NOVARTIS

Package leaflet: Information for the user

Ilaris 150 mg solution for injection in pre-filled pen

canakinumab

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In addition to this leaflet, you will be given a patient card, which contains important safety information that you need before and during treatment with Ilaris.

What is in this leaflet:

1. What Ilaris is and what it is used for

What Ilaris is
Ilaris contains the active substance canakinumab, a monoclonal antibody that belongs to a group of medicines called interleukin inhibitors. It blocks the activity of a substance called interleukin-1 beta (IL-1 beta) in the body, which is present at increased levels in inflammatory diseases.

What Ilaris is used for
Ilaris is used for treatment of the following inflammatory diseases:
- Periodic fever syndromes:
  - Cryopyrin-associated periodic syndromes (CAPS),
  - Tumour necrosis factor receptor associated periodic syndrome (TRAPS),
  - Hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD),
  - Familial Mediterranean fever (FMF).
- Still's disease including adult onset Still's disease (AOSD) and systemic juvenile idiopathic arthritis (SJIA)
- Gouty arthritis

More information on each of these diseases is given below.

Periodic fever syndromes
Ilaris is used in adults and children aged 2 years and older to treat the following:
- Cryopyrin-associated periodic syndromes (CAPS) – this is a group of auto-inflammatory diseases, which include:
  - Muckle-Wells syndrome (MWS),
  - Neonatal-onset multisystem inflammatory disease (NOMID), also called chronic infantile neurological, cutaneous, articular syndrome (CINCA),
  - Severe forms of familial cold auto-inflammatory syndrome (FCAS) / familial cold urticaria (FCU) presenting with signs and symptoms beyond cold-induced urticarial skin rash.
- Tumour necrosis factor receptor associated periodic syndrome (TRAPS)
- Hyperimmunoglobulin D syndrome (HIDS) also known as mevalonate kinase deficiency (MKD)
- Familial Mediterranean fever (FMF): Ilaris is used to treat FMF. Ilaris can be used together with colchicine, if appropriate.

In patients with periodic fever syndromes (CAPS, TRAPS, HIDS/MKD and FMF), the body produces too much IL-1 beta. This may cause fever, headache, fatigue, skin rash, or painful joints and muscles. By blocking the activity of IL-1 beta, Ilaris may improve these symptoms.

Still's disease
Ilaris is used in adults, adolescents and children to treat active Still's disease including adult-onset Still's disease (AOSD) and systemic juvenile idiopathic arthritis (SJIA) in patients aged 2 years and older if other treatments have not worked well enough. Ilaris can be used alone or in combination with methotrexate.

Still's disease including SJIA and AOSD is an inflammatory disease that can cause pain, swelling and inflammation of one or more joints, as well as rash and fever. A pro-inflammatory protein called IL-1 beta plays an important role in Still's disease inflammation. Ilaris blocks the activity of IL-1 beta, which may improve the signs and symptoms of Still's disease.

Gouty arthritis
Ilaris is used in adults to treat the symptoms of frequent gouty arthritis attacks if other treatments have not worked well enough.

Gouty arthritis is caused by the formation of urate crystals. These crystals cause excessive production of IL-1 beta, which in turn can lead to sudden, severe pain, redness, warmth and swelling in a joint (known as a gouty arthritis attack). By blocking the activity of IL-1 beta, Ilaris may lead to an improvement in these symptoms.

2. What you need to know before you use Ilaris

Do not use Ilaris
- if you are allergic to canakinumab or any of the other ingredients of this medicine (listed in section 6).
- if you have, or suspect you have, an active and severe infection.

Warning and precautions
Talk to your doctor before using Ilaris if any of the following applies to you:
- if you currently have an infection or if you have had repeated infections or a condition such as a known low level of white blood cells which makes you more likely to get infections.
- if you have or have ever had tuberculosis or direct contact with a person with an active tuberculosis infection. Your doctor may check whether you have tuberculosis using a specific test.
- if you have signs of a liver disorder such as yellow skin and eyes, nausea, loss of appetite, dark-coloured urine and light-coloured stools.
- if you need to have any vaccinations. You are advised to avoid being vaccinated with a type of vaccine called a live vaccine while being treated with Ilaris (see also "Other medicines and Ilaris").
- This medicine contains 0.4 mg of polysorbate 80 in each 1 ml of solution for injection. Polysorbates may cause allergic reactions. Tell your doctor if you or your child have any known allergies.

Contact your doctor immediately
- If you have ever developed an atypical, widespread rash or skin peeling after taking Ilaris.

The serious skin reaction, DRESS (drug reaction with eosinophilia and systemic symptoms), has rarely been reported in association with Ilaris treatment, predominantly in patients with systemic juvenile idiopathic arthritis (sJIA). Seek medical attention immediately if you notice an atypical, widespread rash, which may occur in conjunction with high body temperature and enlarged lymph nodes.

