

TREATMENT

GUIDE

**Your treatment.
Your questions answered.**

INDICATIONS

KINERET® (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

Please see Important Safety Information on pages 26 and 27. [Click here](#) for full Prescribing Information for KINERET, including Patient Information.

Patients in this material have experience with KINERET, but may no longer be on treatment.

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.

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What should I know about KINERET® (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)

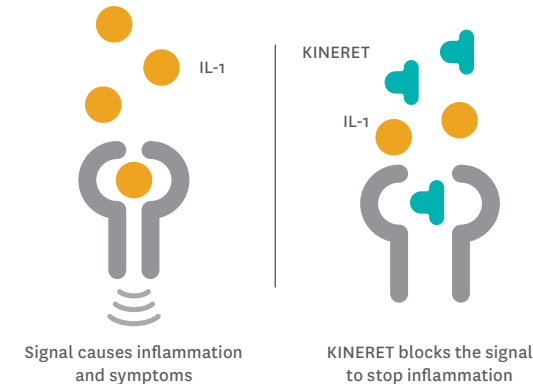
Before starting KINERET, tell your healthcare provider if you:

- 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
- 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:

FEVER

VOMITING

RASH

HEADACHE

JOINT PAIN

EYE REDNESS & PAIN

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.

Please see Important Safety Information on pages 26 and 27. [Click here](#) for full Prescribing Information for KINERET, including Patient Information.



HOW TO USE

KINERET® (anakinra)

INJECTIONS

“

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

– Megan, an RA patient on KINERET

”

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

Please see Important Safety Information on pages 26 and 27. [Click here](#) for full Prescribing Information for KINERET, including Patient Information.

How is KINERET® (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

If you need extra injection supplies (sharps containers, needle clippers, swabs and wipes) just call **Kineret ON TRACK®** at **866.547.0644**, 8:30 AM to 7 PM ET, Monday through Friday.

IMPORTANT SAFETY INFORMATION (cont'd)

KINERET and other medicines may affect each other and cause serious side effects.

KINERET may cause serious side effects, including:

Serious infections. KINERET may lower your ability to fight infections. 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. Due to the risk of infection, you should not receive live vaccines while you use KINERET.

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 may cause serious side effects, including: (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.

Please see Important Safety Information on pages 26 and 27. [Click here](#) for full Prescribing Information for KINERET, including Patient Information.

Preparing your injection

- 1 Set up a clean and flat workspace such as a table
- 2 Take 1 KINERET® (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

- 6 Gather your supplies



✓ Alcohol swabs or wipes



✓ Dry gauze, tissue, and/or cotton ball



✓ Puncture-resistant sharps container

- 7 Wash your hands with soap and warm water

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)

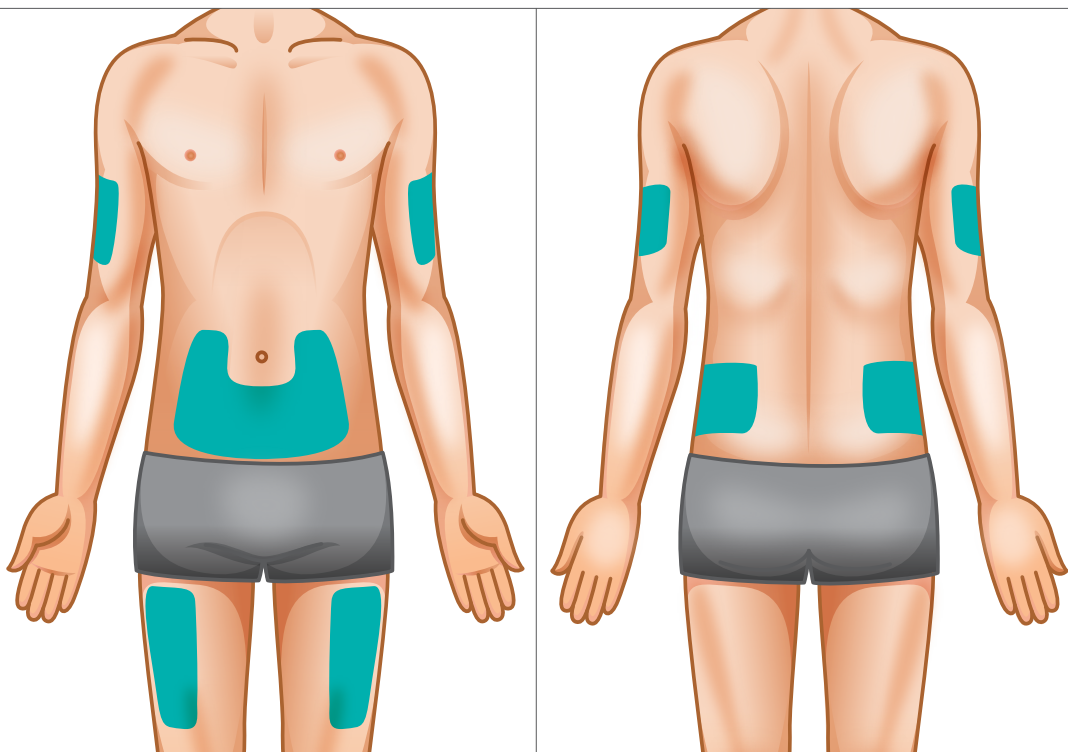
KINERET may cause serious side effects, including: (cont'd)

