

“TODAY, he's  
Not thinking  
about SJIA.”

Once-monthly **ILARIS** can help relieve Systemic Juvenile Idiopathic Arthritis (SJIA) symptoms, including fevers (systemic) and painful and/or swollen joints (arthritis).



Images shown are not actual patients or their families.

### APPROVED USE

ILARIS® (canakinumab) is a prescription medicine injected by your healthcare provider just below the skin (subcutaneous) used to treat: Still's disease including Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA) in children 2 years of age and older.

It is not known if ILARIS is safe and effective when used to treat SJIA in children under 2 years of age.

### IMPORTANT SAFETY INFORMATION

**ILARIS can cause serious side effects, including increased risk of serious infections.** ILARIS can lower the ability of your immune system to fight infections. Your healthcare provider should:

- test you for tuberculosis (TB) before you receive ILARIS
- monitor you closely for symptoms of TB during treatment with ILARIS
- check you for symptoms of any type of infection before, during, and after treatment with ILARIS

Please see additional Important Safety Information throughout this brochure, and accompanying Consumer Brief Summary.

**ILARIS**<sup>®</sup>  
(canakinumab)  
150 mg subcutaneous injection



### IMPORTANT SAFETY INFORMATION (cont)

Tell your healthcare provider right away if you have any symptoms of an infection such as fever, sweats or chills, cough, flu-like symptoms, weight loss, shortness of breath, blood in your phlegm, sores on your body, warm or painful areas on your body, diarrhea or stomach pain, or feeling very tired.

You should not receive ILARIS if you are allergic to canakinumab or any of the ingredients in ILARIS.

**ILARIS**<sup>®</sup>  
(canakinumab)  
150 mg subcutaneous injection

Please see additional Important Safety Information throughout this brochure, and accompanying Consumer Brief Summary.

## ILARIS May Be Right for Your Child

Everyday life is filled with a lot of unknowns when your child has Systemic Juvenile Idiopathic Arthritis (SJIA), also known as Still's disease. As a parent, you just don't know if and when flares will happen, so the disease will always be on your mind. But you want your kid to **not always think about it.**

Once-monthly ILARIS is an injectable biologic medicine that's **proven to help provide relief** of arthritic symptoms, such as painful and/or swollen joints, and systemic symptoms such as fever. ILARIS was specifically studied and approved by the US Food and Drug Administration (FDA) for kids 2 years of age and older with active SJIA.

Managing a rare condition like SJIA isn't easy, but it's important to know that **you're not alone** in this—we're here to help. Read this brochure to learn more about ILARIS and the full range of services offered through ILARIS Companion. Then, ask your child's doctor if ILARIS may be right for your child.

Sincerely,  
The ILARIS Team





# ILARIS Results

**ILARIS**<sup>®</sup>  
(canakinumab)  
150 mg subcutaneous injection

Please see additional Important Safety Information throughout this brochure, and accompanying Consumer Brief Summary.



STUDY RESULTS

SAFETY  
CONSIDERATIONS

HOW IT WORKS

DOSING & SUPPORT

HELPFUL TIPS

## Proven Results with ILARIS

ILARIS® (canakinumab) is a once-a-month injectable biologic medicine that's FDA approved for active Systemic Juvenile Idiopathic Arthritis (SJIA) in children 2 years of age and older. The FDA approval was based on studies that included 190 children.

ILARIS has been shown to help with both the systemic (fever) and arthritic (painful and/or swollen joints) symptoms of active SJIA, including:



FEVERS



PAINFUL JOINTS



SWOLLEN JOINTS

### ILARIS Helps Provide Fast Symptom Relief

In a study, SJIA symptom improvements were seen after the first dose of ILARIS.



**3 days** after taking their first dose of ILARIS,  
**100% of kids with SJIA had no fever.**

**15 days** after their first dose of ILARIS,  
approximately

**8 out of 10 KIDS**

**experienced improvement** in their SJIA symptoms (fever and painful and/or swollen joints).



### ILARIS Can Reduce or Stop Corticosteroid Use\*



- **Almost half (46%, 42/92)** of the children whose SJIA symptoms were controlled appropriately were able to **stop taking corticosteroids completely**
- Of the children whose SJIA symptoms were controlled, **nearly two-thirds (62%, 57/92)** were on a **lower dose of corticosteroids**

\*One hundred twenty-eight patients entered the clinical study taking corticosteroids. Ninety-two of these patients entered a part of the clinical trial (up to 5 months) to see if they could reduce or stop taking corticosteroids.

