ILARIS®

canakinumab

150mg powder for solution for injection
150 mg/1mL solution for injection

What is in this leaflet

Read all of this leaflet carefully before you start using this medicine.

This leaflet answers some common questions about ILARIS. It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given ILARIS against the benefits your doctor expects it will have for you. This medicine has been prescribed only for you. Do not give it to anybody else or use it for any other illnesses.

If any of the side effects affects you severely, or if you notice any side effects not listed in this leaflet, or if you have any concerns about being given this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet. You may need to read it again.

What ILARIS is used for

ILARIS is intended for treatment of Cryopyrin-Associated Periodic Syndromes (CAPS). It belongs to a group of medicines called interleukin inhibitors. The active substance in ILARIS is canakinumab, a fully-human monoclonal antibody. It blocks the activity of a substance called interleukin-1 beta (IL-1 beta), which is present at increased levels in inflammatory diseases such as CAPS.

ILARIS is used in adults, adolescents and children aged 2 years and older with a body weight of 7.5kg and above to treat the following auto-inflammatory diseases which are collectively known as Cryopyrin-Associated Periodic Syndromes (CAPS), including:

- Muckle-Wells Syndrome (MWS),
- Neonatal-Onset Multisystem Inflammatory Disease (NOMID) also called Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA),
- Severe forms of Familial Cold Autoinflammatory Syndrome (FCAS), also called Familial Cold Urticaria (FCU), presenting with signs and symptoms of cold-induced urticarial rash.

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

ILARIS selectively binds to IL-1 beta, blocking its activity and leading to an improvement in symptoms.

If you have any questions about how ILARIS works or why this medicine has been prescribed for you, ask your doctor.

Before you use ILARIS

Follow all the doctor's instructions carefully. They may differ from the general information contained in this leaflet.

When you or your child must not be given it

Do not use ILARIS if:

- you are allergic (hypersensitive) to canakinumab or any of the other ingredients of ILARIS at the end of this leaflet
- you have an active, severe infection. If you think you may be allergic or have an infection, do not take ILARIS until you ask your doctor for advice**.**
- your child is below 2 years old or has a body weight below 7.5 kg.
- the expiry date on the pack has passed. If the medicine is used after the expiry date has passed, it may not work.
- You notice that the solution is not clear or it contains particles.

If you are not sure whether you or your child should be given ILARIS, talk to your doctor.

Before you or your child are given it

Tell your doctor if:
- you currently have an infection or if you have had repeated infections or a condition such as low level of white blood cells, which makes you more likely to get infections.
- you have or have ever had tuberculosis or direct contact with a person with an active tuberculosis infection. Your doctor may also check whether you have developed tuberculosis using a specific test.
- you need to have any vaccinations. You are advised to avoid the type of vaccination called "live vaccines" while being treated with ILARIS (see also below "Using other medicines and vaccines").
- you are pregnant, if you think you are pregnant or if you plan to get pregnant. ILARIS has not been studied in pregnant women and should therefore only be used during pregnancy if clearly needed. Your doctor will discuss with you the potential risk of taking ILARIS during pregnancy.
- you are breast-feeding. It is not known whether ILARIS is excreted in human milk, therefore breast-feeding is not recommended when being treated with ILARIS.

If you have not told your doctor about any of the above, tell them before you or your child is given an injection of ILARIS.

Using other medicines and vaccines

Live vaccines: you or your child are advised to avoid a certain type of vaccination known as a "live vaccines" while being treated with ILARIS. Your doctor may want to check your or your child's vaccination history and give any vaccinations that you or chid have missed before starting treatment with ILARIS. If you or your child needs to have a live vaccine after starting treatment with ILARIS, it is recommended to wait for at least 3 months after the last ILARIS injection and before the next injection.

Medicines called tumor necrosis factor (TNF) inhibitors (such as etanercept, adalimumab or infliximab) should not be used with ILARIS because this may increase the risk of infections. TNF inhibitors are used mainly in rheumatic and autoimmune diseases.

Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription from your pharmacy, supermarket or health food shop.

