Ilaris®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I using Ilaris?

Ilaris contains the active ingredient canakinumab. Ilaris is used to treat Cryopyrin-Associated Periodic Syndromes (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), Familial Mediterranean Fever (FMF) and Systemic Juvenile Idiopathic Arthritis (sJIA). For more information, see Section 1. Why am I using Ilaris? in the full CMI.

2. What should I know before I use Ilaris?

Do not use if you have ever had an allergic reaction to canakinumab or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.
For more information, see Section 2. What should I know before I use Ilaris? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ilaris and affect how it works.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Ilaris?

- Ilaris is given as an injection under the skin. Refer to section 4 in the full CMI for the amount of Ilaris that is given. It also depends on the condition.

More instructions can be found in Section 4. How do I use Ilaris? in the full CMI.

5. What should I know while using Ilaris?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Ilaris
Things you should not do	• Do not stop using or giving this medicine unless your doctor tells you. • Do not take 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
Looking after your medicine	• Keep it in a refrigerator (2°C to 8°C). Do not freeze it. Keep the vial in the outer carton in order to protect it from light.

For more information, see Section 5. What should I know while using Ilaris? in the full CMI.

6. Are there any side effects?

- Common side effects include symptoms of a viral infection or bronchitis, redness, pain or itching at the site of injection, sore throat, runny nose, blocked nose, sneezing, feeling of pressure or pain in the cheeks or forehead, dizziness or spinning sensation, vaginal yeast infection.
- Serous side effects where you must immediately call your doctor or go to hospital include spontaneous bleeding or bruising, fever, cough, difficulty or painful breathing, persistent cough, weight loss and low grade fever, constant "flu-like" symptoms, signs of an allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other part of the body, difficulty breathing or swallowing, nausea, dizziness, palpitations, burning sensation on urination or increased urgency to urinate, fever lasting longer than three days, or any other symptoms possibly related to an infection, stomach pain.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Ilaris®

Active ingredient: canakinumab

Consumer Medicine Information (CMI)

This leaflet provides important information about using Ilaris. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Ilaris.**

Where to find information in this leaflet:

1. Why am I using Ilaris?
2. What should I know before I use Ilaris?
3. What if I am taking other medicines?
4. How is Ilaris given?
5. What should I know while using Ilaris?
6. Are there any side effects?
7. Product details

1. Why am I using Ilaris?

Ilaris contains the active ingredient canakinumab. Ilaris belongs to a group of medicines called interleukin inhibitors. The active substance in Ilaris is canakinumab, a fully-human monoclonal antibody.

Ilaris is intended for treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), Familial Mediterranean Fever (FMF) and Systemic Juvenile Idiopathic Arthritis (sJIA).

Ilaris 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, TRAPS, HIDS/MKD, FMF and sJIA.

CAPS is the collective term for the following auto-inflammatory diseases:

- Familial Cold Auto-inflammatory Syndrome (also called Familial Cold Urticaria)
- Muckle-Wells Syndrome
- Neonatal-Onset Multisystem Inflammatory Disease (also called Chronic Infantile Neurological, Cutaneous, Articular Syndrome)

With these conditions, the body produces excessive amounts of IL-1 beta. This may lead to symptoms such as fever, headache, fatigue, skin rash, painful joints and muscles. In some people, more severe outcomes such as hearing impairment are observed.

Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)

ILARIS is used to treat Tumor Necrosis Factor (TNF) Receptor Associated Periodic Syndrome (TRAPS) in adults and children ages 2 years and older.

Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)

ILARIS is used to treat Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adults and children ages 2 years and older.

Familial Mediterranean Fever (FMF)

ILARIS is used to treat Familial Mediterranean Fever (FMF) in adults and children ages 2 years and older when the medicine "colchicine" is not suitable, such as in patients who cannot be treated with colchicine, who do not tolerate colchicine or when colchicine does not work well enough. Ilaris can be used alone or together with colchicine.

In patients with CAPS, TRAPS, HIDS/MKD and FMF, 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.