### IMPORTANT SAFETY INFORMATION (cont)

**Before receiving ILARIS, tell your healthcare provider about all your medical conditions, including if you:**

- think you have or are being treated for an active infection
- have symptoms of infection
- have a history of infections that keep coming back
- have a history of low white blood cells
- have or have had HIV, Hepatitis B, or Hepatitis C
- are scheduled to receive any immunizations (vaccines).  
You should not get live vaccines if you are receiving ILARIS

Please see additional Important Safety Information throughout this brochure, and accompanying Consumer Brief Summary.

**ILARIS**  
(canakinumab)  
150 mg subcutaneous injection



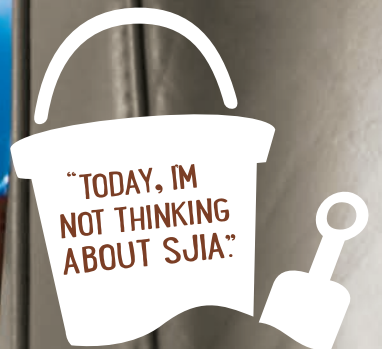
“TODAY, SJIA<sup>is</sup>  
Riding in the  
way, Way Back.”

#### IMPORTANT SAFETY INFORMATION (cont)

- are pregnant or planning to become pregnant. It is not known if ILARIS will harm your unborn baby. Tell your healthcare provider right away if you become pregnant while receiving ILARIS
- received canakinumab while you were pregnant. It is important that you tell your baby's healthcare provider before any vaccinations are given to your baby within 4-12 months after you received your last dose of canakinumab before giving birth
- are breastfeeding or planning to breastfeed. It is not known if ILARIS passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you receive ILARIS

**ILARIS**<sup>®</sup>  
(canakinumab)  
150 mg subcutaneous injection

Please see additional Important Safety Information throughout this brochure, and accompanying Consumer Brief Summary.





## ILARIS Safety Considerations



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

- medicines that affect the immune system
- medicines called interleukin-1 (IL-1) blocking agents such as Kineret® (anakinra) or Arcalyst® (rilonacept)
- medicines called Tumor Necrosis Factor (TNF) inhibitors such as Enbrel® (etanercept), Humira® (adalimumab), Remicade® (infliximab), Simponi® (golimumab), or Cimzia® (certolizumab pegol)
- medicines that affect enzyme metabolism.

Ask your healthcare provider for a list of these medicines if you are not sure.

**ILARIS**  
(canakinumab)  
150 mg subcutaneous injection

Please see additional Important Safety Information throughout this brochure, and accompanying Consumer Brief Summary.

## IMPORTANT SAFETY INFORMATION (cont)

ILARIS can cause serious side effects including:

- **serious infections**
- **decreased ability of your body to fight infections (immunosuppression).** For people treated with medicines that cause immunosuppression like ILARIS, the chances of getting cancer may increase
- **allergic reactions.** Allergic reactions can happen while receiving ILARIS. Call your healthcare provider right away if you have any of these symptoms of an allergic reaction: difficulty breathing or swallowing, nausea, dizziness or feeling faint, rash, itching or hives, palpitations (feels like your heart is racing), or low blood pressure
- **risk of infection with live vaccines.** You should not get live vaccines if you are receiving ILARIS. Tell your healthcare provider if you are scheduled to receive any vaccines

**The most common side effects of ILARIS when used for the treatment of Still's disease (AOSD and SJIA) include:** cold symptoms, upper respiratory tract infection, pneumonia, runny nose, sore throat, urinary tract infection, nausea, vomiting and diarrhea (gastroenteritis), stomach pain, and injection site reactions (such as redness, swelling, warmth, or itching).

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

All trademarks and registered trademarks are the property of their respective owners.

## ILARIS was specifically studied and FDA-approved for kids 2 years of age and older with active Systemic Juvenile Idiopathic Arthritis (SJIA).



**During SJIA studies:**

- ILARIS wasn't shown to affect the risk of developing macrophage activation syndrome (MAS), but no conclusion can be made
- No children stopped treatment with ILARIS due to injection-site reactions
  - Up to 14% had injection-site reactions: most were mild



A graphic on a blue background featuring a CD with the text 'HOW ILARIS' on its surface and the word 'WORKS' written in a large, white, curved font to its right. Several musical notes are scattered around the CD.

