

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.

1. Why am I using Ilaris?

Ilaris contains the active ingredient canakinumab. Ilaris is intended for treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) 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?

- Your healthcare provider will prescribe the dose of Ilaris that is right for you. Use Ilaris exactly as prescribed.
- Do not try to inject Ilaris yourself until you or your caregiver has been shown how to by your healthcare provider.
- 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.

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	<ul style="list-style-type: none">• Do not take Ilaris and tell your doctor if you experience serious skin reaction or any signs of an allergic such as difficulty breathing or swallowing, nausea,
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	<p>dizziness, skin rash, itching, hives, low blood pressure or palpitations</p> <ul style="list-style-type: none"> • Tell your doctor you are taking Ilaris if you plan to get vaccinated as some vaccines may not be suitable for you
Things you should not do	<ul style="list-style-type: none"> • Do not take Ilaris to treat any other complaints unless your doctor tells you to • Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools until you know how Ilaris affects you.
Drinking alcohol	<ul style="list-style-type: none"> • Not applicable
Looking after your medicine	<ul style="list-style-type: none"> • Keep it in a refrigerator at 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?

All medicines can have side effects although not everybody gets them. The most common side effects of Ilaris include the common cold, urinary tract infection, respiratory infection, viral infection, redness or pain at site of injection, dizziness or spinning sensation and 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(s): *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 do I use Ilaris?](#)
- [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. Canakinumab is a fully-human monoclonal antibody. Ilaris belongs to a group of medicines called interleukin inhibitors. 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 and sJIA

Ilaris is used for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) and Systemic Juvenile Idiopathic Arthritis (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.

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.

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.

Check with your doctor if you:

- have an infection or a history of recurring infections, including tuberculosis
- have neutropenia, where certain white blood cell counts are low
- have 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.

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.

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.

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.

4. How Ilaris is given?

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

They may differ from the information contained in this leaflet.

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.
- 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.

Do not exceed the recommended dose.

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 the 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.

How long to take it

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

If you forget to use 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 sJIA)s, 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.

Call your doctor straight away 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.

Do not take Ilaris and tell your doctor if you experience a serious skin reaction or 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

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.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. 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.

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

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">● 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	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
<ul style="list-style-type: none">● spontaneous bleeding or bruising	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you

Serious side effects	What to do
<ul style="list-style-type: none"> ● fever, sore throat or mouth ulcers due to infections ● fever, cough, difficulty or painful breathing, wheezing, pain in chest when breathing ● persistent cough, weight loss and low grade fever ● constant "flu-like" symptoms such as fever, chills, sore throat, aching joints, swollen glands, cough, difficulty swallowing, headache or any other signs of infection ● 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 ● burning sensation on urination or increased urgency to urinate 	<p>notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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. ● stomach pain 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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

Active ingredient (main ingredient)	canakinumab
Other ingredients (inactive ingredients)	mannitol L-histidine L-histidine hydrochloride monohydrate polysorbate 80 water for injection
Potential allergens	This medicine does not contain gluten, tartrazine or any other azo dyes

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

What Ilaris looks like

Ilaris powder for injection vial only is a white, lyophilised powder that is reconstituted with water for injections (Aust R 159573).

Ilaris solution for injection is a colourless to slightly brownish yellow solution, in a 2 mL colourless glass vial with grey rubber stopper and green flip off cap (AUST R 279239)

Who distributes Ilaris

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone 1 800 671 203

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