Still's disease
- Patients with Still's disease may develop a condition called macrophage activation syndrome (MAS), which can be life-threatening. Your doctor will monitor you for potential triggering factors of MAS that include infections and re-activation of the underlying Still's disease (flare).

Traceability
Every time you/your child get a new pack of Ilaris, it is important you note down the name of the medicine and the date of administration together with the batch number and keep this information in a safe place.

Children and adolescents
- **CAPS, TRAPS, HIDS/MKD, FMF and SJIA**: Ilaris can be used in children aged 2 years and older.
- **Gouty arthritis**: Ilaris is not recommended for children or adolescents under 18 years of age.

Other medicines and Ilaris
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.
- Live vaccines: You are advised to avoid being vaccinated with a type of vaccine called a live vaccine while you are being treated with Ilaris. Your doctor may want to check your vaccination history and give you any vaccinations that you have missed before you start treatment with Ilaris. If you need to be given a live vaccine after starting treatment with Ilaris, discuss this with your doctor. A live vaccine should normally be given 3 months after your last injection of Ilaris and 3 months before the next one.
- Medicines called tumour necrosis factor (TNF) inhibitors, such as etanercept, adalimumab or infliximab. These are used mainly in rheumatic and autoimmune diseases. They should not be used with Ilaris because this may increase the risk of infections.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
- You are advised to avoid becoming pregnant and must use adequate contraception while using Ilaris and for at least 3 months after the last Ilaris treatment. It is important to tell your doctor if you are pregnant, if you think you may be pregnant or are planning to have a baby. Your doctor will discuss with you the potential risks of taking Ilaris during pregnancy.
- If you received canakinumab while you were pregnant, it is important that you inform the baby's doctor or nurse before any vaccinations are given to your baby. Your baby should not receive live vaccines until at least 16 weeks after you received your last dose of canakinumab before giving birth.
- It is not known whether Ilaris passes into human milk. Your doctor will discuss with you the potential risks of taking Ilaris before breast-feeding.

Driving and using machines
Ilaris treatment may give you a spinning sensation (dizziness or vertigo) or intense tiredness (asthenia). This should be borne in mind when considering your ability to perform tasks that require judgement or motor skills. If you feel a spinning sensation or feel tired, do not drive or use any tools or machines until you are feeling normal again.

3. How to use Ilaris

Always use this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Keep your doctor informed of your condition and any symptoms before you use or are given Ilaris (see section 2). Your doctor may decide to delay or interrupt your treatment, but only if necessary.

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 gouty arthritis, your treatment will be overseen by a doctor with specialist training. Ilaris should be injected by a healthcare professional only.
If you have CAPS, TRAPS, HIDS/MKD, FMF or Still's disease (AOSD or SJIA), and are aged 12 years or older and weigh more than 40 kg, you may inject yourself with Ilaris after proper training, or a caregiver may inject it for you.

How much Ilaris to use
Cryopyrin- associated periodic syndromes (CAPS)
The recommended starting dose of Ilaris is:
- *Adults and children aged 4 years or more*
  - 150 mg for patients who weigh more than 40 kg
  - 2 mg/kg for patients who weigh between 15 kg and 40 kg
  - 4 mg/kg for patients who weigh between 7.5 kg and less than 15 kg
- *Children aged 2 or 3 years*
  - 4 mg/kg for patients with body weight of 7.5 kg or more

Ilaris is injected every 8 weeks as a single dose.
- If you have not responded well enough to the treatment after 7 days, your doctor may give you another dose of 150 mg or 2 mg/kg.
- If you respond well enough to the second dose, your treatment will be continued with 300 mg or 4 mg/kg every 8 weeks.
- If you do not respond well enough to the second dose, a third dose of Ilaris at 300 mg or 4 mg/kg may be given.
- If you respond well enough to the third dose, your treatment will be continued at 600 mg or 8 mg/kg every 8 weeks.

For children given a starting dose of 4 mg/kg who have not responded well enough after 7 days, the doctor may give a second dose of 4 mg/kg. If the child responds well enough to this, treatment may be continued with a dose of 8 mg/kg every 8 weeks.

Tumour necrosis factor receptor associated periodic syndrome (TRAPS), hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD) and familial Mediterranean fever (FMF)
The recommended starting dose of Ilaris is:
- *Adults and children aged 2 years or more*
  - 150 mg for patients who weigh more than 40 kg
  - 2 mg/kg for patients who weigh between 7.5 kg and less than 40 kg

Ilaris is injected every 4 weeks as a single dose.
- If you have not responded well enough to the treatment after 7 days, your doctor may give you another dose of 150 mg or 2 mg/kg.
- If you respond well enough to this, your treatment will be continued with 300 mg or 4 mg/kg every 4 weeks.