# HOW ILARIS WORKS

**ILARIS**<sup>®</sup>  
(canakinumab)  
150 mg subcutaneous injection

Please see additional Important Safety Information throughout this brochure, and accompanying Consumer Brief Summary.



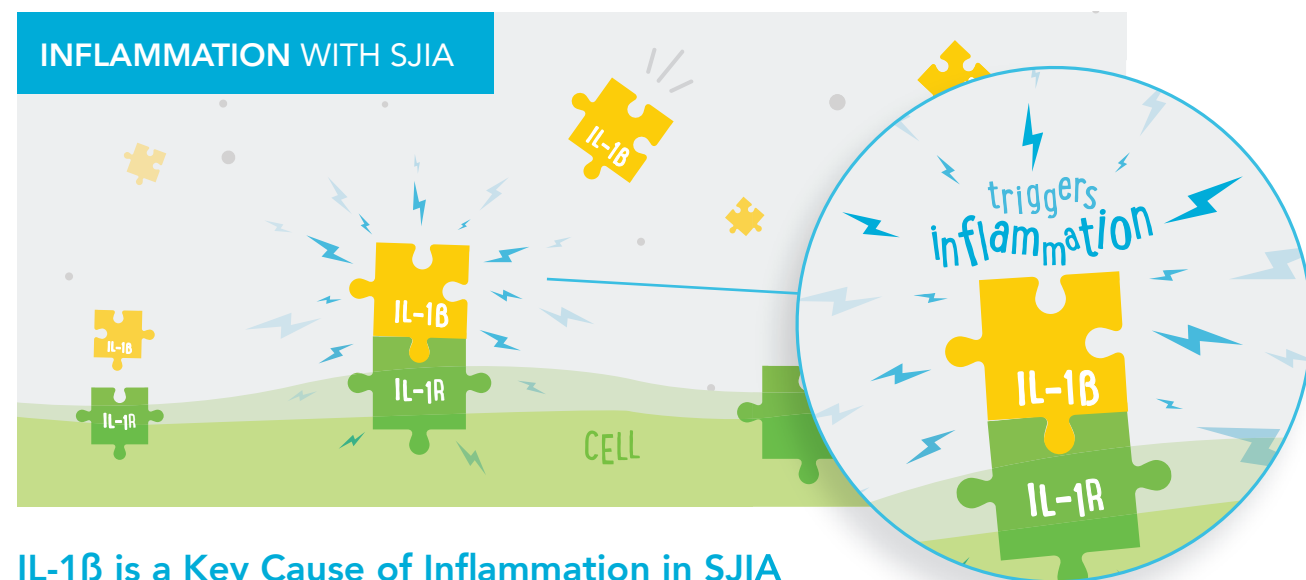
HOW IT WORKS

DOSING & SUPPORT

HELPFUL TIPS

## How ILARIS Works

To understand how ILARIS® (canakinumab) works, it's important to start with the role of the immune system in SJIA and how inflammation (the body's way of protecting itself against sickness or injury) gets triggered in the body.