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.

Please see Important Safety Information on pages 26 and 27. [Click here](#) for full Prescribing Information for KINERET, including Patient Information.

Select your injection site

1 Choose an injection site



IMPORTANT SAFETY INFORMATION (cont'd)

KINERET may cause serious side effects, including: (cont'd)

Amyloidosis. KINERET may cause a buildup of abnormal proteins called amyloids around the injection site (a hard lump under the skin). Avoid using the same site to inject KINERET by rotating to alternating areas of the body. Your doctor may monitor you for amyloidosis.

2 Be sure to choose a new site each time you inject KINERET® (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® at 866.547.0644**, 8:30 AM to 7 PM EST, Monday through Friday, to request assistance from one of our trained nurses.

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

IMPORTANT SAFETY INFORMATION (cont'd)

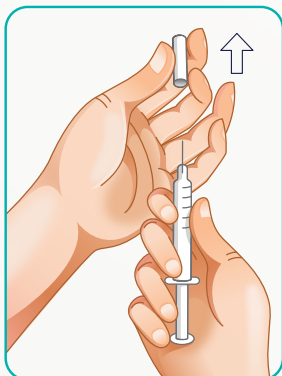
KINERET may cause serious side effects, including: (cont'd)

Low white blood cell count (neutropenia). KINERET may cause you to have a lower number of certain white blood cells (neutrophils). Neutrophils are important in fighting infections. Your doctor should do blood tests to check your white blood cell level before starting and during the first year of treatment with KINERET.

Please see Important Safety Information on pages 26 and 27. [Click here](#) for full Prescribing Information for KINERET, including Patient Information.

Giving your injection

1

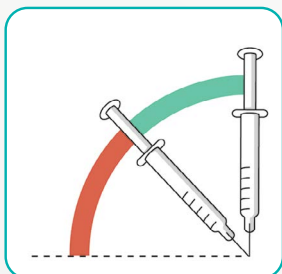


Hold the syringe barrel and pull the cover straight off the needle

2

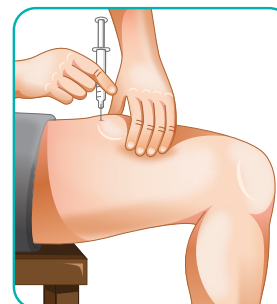
Gently pinch a fold of skin at the cleaned injection site

3



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

4



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

5

Slowly push the plunger all the way down to inject KINERET® (anakinra)

6

When the syringe is empty, pull the needle out of the skin while keeping the needle at the same angle

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



Kineret >>>>>
ON TRACK

If you have questions or concerns about injecting KINERET, call **Kineret ON TRACK®** at **866.547.0644**, 8:30 AM to 7 PM EST, Monday through Friday, to request assistance from one of our 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 already have RA | • Diarrhea | • Sinus infection |
| • Headache | • Joint pain | • Pain in your stomach area |
| • Nausea and vomiting | • Fever | |
| | • Feeling like you have the flu | |
| | • Sore throat or runny nose | |

Please see Important Safety Information on pages 26 and 27. [Click here](#) for full Prescribing Information for KINERET, including Patient Information.