ILARIS is also used for the treatment of:

sJIA is an auto-inflammatory disorder occurring in childhood that can cause pain, swelling and inflammation of one or more joints, as well as rash, recurrent systemic symptoms of fever, enlarged lymph nodes, liver and spleen enlargement, and inflammation of the inner lining of body organs.

The signs and symptoms of SJIA are caused by increased production and/ or increased sensitivity to inflammatory messengers (cytokines) such as IL-1 beta which are released by immune cells.

Ilaris selectively binds to IL-1 beta, blocking its activity and leading to an improvement in signs and symptoms of CAPS and sJIA.

Ask your doctor if you have any questions about why this medicine has been prescribed for you or your child.

Your doctor may have prescribed it for another reason.

Ilaris is available only with a doctor's prescription and is not addictive.

It can be used in adults and children aged 2 years or older with a body weight 7.5 kg and above.

2. What should I know before I use Ilaris?

Warnings

Do not use Ilaris if you are allergic to:

- canakinumab or any of the ingredients listed at the end of this leaflet.
- any other similar medicines (such as medicines of the same class).

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

- Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering..

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Check with your doctor if you have or have had any of the following medical conditions:

- infection or a history of recurring infections, including tuberculosis
- neutropenia, where certain white blood cell counts are low
- macrophage activation syndrome (MAS) - a type of white blood cell condition in patients with sJIA or other rheumatic diseases.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Ilaris is not recommended for use during pregnancy unless clearly needed. Your doctor can discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Breastfeeding is not recommended while you are taking Ilaris. It is not known whether Ilaris passes into breast milk and could affect your baby.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Your doctor will want to know if you are prone to allergies.

If you have not told your doctor about any of the above, tell them before you start taking Ilaris.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Ilaris and affect how it works.

These include:

- vaccinations; you must not be given "live vaccines" while being treated with Ilaris
- medicines called TNF inhibitors (such as etanercept, adalimumab or infliximab) used mainly in rheumatic and autoimmune diseases.

Such medicines may be affected by Ilaris or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Ilaris.

4. How is Ilaris given?

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Keep taking your medicine for as long as your doctor tells you.

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

The injection may be given by your doctor or nurse or you may be taught how to inject yourself with the medicine.

If you do not understand the instructions on the label ask your doctor or pharmacist for help.

How much is given

For CAPS patients, a single dose of Ilaris is injected under the skin (also called subcutaneous injection) every 8 weeks.

The recommended starting dose of Ilaris for CAPS is:

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

Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)

- The recommended starting dose of ILARIS for TRAPS patients is:

Adults and children aged 2 years and above

- 150 mg for patients with body weight of more than 40 kg and above.
- 2 mg/kg with body weight ≤40 kg.
- With a starting dose of 150 mg or 2 mg/kg, if a satisfactory treatment response has not been achieved 7 days after treatment start, a second dose of 150 mg or 2 mg/kg may be considered by your physician. If a full treatment response is then achieved, the higher dosing regimen of 300 mg or 4 mg/kg every 4 weeks should be maintained.
- Do not exceed the recommended dose.

Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)

- The recommended starting dose of ILARIS for HIDS/MKD patients is:

Adults and children aged 2 years and above

- 150 mg for patients with body weight of more than 40 kg and above.
- 2 mg/kg with body weight ≤40 kg.
- With a starting dose of 150 mg or 2 mg/kg, if a satisfactory treatment response has not been achieved 7 days after treatment start, a second dose of 150 mg or 2 mg/kg may be considered by your physician. If a full treatment response is then achieved, the higher dosing regimen of 300 mg or 4 mg/kg every 4 weeks should be maintained.
- Do not exceed the recommended dose.

Familial Mediterranean Fever (FMF)

The recommended starting dose of ILARIS for FMF patients is:

Adults and children aged 2 years and above

- 150 mg for patients with body weight of more than 40 kg and above.
- 2 mg/kg with body weight ≤40 kg.
- With a starting dose of 150 mg or 2 mg/kg, if a satisfactory treatment response has not been achieved 7 days after treatment start, a second dose of 150 mg or 2 mg/kg may be considered by your physician. If a full treatment response is then achieved, the higher dosing regimen of 300 mg or 4 mg/kg every 4 weeks should be maintained.
- Do not exceed the recommended dose.