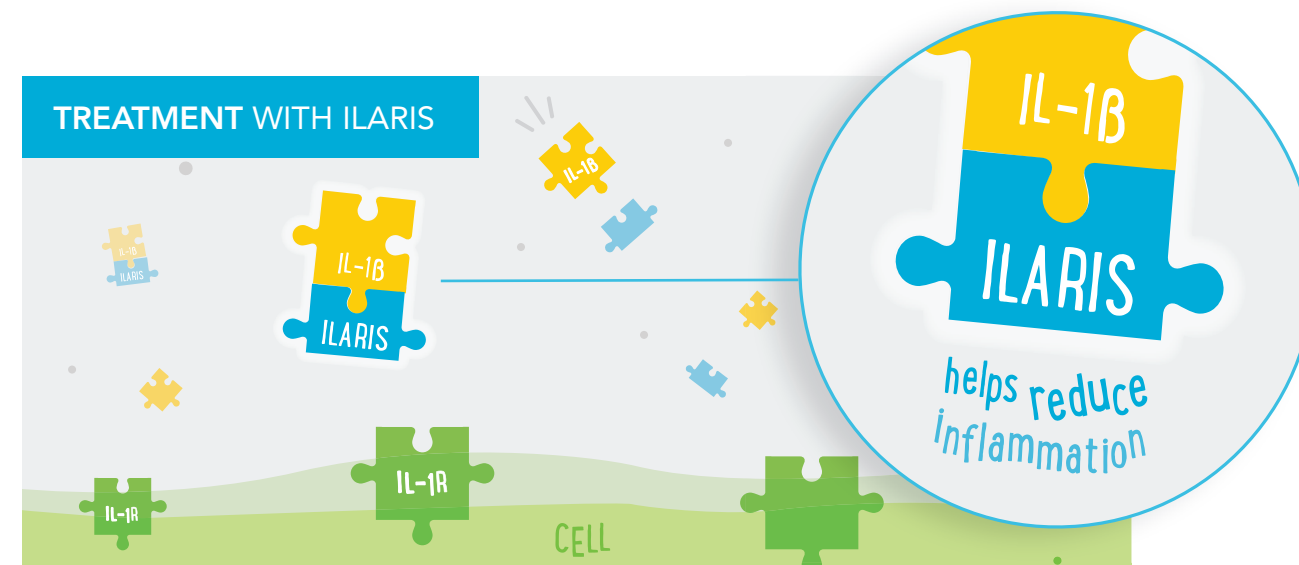


### IL-1 $\beta$ is a Key Cause of Inflammation in SJIA

- For a child with SJIA, the immune system (the body's natural defense system that protects against "foreign" invaders) produces too much of a substance called a cytokine
- Too much of a cytokine called interleukin 1 beta (IL-1 $\beta$ ) is an important cause of inflammation in SJIA. When IL-1 $\beta$  attaches to interleukin-1 receptors (IL-1R), the immune system triggers inflammation
- For those with SJIA, the immune system triggers inflammation even when there's no infection to fight. This causes recurring SJIA symptoms like fever and swollen and/or painful joints

**ILARIS**  
(canakinumab)  
150 mg subcutaneous injection

Please see additional Important Safety Information throughout this brochure, and accompanying Consumer Brief Summary.



### ILARIS Targets IL-1 $\beta$ to Help Reduce Inflammation

- ILARIS is a different kind of treatment for SJIA. It's a biologic medicine, which means it's designed to target a specific source of inflammation. ILARIS targets IL-1 $\beta$
- By attaching to IL-1 $\beta$ , ILARIS helps to block its interaction with IL-1R
- This action helps to stop the immune system from triggering inflammation

### IMPORTANT SAFETY INFORMATION (cont)

#### What is Macrophage Activation Syndrome (MAS)?

MAS is a syndrome associated with Still's disease and some other auto-inflammatory diseases like HIDS/MKD that can lead to death. Tell your healthcare provider right away if your AOSD or SJIA symptoms get worse or if you have any of these symptoms of an infection:

- a fever lasting longer than 3 days
- a cough that does not go away
- redness in one part of your body
- warm feeling or swelling of your skin

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.



“TODAY, *my* SJIA *isn't*  
in the SPOTLIGHT—I am.”

**IMPORTANT SAFETY INFORMATION (cont)**

**ILARIS can cause serious side effects, including increased risk of serious infections.** ILARIS can lower the ability of your immune system to fight infections. Your healthcare provider should:

- test you for tuberculosis (TB) before you receive ILARIS
- monitor you closely for symptoms of TB during treatment with ILARIS
- check you for symptoms of any type of infection before, during, and after treatment with ILARIS

**ILARIS**<sup>®</sup>  
(canakinumab)  
150 mg subcutaneous injection

Please see additional Important Safety Information throughout this brochure, and accompanying Consumer Brief Summary.



“TODAY, I'M NOT THINKING ABOUT SJIA.”



## Once-Monthly Dosing of ILARIS



ILARIS® (canakinumab) is a once-a-month injection. Every 4 weeks, a doctor or nurse will give your child a subcutaneous injection of ILARIS, which means it's administered right underneath the skin.



### ILARIS Companion

Caring for a child with SJIA isn't easy, but our team of professionals is here to help support you. ILARIS Companion is here to help you and your family navigate the treatment journey, providing **resources to help you access and afford treatment**.

For questions about ILARIS Companion, call **866-972-8315**

### ILARIS Home Health Nurse Service

At your doctor's request, a certified home health nurse can administer your child's ILARIS injections in the comfort of your own home. The ILARIS home health nurse:

- Gives your child his or her ILARIS injection—**giving you that moment to focus on comforting your child**
- Can help make sure that your child receives his or her dose of ILARIS on schedule each month
- Comes at **no cost** to eligible patients



This service is available



Ask your child's doctor to call us.

