUR CHILD

As your child grows, their understanding of the medication the treatment—the importance of it comes.

- Colleen, mother of Quinn who is a NOMID patient on KINERET

This represents one patient's experience. Individual results may vary.

### How do I prepare an injection of KINERET<sup>®</sup> (anakinra) for my baby or child?

### The dose of KINERET may be smaller in babies or children<sup>1</sup>

- > The recommended starting dose of KINERET is 1 to 2 mg/kg for patients with neonatal-onset multisystem inflammatory disease (NOMID) or deficiency of interleukin-1 receptor antagonist (DIRA)
- > KINERET comes in 100 mg prefilled syringes

### If you need to prepare a KINERET dose less than 100 mg, follow these steps<sup>1</sup>:



- Hold the syringe with the needle pointing straight up
- 2 Slowly push the plunger rod until you see a tiny liquid drop at the tip of the needle
- **3** Turn the syringe so the needle is pointing down
- 4 Hold the syringe above a sterile gauze or tissue
- 5 Slowly push the plunger until the top of the plunger has reached the correct dose

Once you have prepared the correct dose of KINERET, the injection can be given as described on pages 13-14.



### **KINERET Child Injection Training Video**

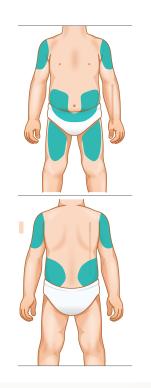
Press play to watch a step-by-step video on how to administer your child's KINERET injection

### **IMPORTANT SAFETY INFORMATION**

#### Do not take KINERET if you are allergic to:

- Proteins made from bacteria called *E. coli*. Ask your healthcare provider if you are not sure
- Anakinra or any of the ingredients in KINERET. See the end of the patient leaflet for a complete list of ingredients in KINERET

### Injection tips for kids:



- Rotate injection sites to avoid soreness. A diary or the KINERET Injection Tracker journal can help keep track of sites
- Make injecting KINERET part of your daily routine
- Involve your child in the injection process
- Have your child help gather supplies
- Let your child choose each day's injection site (ensuring that sites are rotated) or where in your home you will do the injection
- Purchase a selection of fun bandages or ice packs and let your child choose which one to use that day
- As your child grows older and more independent, he/she can learn to administer injections under supervision or independently



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If you have questions or concerns about injection site reactions, call Kineret ON TRACK<sup>™</sup> at 866.547.0644, 8 AM to 8 PM EST, Monday through Friday, to reach one of our KINERET trained nurses.

For questions about your child's treatment, read the KINERET Prescribing Information and/or ask your doctor.

### IMPORTANT SAFETY INFORMATION (cont'd)

Before starting KINERET, tell your healthcare provider if you:

• Have an infection, a history of infections that keep coming back, or other problems that can increase your risk of infections

Please <u>click here</u> or go to page 27 for Important Safety Information. Please <u>click here</u> for full Prescribing Information.

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### WHEN YOU

### HAVE QUESTIONS OR NEED SUPPORT

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Kineret ON TRACK<sup>™</sup> allowed me to work with a case manager and get KINERET<sup>®</sup> (anakinra) sent right to my office.

- Megan, an RA patient on KINERET

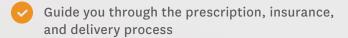


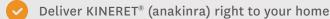
This represents one patient's experience. Individual results may vary.

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# A team of experts supporting you every step of the way

### Kineret ON TRACK<sup>™</sup> Case Managers, nurses, and pharmacy specialists will:





 Provide injection training and support throughout your treatment

Additional training and communications—by email, on the phone, and in person—are available at every step of your journey. All you have to do is ask.

Call Kineret ON TRACK<sup>™</sup> at 866.547.0644, 8 AM to 8 PM EST, Monday through Friday.



### Financial assistance & reimbursement

Case Managers can guide you through the insurance approval process by helping you understand your coverage and finding solutions to help you access KINERET.

> Copay Program offers up to \$13,000 per year to lower out-of-pocket costs to as little as \$0 per month for eligible commercially insured patients\*



> Patient Assistance Program can help eligible patients access KINERET free of charge<sup>+</sup>

### FAQs about KINERET financial assistance

#### How do I find out if my insurance covers KINERET?

A KINERET Case Manager will be able to help you find out if your insurance covers KINERET and better understand your bills and copays.

#### Will I be eligible for the Copay Program?

You may be eligible if you are a U.S. resident and have commercial insurance. You are not eligible if you have a government, state, or federally funded prescription program, including Medicare, Medicaid, Medigap, VA, DOD, or TRICARE.

Will I be eligible for the Patient Assistance Program? You may be eligible if you are a U.S. resident, are uninsured or underinsured, and have met all other eligibility requirements. A KINERET Case Manager can help you understand these requirements and your eligibility.