Systemic Juvenile Idiopathic Arthritis

For sJIA patients with a body weight of 7.5 kg and above, the recommended dose is 4 mg/kg (up to a maximum of 300 mg) injected under the skin every 4 weeks.

Keep taking this medicine for as long as your doctor tells you.

Injecting Ilaris yourself

Discuss with your doctor whether or not you will inject Ilaris yourself.

After proper training in injection technique, you may inject it 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 vials are for individual use only. Never re-use the left-over solution. Any unused product or waste material should be disposed of in accordance with local requirements.

Read the following instructions all the way through before beginning.

Use the following instructions to prepare Ilaris powder for injection:

1. Find a clean, comfortable area.
2. Wash your hands with soap and water.
3. Always use new, unopened needles and syringes. Avoid touching the needles and the tops of the vials.
4. Gather together the necessary items included in the pack:

- one vial of Ilaris powder for injection.

5. Gather together the necessary items not included in the pack:

- one vial of sterile water for injection ("water") (do not refrigerate)
- one 1.0 mL syringe
- one 18 G x 2" (50 mm) needle for reconstituting the powder ("transfer needle")
- one 27 G x 0.5" (13 mm) needle for injecting ("injection needle")
- alcohol swabs
- clean, dry cotton swabs
- an adhesive bandage
- a proper disposal container for used needles, syringe and vials (sharps container).

Use the following list of instructions to make the solution of Ilaris:

1. Remove the protective caps from the Ilaris vial and 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 (bigger one) 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.
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 5 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, colourless or slightly brownish-yellow and free of visible particles.
14. 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.

Use the following list of instructions to prepare the injection:

1. Clean the rubber stopper of the vial containing the Ilaris solution with a new alcohol swab.
2. 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.
3. Do not invert the vial and syringe assembly. Insert the needle all the way into the vial until it reaches the bottom edge.
4. Tip the vial to ensure that the required amount of solution can be drawn into the syringe.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.
5. 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.
6. 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.
7. Remove the transfer needle from the syringe. Place the transfer needle in the sharps container.

Use the following list of instructions to give the injection:

1. Open the wrapper containing the injection needle and attach the needle to the syringe. Set the syringe aside.
2. 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.
3. Clean the injection site with a new alcohol swab. Allow the area to dry. Uncap the injection needle.
4. 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.
5. 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.
6. Do not rub the injection area. If bleeding occurs, apply a clean, dry cotton swab over the area, and press gently for 1 to 2 minutes, or until bleeding stops. Then apply an adhesive bandage.

Use the following instructions to prepare for Ilaris solution for injection:

1. Find a clean, comfortable area.
2. Wash your hands with soap and water.
3. Always use new, unopened needles and syringes. Avoid touching the needles and the tops of the vials.
4. Gather together the necessary items included in the pack:

- one vial of Ilaris solution for injection.

5. Gather together the necessary items not included in the pack:

- one 1.0 mL syringe
- one appropriate size needle (e.g. 21G or larger) with appropriate length for withdrawing the solution ("withdrawal needle").
- one 27 G x 0.5” needle for injecting ("injection needle").
- alcohol swabs

- clean, dry cotton swabs
- an adhesive bandage
- a proper disposal container for used needles, syringe and vials (sharps container).

Use the following list of instructions to prepare the injection:

1. Remove the protective cap from the vial. Do not touch the vial stopper. Clean the stopper with the alcohol swab.
2. Open the wrappers containing the syringe and the withdrawal needle (bigger one) and attach the needle to the syringe.
3. 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.
4. Tip the vial to ensure that the required amount of solution can be drawn into the syringe. 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.

5. 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.
6. 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.
7. Clean the injection site with a new alcohol swab. Allow the area to dry. Uncap the injection needle.
8. 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.
9. 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.

If you forget to have Ilaris

If you forget to inject it, inject the next dose as soon as you remember then contact your doctor to discuss when you should take the next dose.

You should continue with injections at the recommended intervals (8 weeks for CAPS, or 4 weeks for TRAPS, HIDS/MKD o FMF unless your doctor tell you to and 4 weeks for sJIA, as before.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to have your medicine, ask your pharmacist for some hints.