After your injection

- 1 Place a cotton ball or gauze over the injection site and press for several seconds
 - ✗ Don't use an alcohol wipe—it may sting!
- 2 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

The KINERET Injection Tracker is a 4-week grid. Each week (WEEK 1 to WEEK 4) has a 'DATE' field and a grid of 7 rows (DAY 1 to DAY 7) and 2 columns (SITE 1 and SITE 2). To the left of the grid is an anatomical diagram of a person's back and buttocks with numbered injection sites (1-7) and a 'Notes' section. To the right of the grid is another anatomical diagram of a person's back and buttocks with numbered injection sites (1-7) and a 'Notes' section.

IMPORTANT SAFETY INFORMATION (cont'd)

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

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

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
- ✓ Don'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 see Important Safety Information on pages 26 and 27. [Click here](#) for full Prescribing Information for KINERET, including Patient Information.



WHAT TO KNOW

ABOUT USING

KINERET® (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.

Please see Important Safety Information on pages 26 and 27.
[Click here](#) for full Prescribing Information for KINERET,
including Patient Information.

How do I prepare an injection of KINERET® (anakinra) for my baby or child?

The dose of KINERET may be smaller in babies or children

- > 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:

- 1 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

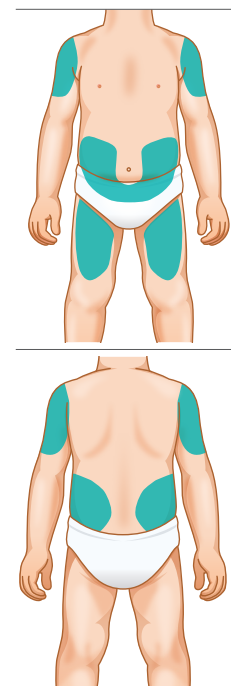
Press play to watch a step-by-step video on how to administer your child's KINERET injection

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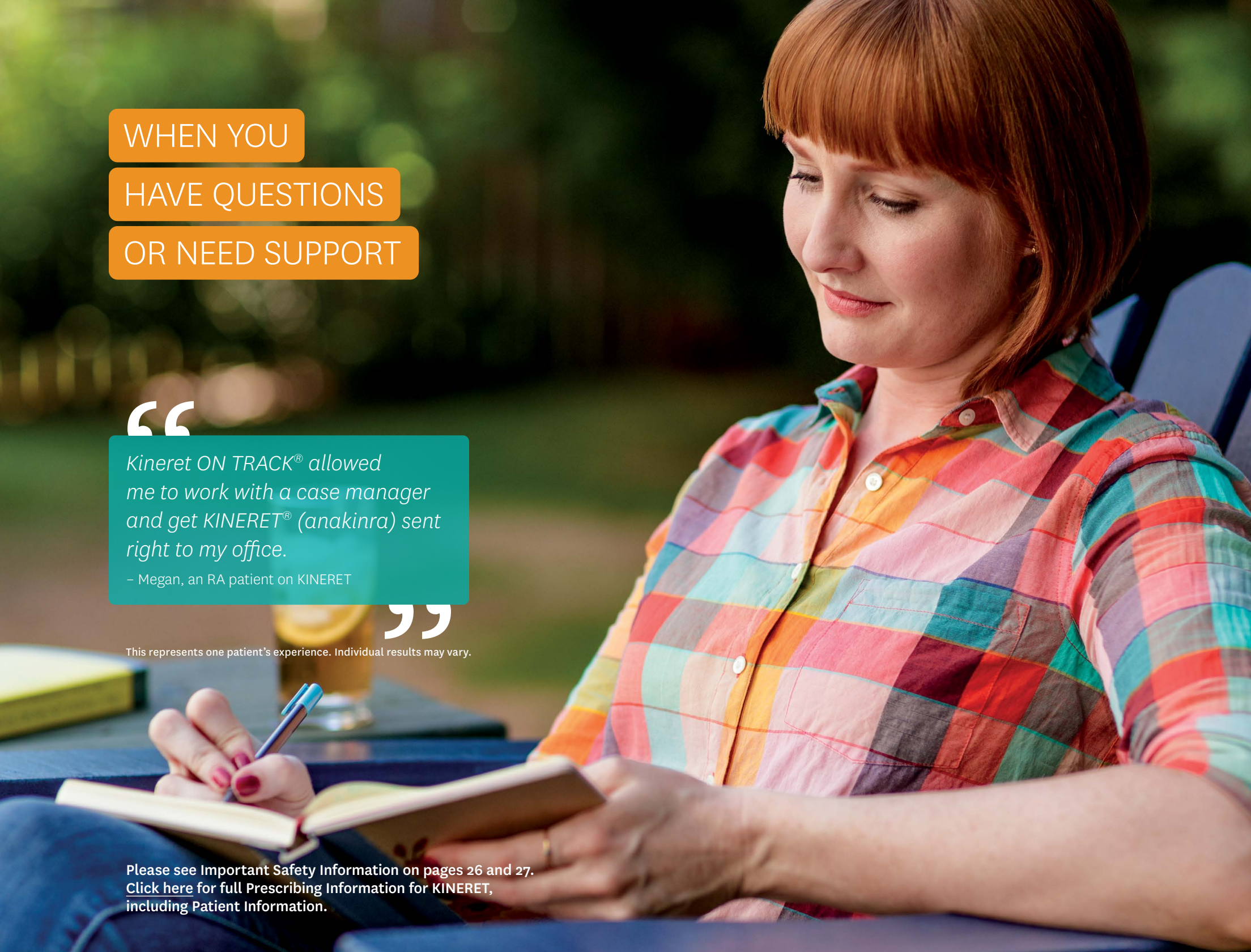
For questions about your child's treatment, read the KINERET Prescribing Information and/or ask your doctor.