How ILARIS is given

How much is given

The recommended starting dose of ILARIS for CAPS patients is:

- 150 mg for adults and children aged 4 years and above with body weight of more than 40 kg.
- 2 mg/kg for adults and children aged 4 years and above with body weight between 15 kg and 40 kg (example: a 25 kg child should receive a 50 mg injection).
- 4 mg/kg for children aged 4 years and above with body weight of 7.5 kg to less than 15 kg.
- 4 mg/kg for children aged 2 years to less than 4 years with body weight of 7.5 kg or more.

Every 8 weeks a single dose of ILARIS is injected under the skin.

If the skin rash and other inflammation symptoms have not resolved 7 days after treatment start, your treating physician may consider a second dose of 150 mg (body weight more than 40 kg) or 2mg/kg (body weight between 15 kg and 40 kg). Depending on the effect achieved, your treating physician may decide to increase your regular dose to 300 mg (body weight more than 40 kg) or to 4 mg/kg (body weight between 15 kg and 40 kg) every 8 weeks. If a satisfactory clinical response has not been achieved 7 days after this second dose, a third dose of ILARIS at 300 mg (body weight more than 40 kg) or 4 mg/kg (body weight between 15 kg and 40 kg) can be considered. If a full treatment response is then achieved, your doctor will advise you if the higher dosing regimen of 600 mg or 8 mg/kg every 8 weeks should be maintained.

With a starting dose of 4 mg/kg, if a satisfactory treatment response has not been achieved 7 days after treatment start, a second dose of 4 mg/kg may be considered by your physician. If a full treatment response is then achieved, your doctor will advise you if the higher dosing regimen of 8 mg/kg every 8 weeks should be maintained.

Do not exceed the recommended dose.

How it is given

ILARIS is intended for subcutaneous use. This means that it is injected through a short needle into the fatty tissue just under the skin.

If you have CAPS, you may inject yourself after proper training or a caregiver may inject you. Always use ILARIS exactly as your doctor has told you. You should check with your doctor, nurse or pharmacist if you are not sure.

Keep your doctor informed of your condition and any symptoms, before you use or are given ILARIS (see section above on “Before you use ILARIS”). Your doctor may decide to delay or interrupt your treatment, but only if necessary.

Injecting ILARIS yourself

You may inject ILARIS yourself or as a caregiver to your child after receiving proper training in injection technique.

- You and your doctor should decide together whether or not you will inject ILARIS yourself.
- Your doctor or nurse will show you how to inject yourself.
- Do not try to inject yourself if you have not been properly trained or if you are not sure how to do it.
- Ilaris 150 mg/1mL solution for injection, Ilaris 150 mg powder for injection vials are for individual use only. Any unused product or waste material should be disposed of appropriately.
- Never re-use the left-over solution after injecting the required dose.

For instructions on how to inject yourself with ILARIS, please read the section “Instructions for use”. If you have any questions, contact your doctor, nurse or pharmacist.

How long to use ILARIS

You should continue using ILARIS for as long as your doctor tells you.

If you use more ILARIS than you should

You should not inject ILARIS earlier than 8 weeks after the last dose, unless your doctor tells you to. If you accidentally inject more ILARIS or sooner than you should, you should tell your doctor, nurse or pharmacist as soon as possible.

If you miss a dose

If you have forgotten to inject a dose of ILARIS, inject the next dose as soon as you remember. Then talk to your doctor to discuss when you should inject the next dose. You should then continue with injections at 8-week intervals, as before.

If you have any further questions on the use of this product, ask your doctor, nurse or pharmacist.

After you have been given ILARIS

Tell your doctor immediately if you notice any of the following symptoms

- Fever lasting longer than 3 days or any other symptoms possibly related to an infection (including serious infection), such as prolonged cough, phlegm, chest pain, difficulty breathing, ear pain, prolonged headache or localised redness, warmth or swelling of your skin. These may be symptoms of a typical infection or one that may be more serious (opportunistic infections).
- Signs of an allergic reaction such as difficulty breathing or swallowing, nausea, dizziness, skin rash, itching, hives, palpitations or low blood pressure.

Persistent cough, weight loss and low grade fever, which could be signs of a tuberculosis infection.