If you use too much Ilaris

If you think that you have used too much Ilaris, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Ilaris?

Things you should do

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will do tests (such as liver function test and white blood cells test) from time to time to make sure the medicine is working and to prevent unwanted side effects.

Tell your doctor if you have a temperature or chills, or another sign of an infection.

You may need medical treatment.

Patients with sJIA or other rheumatic condition may develop MAS, which can be life-threatening. Your doctor will monitor you for known triggers that include infections and worsening of sJIA.

Tell your doctor if you experience any signs of an allergic reaction such as difficulty breathing or swallowing, nausea, dizziness, skin rash, itching, hives, low blood pressure or palpitations.

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 taking Ilaris.

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

Things you should not do

Do not take 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.

Looking after your medicine

If you have to store Ilaris:

- Keep it in a refrigerator (2°C to 8°C). Do not freeze it.

- Keep the vial in the outer carton in order to protect it from light.
- Do not store Ilaris or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on a window sill.

Keep the medicine where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you or your child does not feel well while taking Ilaris.

All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You or your child may need medical attention if you or your child gets some of the side effects.

Do not be alarmed by the following lists of side effects. You or your child may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• symptoms of a viral infection or bronchitis such as shivering, chills, malaise, loss of appetite, body aches, cough, phlegm. • redness, pain or itching at the site of injection • combination of sore throat, runny nose, blocked nose, sneezing, feeling of pressure or pain in the cheeks or forehead, with or without fever • dizziness or spinning sensation. • vaginal yeast infection	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• spontaneous bleeding or bruising, which may be linked to low levels of blood platelets (thrombocytopenia)	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**
• fever, sore throat or mouth ulcers due to infections (may be symptoms of low levels of white blood cells) • fever, cough, difficulty or painful breathing, wheezing, pain in chest when breathing (pneumonia) • persistent cough, weight loss and low grade fever (tuberculosis infection) • constant "flu-like" symptoms such as fever, chills, sore throat, aching joints, swollen glands, cough, difficulty swallowing, headache or any other signs of infection such as infection of a cut or scratch • signs of an allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other part of the body; shortness of breath, wheezing or difficulty breathing or swallowing, nausea, dizziness, palpitations or low blood pressure • burning sensation on urination or increased urgency to urinate. • fever lasting longer than three days or any other symptoms possibly related to an infection, such as prolonged cough, phlegm, chest pain, blood in sputum, difficulty breathing, ear pain, prolonged headache or localized redness, warmth or swelling of your skin. These may be symptoms of a typical infection or one that may be more serious (opportunistic infections) • Stomach pain	

The above list includes serious side effects. You or your child may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice anything else that is making you or your child feel unwell, such as increased irritability.

Other side effects not listed here or not yet known may happen in some people. Some of these side effects can only be found by laboratory testing.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Ilaris contains

Ilaris powder for injection vials

Active ingredient (main ingredient)	canakinumab
Other ingredients (inactive ingredients)	sucrose histidine histidine hydrochloride monohydrate polysorbate 80 dilute hydrochloric acid.
Potential allergens	None

Ilaris solution for injection vials

Active ingredient (main ingredient)	canakinumab
Other ingredients (inactive ingredients)	mannitol L-histidine L-histidine hydrochloride monohydrate polysorbate 80 water for injection.
Potential allergens	None

Do not take this medicine if you are allergic to any of these ingredients.

This medicine does not contain gluten, tartrazine or any other azo dyes.

What Ilaris looks like

Ilaris powder for Injection

Ilaris is supplied as a powder for injection in a single-use glass vial.

The powder is white. It can be in a whole or a fragmented cake.

Each pack contains one or four single-dose vials.

Ilaris solution for injection

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.

Australian Registration Numbers:

AUST R 159573 - powder for injection vial only

AUST R 279239 – solution for injection

Who distributes Ilaris

Ilaris is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

Level 25, Victoria Cross Tower

155 Miller Street

North Sydney NSW 2060

Telephone 1 800 671 203

® = Registered Trademark

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