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

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WHEN YOU

HAVE QUESTIONS

OR NEED SUPPORT

“

Kineret ON TRACK[®] allowed me to work with a case manager and get KINERET[®] (anakinra) sent right to my office.

– Megan, an RA patient on KINERET

”

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A team of experts supporting you every step of the way

Kineret ON TRACK® can:

- ✓ Provide information regarding patient insurance coverage and financial assistance information that may be available
- ✓ Triage the KINERET® (anakinra) prescription to an in-network specialty pharmacy, that typically mails the prescription directly to your home
- ✓ Provide injection training and support if ordered by your healthcare provider

Call Kineret ON TRACK® at 866.547.0644,
8:30 AM to 7 PM EST, Monday through Friday.



Patient Assistance Offerings

Kineret ON TRACK® can provide information about potential programs that may be available to patients.

- > **The KINERET Copay Assistance Program*** for eligible patients who have commercial prescription insurance. Patients may pay as little as \$0 per prescription, up to a maximum benefit of \$13,000 per calendar year
- > **The KINERET Patient Assistance Program (PAP)[†]** provides KINERET, at no cost, to patients who meet the PAP program eligibility requirements^{†,‡}



Injection Training and Support

Our trained nurses are available, as needed, to help you learn about injection training.

- > One-on-one injection training via telephone or video conference
- > Information to help understand common injection site reactions
- > Guidance on injection site rotation and injection tracking



Getting KINERET Delivered

Kineret ON TRACK® can triage the KINERET prescription to an in-network specialty pharmacy.

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

For more information, call Kineret ON TRACK® at
866.547.0644, 8:30 AM to 7 PM ET, Monday through Friday.

*In order to participate in the KINERET Copay Assistance Program ("Program"), a patient must have commercial prescription insurance for KINERET. This Program is not valid for patients whose prescription claims are reimbursed, in whole or in part, by any state or federal government program, including (but not limited to) Medicaid, Medicare, Medigap, Department of Defense (DoD), Veterans Affairs (VA), TRICARE, Puerto Rico Government Insurance, or any state patient or pharmaceutical assistance program. This offer is not valid for patients paying with cash. The Program is void where prohibited by law. Certain rules and restrictions apply. Sobi reserves the right to revoke, rescind, or amend this offer without notice. This Program is not insurance.

[†]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.

[‡]Program subject to eligibility requirements and program terms and conditions.

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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.

Amyloidosis. KINERET may cause a buildup of abnormal proteins called amyloids around the injection site (a hard lump under the skin). Avoid using the same site to inject KINERET by rotating to alternating areas of the body. Your doctor may monitor you for amyloidosis.

Low white blood cell count (neutropenia). KINERET may cause you to have a lower number of certain white blood cells (neutrophils). Neutrophils are important in fighting infections. Your doctor should do blood tests to check your white blood cell level before starting and during the first year of treatment with KINERET.

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
- RA gets worse with treatment, if you already have RA
- Headache
- Nausea and vomiting
- Diarrhea
- Joint pain
- Fever
- Feeling like you have the flu
- Sore throat or runny nose
- 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.

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 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.



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