Things you must do

Keep all of your doctor's appointments so that your progress can be checked. Your doctor will do tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

If you want to be vaccinated, tell your doctor you are taking Ilaris before you have the vaccination. Some vaccines may not be suitable for you.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Ilaris.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Things you must not do

Do not use Ilaris to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Adverse Effects

As with all medicines, patients treated with ILARIS may experience side effects, although not everybody gets them. Most of the side effects are mild to moderate and will generally disappear a few days to a few weeks after treatment, but some side effects may be serious with medicines such as ILARIS and require your special attention to seek the care of your doctor.

Potentially serious side effects

Very common:
- Fever lasting longer than 3 days or any other symptoms that might be due to an infection (for example, viral infection, bronchitis and ear infections have been reported). These include shivering, chills, malaise, loss of appetite, body aches typically in connection with a sudden onset of illness, cough, phlegm, chest pain, difficulty breathing, ear pain, prolonged headache or localized redness, warmth or swelling of your skin or inflammation of connective tissue (cellulitis).
- Spontaneous bleeding or bruising, which could be linked to low levels of blood platelets (thrombocytopenia).

Common:
- Fever, sore throat or mouth ulcers due to infections, which could be symptoms of low levels of white blood cells (leucopenia, neutropenia). Your doctor should check your blood regularly if necessary.
- Feeling dizzy, spinning sensation (vertigo).
- Fever, cough, difficulty or painful breathing, wheezing, pain in chest when breathing (pneumonia).

Not known (frequency cannot be estimated form the available data):

- Allergic reactions with rash and itching and possibly also hives, difficulty breathing or swallowing, dizziness, palpitations or low blood pressure.
- Persistent cough, weight loss and low grade fever, which could be signs of a tuberculosis infection.

Tell your doctor immediately, if you notice any of the side effects above.

Other possible side effects are

Very common:
- Combination of sore throat, runny nose, blocked nose, sneezing, feeling of pressure or pain in the cheeks and/or forehead with or without fever (nasopharyngitis, sinusitis)
- Painful and frequent urination with or without fever (urinary tract infection)
- Stomach pain and feeling sick (gastroenteritis)
- Abdominal pain
- Skin reaction such as redness or swelling at the site of injection

Common:
- Being sick (vomiting)
- Abnormal levels of triglycerides in the blood (lipid metabolism disorder)
- Abnormal liver function test results (transaminases increased)
- High level of bilirubin in the blood with or without yellow skin and eyes (hyperbilirubinemia)
- Feeling weak (asthenia), tiredness
- Back pain
- Combination of sore throat, fever, swollen or red tonsils, cough, difficulty to swallow and headache (tonsillitis)

Uncommon:
- Heartburn (gastroesophageal reflux)

If any of these affects you severely, or if you notice any side effects not listed in this leaflet, tell your doctor, nurse or pharmacist as soon as possible.

Storage

- Keep out of the reach and sight of children.
- Store ILARIS vials in a refrigerator (2°C to 8°C). Do not freeze. Store in the original package in order to protect from light.
- After preparing the ILARIS solution, inject within 1 hour. If the solution is not used within 1 hour of preparation, it should be stored in the refrigerator (2°C to 8°C) and used within 24 hours.

Product description

What it looks like

ILARIS is supplied in packs containing vials of solution only or powder only.

ILARIS 150mg/1mL vials:

ILARIS is supplied as a solution for injection. It is provided in a single-use vial. The solution is colourless to slightly brownish yellow.

Each pack contains one single-use vial. Not all pack sizes may be marketed in your country.

ILARIS 150 mg vials:

ILARIS is a white powder in a single-use glass vial. It can be in a whole or a fragmented cake.

Each pack contains one or four single-dose vials. Not all pack sizes may be marketed.

Ingredients

The active substance of ILARIS is canakinumab. One vial of powder contains 150 mg canakinumab. One vial of solution contains 150 mg canakinumab.

The other ingredients in the powder are sucrose, L-histidine, L-histidine HCl monohydrate, polysorbate 80.

The other ingredients in the solution are mannitol, L-histidine, L-histidine HCl monohydrate, polysorbate 80, water for injection.