If you would like to enroll in the KINERET financial assistance program, simply contact a Kineret ON TRACK<sup>™</sup> Case Manager at: 866.547.0644, 8 AM to 8 PM EST, Monday through Friday or fill out the mailer included in your Kineret ON TRACK<sup>™</sup> Welcome Kit.

\*Patient must be a resident of the US or Puerto Rico. Patient must be commercially insured. There are no income requirements to participate in the program. Patient is not enrolled in any government, state, or federally funded prescription program, including Medicare, Medicaid, Medigap, VA, DOD, or TRICARE.

<sup>†</sup>Patients must be US citizens or legal residents under the care of a licensed practicing healthcare provider and prescribed KINERET. Other terms and conditions apply.



### Injection training and support

Our KINERET<sup>®</sup> (anakinra) Trained Nurses are available, as needed, to help you learn about injection training.

- > One-on-one virtual or in-home injection training
- > Tips and advice to help address common injection site reactions
- > Guidance on injection site rotation and injection tracking

If you'd like to arrange an in-home or virtual visit for injection training, call us at Kineret ON TRACK<sup>™</sup> at **866.547.0644**, 8 AM to 8 PM EST, Monday through Friday.

### Getting KINERET delivered

Pharmacy Specialists ensure you have access to a continuous supply of KINERET.

- > Prescription delivery directly to your home
- > Supplementary supplies needed for injection
- > Refill reminders, emergency shipments, and more

### FAQs about your KINERET supply

What happens if I am not at home to receive my KINERET shipment?

You can choose to be at home to sign for your shipment of KINERET, or you can opt to waive the signature requirement. Every month you will receive a refill call, and at this time you can change the address where your shipment is to be delivered.

What happens if I need an emergency supply of KINERET?

If you need an emergency supply of KINERET, call your KINERET Pharmacy Specialist at **800.850.4306** and press option 4. Specialists are available to answer your calls during business hours (8 AM to 8 PM EST, Monday through Friday). At night or on the weekend, you can leave a voice message and we will get back to you within 2 hours.

To speak to a KINERET Pharmacy Specialist, call **800.850.4306**, 8 AM to 8 PM EST, Monday through Friday.



### Kineret ON TRACK™ guidance

You can sign up for Kineret ON TRACK<sup>™</sup> Guidance to receive extra support.

- > Educational materials that help you know what to expect
- > Tips and techniques through regular communications
- > Online resources packed with useful information

#### FAQs about Kineret ON TRACK™ guidance

#### What is the difference between Kineret ON TRACK™ and Kineret ON TRACK™ Guidance?

When you place your KINERET order, you are eligible for all the Kineret ON TRACK™ offerings. Kineret ON TRACK™ Guidance is part of those offerings, enabling you to receive ongoing support—by email and on the phone—throughout your treatment when you agree to receive product and marketing information from Sobi.

### Will my information be used for anything other than prescription fulfillment?

Your information will be stored in the Kineret ON TRACK<sup>™</sup> database, and will only be used for Kineret ON TRACK<sup>™</sup> and Kineret ON TRACK<sup>™</sup> Guidance communications.

### If I unsubscribe from Kineret ON TRACK<sup>™</sup> Guidance emails, will I stop getting my medication?

You will still be able to get your medication if you unsubscribe from the Kineret ON TRACK™ Guidance emails.

If you would like to sign up for Kineret ON TRACK<sup>™</sup> Guidance, fill out the mailer in the Kineret ON TRACK<sup>™</sup> Welcome Kit or call us at **866.547.0644**, 8 AM to 8 PM EST, Monday through Friday.

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**Serious allergic reactions.** Stop using KINERET, call your healthcare provider, and get emergency help right away if you have any of these symptoms of a serious allergic reaction: swelling of your face, lips, mouth, or tongue; trouble breathing; wheezing; severe itching; skin rash, redness, or swelling outside of the injection site area; dizziness or fainting; fast heartbeat or pounding in your chest (tachycardia); or sweating. People with DIRA may have an increased risk of allergic reactions, especially in the first several weeks

**Decreased ability of your body to fight infections (immunosuppression).** It is not known if treatment with medicines that cause immunosuppression, like KINERET, affect your risk of getting cancer

Low white blood cell count (neutropenia). KINERET may cause you to have a lower number of certain white cells (neutrophils). Neutrophils are important in fighting infections. You should have blood tests before starting treatment with KINERET, then monthly for 3 months. After the first 3 months you should have your blood tested every 3 months for up to 1 year

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- $\cdot$  RA gets worse with treatment, if you already have RA
- Headache
- $\cdot$  Nausea and vomiting
- Diarrhea
- Joint pain
- Fever
- Feeling like you have the flu
- Sore throat or runny nose
- $\boldsymbol{\cdot}$  Sinus infection
- Pain in your stomach area

Tell your healthcare provider if you have any side effect that bothers you or does not go away.

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To report suspected side effects, contact Sobi North America at 1-866-773-5274 or FDA at 1-800-FDA-1088



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