

Information for Patients

See patient information leaflet.

Patient Information

ILARIS® (i-LAHR-us)

(canakinumab)

Read the Patient Information that comes with ILARIS before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or treatment.

What is ILARIS? ILARIS is a prescription medicine injected just below the skin (subcutaneous) used in adults and children 4 years and older to treat auto-inflammatory diseases known as Cryopyrin-Associated Periodic Syndromes (CAPS), including:

- Familial Cold Autoinflammatory Syndrome (FCAS)
- Muckle-Wells Syndrome (MWS),

It is not known if ILARIS is safe or effective in children under 4 years of age.

Who should not take ILARIS?

Do not take ILARIS if you:

- are allergic to canakinumab or any of the ingredients in ILARIS. See the end of this Patient Information leaflet for a complete list of the ingredients in ILARIS.

What should I tell my healthcare provider before taking ILARIS?

Before you take ILARIS, tell your healthcare provider if you:

- think you have an infection
- are being treated for an infection
- have signs of an infection, such as fever, cough, or flu-like symptoms
- have a history of infections that keep coming back
- have or have had HIV, Hepatitis B, or Hepatitis C
- have an immune system problem. People with these conditions have a higher chance for infections.
- have tuberculosis (TB), or if you have been in close contact with someone who has or has had tuberculosis
- are scheduled to receive any immunizations (vaccines). You should not get 'live vaccines' if you take 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 taking ILARIS.
- are breastfeeding or planning to breastfeed. It is not known if ILARIS passes into your breast milk. You and your healthcare provider should decide if you will take ILARIS or breastfeed. You should not do both.

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

- Medicines that affect your immune system
- IL-1 blocking agents such as Kineret® (anakinra), Arcalyst® (rilonacept)
- Tumor Necrosis Factor (TNF) inhibitors such as Enbrel® (etanercept)
- Humira® (adalimumab), or Remicade® (infliximab)
- Medicines that can affect enzyme metabolism. Ask your healthcare provider if you are not sure.

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

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How will I receive ILARIS?

- Do not receive ILARIS if you have an infection.
- ILARIS is given by your healthcare provider every 8 weeks
- Your healthcare provider may change your dose if needed.

What are the possible side effects of ILARIS?

ILARIS can cause serious side effects including:

- serious infections. Symptoms of an infection may include:
 - 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
- decrease your body's ability to fight infections (immunosuppression)

Other serious side effects may occur while you are taking and after you finish taking ILARIS including allergic reactions.

Symptoms of an allergic reaction may include:

- rash (hives)
- swollen face
- problems breathing or swallowing

Call your healthcare provider right away or get emergency medical help if you have any of the signs of an infection or allergic reaction.

The most common side effects include:

- cold symptoms
- diarrhea
- flu (influenza)
- runny nose
- nausea
- headache
- injection site reaction (such as redness, swelling, warmth, itching)
- feeling like you are spinning (vertigo)

Tell your healthcare provider if you have any side effect that bothers you or that 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 patient information leaflets. Do not use ILARIS for a condition for which it was not prescribed.

This leaflet summarizes the most important information about ILARIS. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about

ILARIS that was written for health professionals. For more information about ILARIS, call 1-877-452-7471 or visit www.ILARIS.com.

What are the ingredients in ILARIS?

Active ingredients: canakinumab

Inactive ingredients: sucrose, L-histidine, L-histidine HCl monohydrate, polysorbate 80, preservative-free Sterile Water for Injection.

What is CAPS Disease?

In patients with CAPS, the body produces excessive amounts of a chemical messenger called interleukin-1 beta (IL-1 β). This may lead to symptoms such as fever, headache, fatigue, skin rash, painful joints and muscles. In some patients, more severe outcomes such as hearing impairment are observed.

Kineret[®], Arcalyst[®], Enbrel[®], Humira[®], Remicade[®] are trademarks of Amgen, Regeneron, Immunex Corporation, Abbott Laboratories, Centocor Ortho Biotech Inc., respectively.

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