Instructions for use

Please note that the preparation of the powder for solution for injection and powder and solvent for solution for injection takes about 30 minutes. The solution for injection requires no preparation.

For a pack containing ILARIS 150 mg powder vial only

Before beginning

Read these instructions all the way through before beginning.

- Find a clean, comfortable area.
- Wash your hands with soap and water.
- Check the expiry dates on the vial and syringes. Do not use if the expiry date has passed (last day of the month stamped on the vial).
- Always use new, unopened needles and syringes. Avoid touching the needles and the tops of the vials.

What else you will need

- One vial of sterile water for injections, at room temperature (‘diluent’)
- One 1.0mL syringe
- One 18G x 50mm needle for reconstituting the powder (‘transfer needle’)
- One 27G x 13mm needle for injecting the solution (‘injection needle’)
- Alcohol swabs
- Clean, dry cotton swabs
- An adhesive plaster

- A disposal container for used needles, syringes and vials ('sharps container').

Reconstituting ILARIS into a solution for injection

1. Remove the protective caps from the Ilaris powder vial and the diluent (water) vial. Do not touch the vial stoppers. Clean the stoppers with the alcohol swab.
2. Open the wrappers containing the syringe and the transfer needle and attach the needle to the syringe.
3. Carefully remove the cap from the transfer needle and set the cap aside. Pull the plunger all the way down to the 1.0 mL mark, filling the syringe with air. Insert the needle into the water vial through the centre of the rubber stopper of the diluent vial.
4. Gently push the plunger all the way down until air is injected into the vial.
5. Invert the vial and syringe assembly and bring to eye level.
6. Make sure the tip of the transfer needle is covered by the water and slowly pull the syringe plunger down to slightly past the 1.0 mL mark. If you see bubbles in the syringe, remove bubbles as instructed by your healthcare provider or pharmacist.
7. Make sure 1.0 mL of water is in the syringe, then withdraw the needle from the vial. (There will be water remaining in the vial).
8. Insert the transfer needle through the centre of the stopper of the vial of ILARIS powder, taking care not to touch the needle or the stopper. Slowly inject 1.0 mL of water in to the vial containing the ILARIS powder.
9. Carefully remove the syringe with the transfer needle from the vial and recap the needle as instructed by your healthcare provider or pharmacist.
10. Without touching the rubber stopper, swirl (do not shake) the vial slowly at an angle of about 45 degrees for approximately 1 minute. Allow to stand for 5 minutes.
11. Gently turn the vial head over tail ten times, again taking care not to touch the rubber stopper.
12. Allow to stand for about 15 minutes at room temperature to obtain a clear solution. Do not shake. Do not use if particles are present in the solution.
13. Make sure all of the solution is in the bottom of the vial. If drops remain on the stopper, tap the side of the vial to remove them. The solution should be clear and essentially free of visible particles. The solution should be colourless or may have a slight brownish-yellow tint.

    If not used within 1 hour of mixing, the solution should be stored in the refrigerator (2 to 8°C) and used within 24 hours.

Preparing the injection

14. Clean the rubber stopper of the vial containing the ILARIS solution with a new alcohol swab.
15. Uncap the transfer needle again. Pull the plunger of the syringe all the way down to the 1.0 mL mark, filling the syringe with air. Insert the syringe needle into the vial of ILARIS solution through the centre of the rubber stopper. Gently push the plunger all the way down until air is injected into the vial. Do not inject air into the medication.
16. **Do not** invert the vial and syringe assembly. Insert the needle all the way into the vial until it reaches the bottom edge.
17. Tip the vial to ensure that the required amount of solution can be drawn into the syringe. NOTE: The required amount depends on the dose to be administered (0.2 mL to 1.0 mL). Your healthcare provider will instruct you on the right amount for you.
18. Slowly pull the syringe plunger up to the correct mark (0.2 to 1.0 mL), filling the syringe with ILARIS solution. If there are air bubbles in the syringe, remove bubbles as instructed by your healthcare provider. Ensure that the correct amount of solution is in the syringe.