\*and Puerto Rico.

### Access to ILARIS

We're committed to helping you get access to ILARIS. Our representatives work with you and your child's doctor to **help you get started**, including:

- Contacting your insurance company
- Providing co-pay\* assistance for eligible patients with commercial insurance
- Verifying insurance benefits and investigation of coverage
- Providing information about alternative assistance options for uninsured patients
- Addressing coverage issues
- Assisting with prior authorization and appeals, if needed

\*Limitations apply. Please contact ILARIS Companion at 866-972-8315 for more information.

### IMPORTANT SAFETY INFORMATION (cont)

Tell your healthcare provider right away if you have any symptoms of an infection such as fever, sweats or chills, cough, flu-like symptoms, weight loss, shortness of breath, blood in your phlegm, sores on your body, warm or painful areas on your body, diarrhea or stomach pain, or feeling very tired.

You should not receive ILARIS if you are allergic to canakinumab or any of the ingredients in ILARIS.



Please see additional Important Safety Information throughout this brochure, and accompanying Consumer Brief Summary.



Helpful



**ILARIS**<sup>®</sup>  
(canakinumab)  
150 mg subcutaneous injection

Please see additional Important Safety Information throughout this brochure, and accompanying Consumer Brief Summary.



HELPFUL TIPS

## Real Advice From Real Caregivers

Most people don't understand what life is like when someone in your family has a rare and complex disease like SJIA. But it's important to remember that you're not alone. Here are some helpful tips provided by parents of kids with SJIA to help support you in continuing to be your child's best advocate:



“Ask  
challenging  
questions.  
Nothing is  
off limits.”

“Feel  
Confident  
taking the lead.”



“Trust  
your own  
instincts.”



“Don't allow  
SJIA to define  
your child.”

“Keep Learning  
about SJIA and available  
treatments—it's good  
to know your options.”



“Surround yourself  
with people who care  
and want to learn.”

“Share  
your observations  
with your  
child's doctor.”

### IMPORTANT SAFETY INFORMATION (cont)

Before receiving ILARIS, tell your healthcare provider about all your medical conditions, including if you:

- think you have or are being treated for an active infection
- have symptoms of infection
- have a history of infections that keep coming back
- have a history of low white blood cells
- have or have had HIV, Hepatitis B, or Hepatitis C
- are scheduled to receive any immunizations (vaccines).  
You should not get live vaccines if you are receiving ILARIS

**ILARIS**<sup>®</sup>  
(canakinumab)  
150 mg subcutaneous injection

Please see additional Important Safety Information throughout this brochure, and accompanying Consumer Brief Summary.





For more information, talk to your  
child's doctor and visit [ILARIS.com](http://ILARIS.com).



**Novartis Pharmaceuticals Corporation**  
East Hanover, New Jersey 07936-1080

© 2020 Novartis

6/20

**ILARIS**<sup>®</sup>  
(canakinumab)  
150 mg subcutaneous injection

ILA-1390451

# ILARIS® (i-LAHR-us) (canakinumab) injection for subcutaneous use

## What is the most important information I should know about ILARIS?

ILARIS can cause serious side effects, including:

- **Increased risk of serious infections.** ILARIS can lower the ability of your immune system to fight infections. Your healthcare provider should:
  - test you for tuberculosis (TB) before you receive ILARIS
  - monitor you closely for symptoms of TB during treatment with ILARIS
  - check you for symptoms of any type of infection before, during, and after your treatment with ILARIS

Tell your healthcare provider right away if you have any symptoms of an infection such as fever, sweats or chills, cough, flu-like symptoms, weight loss, shortness of breath, blood in your phlegm, sores on your body, warm or painful areas on your body, diarrhea or stomach pain, or feeling very tired.

## What is ILARIS?

ILARIS is a prescription medicine injected by your healthcare provider just below the skin (subcutaneous) used to treat:

- Still's disease including Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA) in children 2 years and older.

It is not known if ILARIS is safe and effective when used to treat SJIA in children under 2 years of age.

## Who should not receive ILARIS?

- Do not receive ILARIS if you are allergic to canakinumab or any of the ingredients in ILARIS. See the Medication Guide for a complete list of ingredients in ILARIS.