19. Remove the syringe and needle from the vial. (There may be solution remaining in the vial.) Recap the transfer needle as instructed by your healthcare provider or pharmacist. Remove the transfer needle from the syringe. Place the transfer needle in the sharps container.
20. Open the wrapper containing the injection needle and attach the needle to the syringe. Set the syringe aside.

Giving the injection

21. Choose an injection site on the upper arm, upper thigh, abdomen or buttocks. Do not use an area that has a rash or broken skin, or is bruised or lumpy. Avoid injecting into scar-tissue as this may lead to insufficient exposure to canakinumab. Avoid injecting into a vein.
22. Clean the injection site with a new alcohol swab. Allow the area to dry. Uncap the injection needle.
23. Gently pinch the skin up at the injection site. Hold the syringe at a 90-degree angle and in a single, smooth motion, push the needle straight down completely into the skin.
24. Keep the needle all the way in the skin while slowly pushing the syringe plunger down until the barrel is empty. Release the pinched skin and pull the needle straight out. Dispose of the needle and syringe in the sharps container without recapping or removing the needle.

For a pack containing ILARIS solution for injection vial only

Before beginning

- Find a clean, comfortable area.
- Wash your hands with soap and water.
- After removing the vial from the refrigerator, check the expiry dates on the vial. Do not use if the expiry date has passed (last day of the month stamped on the vial).
- Let the vial stand unopened for 10 minutes to allow the contents to reach room temperature. Do not expose the vial to heat.
- Always use new, unopened needles and syringes. Avoid touching the needles and the top of the vial.

Read these instructions all the way through before beginning.

Gather together the necessary items

A. One vial of ILARIS solution for injection (keep refrigerated at 2°C to 8°C).
B. One 1.0 mL syringe.
C. One appropriate size needle (e.g. 21G or larger) with appropriate length for withdrawing the solution (“withdrawal needle”).
D. One 27 G x 0.5” needle for injecting (“injection needle”).
E. Alcohol swabs.
F. Clean, dry cotton swabs.
G. An adhesive plaster.
H. A proper disposal container for used needles, syringe and vials (sharps container).

Preparing the injection

1. Remove the protective cap from the vial (A). Do not touch the vial stopper. Clean the stopper with the alcohol swab (E).

2. Open the wrappers containing the syringe (B) and the withdrawal needle (C) (bigger one) and attach the needle to the syringe.

1. Carefully remove the cap from the withdrawal needle and set the cap aside. Insert the syringe needle into the vial of ILARIS solution through the centre of the rubber stopper (Fig. 1).

2. Tip the vial to ensure that the required amount of solution can be drawn into the syringe (Fig. 2). Slowly pull the syringe plunger up to the correct mark, filling the syringe with ILARIS solution. If there are air bubbles in the syringe, remove bubbles as instructed by your healthcare provider. Ensure that the correct amount of solution is in the syringe.

NOTE: The required amount depends on the dose to be administered. Your healthcare provider will instruct you on the right amount for you.

3. Remove the needle and syringe from the vial and recap the withdrawal needle. Remove the withdrawal needle from the syringe and place in sharps container. Open the wrapper containing the injection needle and attach the needle to the syringe. Immediately proceed to administering the injection.

4. Choose an injection site on the upper arm, upper thigh, abdomen or buttocks. Do not use an area that has a rash or broken skin, or is bruised or lumpy. Avoid injecting into scar-tissue as this may lead to insufficient exposure to canakinumab. Avoid injecting into a vein.

5. Clean the injection site with a new alcohol swab. Allow the area to dry. Uncap the injection needle.

6. Gently pinch the skin up at the injection site. Hold the syringe at a 90-degree angle and in a single, smooth motion, push the needle straight down completely into the skin (Fig. 3).

7. Keep the needle all the way in the skin while slowly pushing the syringe plunger down until the barrel is empty (Fig. 4). Release the pinched skin and pull the needle straight out. Dispose of the needle and syringe in the sharps container without recapping or removing the needle.

Supplier

ILARIS is supplied in New Zealand by:

Novartis New Zealand Limited
PO Box 99102
Newmarket
Auckland 1149

Telephone 0800 354 335

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