## What should I tell my healthcare provider before receiving ILARIS?

Before you receive ILARIS, tell your healthcare provider about all your medical conditions, including if you:

- think you have or are being treated for an active infection
- have symptoms of an infection
- have a history of infections that keep coming back
- have a history of low white blood cells
- have or have had HIV, Hepatitis B, or Hepatitis C
- are scheduled to receive any immunizations (vaccines). You should not get 'live vaccines' if you are receiving ILARIS.
- are pregnant or planning to become pregnant. It is not known if ILARIS will harm your unborn baby. Tell your healthcare provider right away if you become pregnant while receiving ILARIS.
- received ILARIS while you were pregnant. It is important that you tell your baby's healthcare provider before any vaccinations are given to your baby within 4-12 months after you received your last dose of ILARIS before giving birth.
- are breastfeeding or planning to breastfeed. It is not known if ILARIS passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you receive ILARIS.

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

- medicines that affect your immune system
- medicines called IL-1 blocking agents such as Kineret® (anakinra), Arcalyst® (rilonacept)
- medicines called Tumor Necrosis Factor (TNF) inhibitors such as Enbrel® (etanercept), Humira® (adalimumab), Remicade® (infliximab), Simponi® (golimumab), or Cimzia® (certolizumab pegol)
- medicines that affect enzyme metabolism

Ask your healthcare provider for a list of these medicines if you are not sure.

## Brief Summary of Important Risk Information

The risk information provided here is not comprehensive. To learn more, talk about ILARIS with your healthcare provider or pharmacist. For the FDA-approved product labeling, call 1-877-452-7471 or visit [www.ILARIS.com](http://www.ILARIS.com).

## How will I receive ILARIS?

- ILARIS is given by your healthcare provider every 4 weeks for AOSD and SJIA.

## What are the possible side effects of ILARIS?

ILARIS can cause serious side effects, including:

- See "What is the most important information I should know about ILARIS?"
- **decreased ability of your body to fight infections (immunosuppression).** For people treated with medicines that cause immunosuppression like ILARIS, the chances of getting cancer may increase.
- **allergic reactions.** Allergic reactions can happen while you are receiving ILARIS. Call your healthcare provider right away if you have any of these symptoms of an allergic reaction:
  - difficulty breathing or swallowing, nausea, dizziness or feeling faint, rash, itching or hives, palpitations (feels like your heart is racing), low blood pressure.
- **risk of infection with live vaccines.** You should not get live vaccines if you are receiving ILARIS. Tell your healthcare provider if you are scheduled to receive any vaccines.

The most common side effects of ILARIS for Still's disease (AOSD and SJIA) include:

- cold symptoms, upper respiratory tract infection, pneumonia, runny nose, sore throat, urinary tract infection, nausea, vomiting and diarrhea (gastroenteritis), stomach pain, and injection site reactions (such as redness, swelling, warmth, itching).

Tell your healthcare provider about any side effect that bothers you or does not go away. These are not all the possible side effects of ILARIS. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

## General information about the safe and effective use of ILARIS.

Medicines are sometimes prescribed for purposes other than those listed in Medication Guide. You can ask your healthcare provider or pharmacist for information about ILARIS that was written for health professionals.

## What is Still's Disease (AOSD and SJIA)?

Still's disease (which is referred to as AOSD in adults and SJIA in children) is an autoinflammatory disorder which can be caused by having too much or being too sensitive to certain proteins, including interleukin-1 $\beta$  (IL-1 $\beta$ ), and can lead to symptoms such as fever, rash, headache, feeling very tired (fatigue), or painful joints and muscles.

## What is Macrophage Activation Syndrome (MAS)?

MAS is a syndrome associated with Still's disease and some other autoinflammatory diseases like HIDS/MKD that can lead to death. Tell your healthcare provider right away if your AOSD or SJIA symptoms get worse or if you have any of these symptoms of an infection: a fever lasting longer than 3 days, a cough that does not go away, redness in one part of your body, warm feeling or swelling of your skin.

Distributed by: Novartis Pharmaceuticals Corporation  
East Hanover, New Jersey 07936

© Novartis

Kineret®, Arcalyst®, Enbrel®, Humira®, Remicade®, Simponi®, and Cimzia® are trademarks of Amgen, Regeneron, Immunex Corporation, Abbott Laboratories, Centocor Ortho Biotech Inc., Janssen Biotech Inc., and the UCB Group of companies, respectively.

ILA-1390445 Revised: June 2020