Still's disease (SJIA and AOSD)
The recommended dose of Ilaris for patients with Still's disease with body weight of 7.5 kg and above is 4 mg/kg (up to a maximum of 300 mg). Ilaris is injected every 4 weeks as a single dose.

Gouty arthritis
Your doctor will discuss with you the need to start or adjust a urate lowering therapy to lower the uric acid level in your blood.

The recommended dose of Ilaris for adult gouty arthritis patients is 150 mg given as a single dose at the time of a gouty arthritis attack.

If you need another treatment with Ilaris, and got relief from the last dose, you must wait at least 12 weeks before the next dose.

Injecting Ilaris yourself or injecting a patient with Ilaris
If you are a patient aged 12 years or older with a body weight more than 40 kg with CAPS, TRAPS, HIDS/MKD, FMF or Still's disease (AOSD or SJIA), or a caregiver of a patient with one of these conditions, you may administer Ilaris injections yourself after proper training in the correct injection technique. Adolescent patients may require the supervision of an adult caregiver to perform self-injection.
- The patient or caregiver and the doctor should decide together who will administer the Ilaris injections.
- The doctor or nurse will demonstrate how to administer Ilaris injections.
- Do not try to administer an injection yourself if you have not been properly trained or if you are not sure how to do it.
- Ilaris 150 mg/ml solution for injection is supplied in a single-use pre-filled pen for individual use.

For instructions on how to administer Ilaris injections, please read the section "Instructions for use of the Ilaris 150 mg SensoReady pen" at the end of this leaflet. If you have any questions, talk to your doctor, pharmacist or nurse.

How long to use Ilaris
- **CAPS, TRAPS, HIDS/MKD, FMF or Still's disease (AOSD or SJIA)**: You should continue using Ilaris for as long as the doctor tells you.
- **Gouty arthritis**: If you have a gouty arthritis attack, you will be given a single dose of Ilaris. If you experience a new attack, your doctor may consider giving you a new dose of Ilaris but not earlier than 12 weeks from the previous dose.

If you use more Ilaris than you should
If you accidentally inject more Ilaris than the recommended dose, it is unlikely to be serious, but you should inform your doctor, pharmacist or nurse as soon as possible.

If you forget to use Ilaris
If you have CAPS, TRAPS, HIDS/MKD, FMF or Still's disease (AOSD or SJIA) and have forgotten to inject a dose of Ilaris, inject the next dose as soon as you remember. Then talk to the doctor to discuss when you should inject the next dose. You should then continue with injections at the recommended intervals as before.

If you stop using Ilaris
Stopping your treatment with Ilaris may cause your condition to get worse. Do not stop taking Ilaris unless your doctor tells you to.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects could be serious. Tell your doctor immediately, if you notice any of the side effects below:
- Fever lasting longer than 3 days or any other symptoms that might suggest a serious infection. These include shivering, chills, malaise, loss of appetite, body aches, typically in connection with a sudden onset of illness, sore throat or mouth ulcers, cough, phlegm, chest pain, difficulty breathing, ear pain, prolonged headache or localised redness, warmth or swelling of your skin or inflammation of connective tissue (cellulitis). These symptoms could be due to a serious infection, an unusual infection (opportunistic infection) or be related to low levels of white blood cells (called leukopenia or neutropenia). Your doctor may check your blood regularly if considered necessary.
- Allergic reactions with rash and itching and possibly also hives, difficulty breathing or swallowing, dizziness, unusual awareness of your heart beat (palpitations) or low blood pressure.

Other side effects of Ilaris include:
Very common (may affect more than 1 in 10 people):
- Infections of any kind. These can include:
  - Respiratory infections such as chest infection, flu, sore throat, runny nose, blocked nose, sneezing, feeling of pressure or pain in the cheeks or forehead with or without fever (pneumonia, bronchitis, influenza, sinusitis, rhinitis, pharyngitis, tonsilitis, nasopharyngitis, upper respiratory tract infection).
  - Other infections such as ear infection, skin infection (cellulitis), stomach pain and feeling sick (gastroenteritis) and painful and frequent urination with or without fever (urinary tract infection).
- Upper abdominal pain.
- Pain in joints (arthralgia).
- Drop in level of white blood cells (leukopenia).
- Abnormal kidney function test results (creatinine renal clearance decreased, proteinuria).
- Injection site reaction (such as redness, swelling, warmth and itching).

Common (may affect up to 1 in 10 people):
- Candida - vaginal yeast infection (vulvovaginal candidiasis).
- Feeling dizzy, spinning sensation (dizziness or vertigo).
- Pain in the back or muscles.
- Feeling weak or very tired (fatigue, asthenia).
- Drop in level of white blood cells which help prevent infection (neutropenia).
- Abnormal levels of triglycerides in your blood (lipid metabolism disorder).
- Abnormal liver function test results (transaminases increased) or high level of bilirubin in the blood, with or without yellow skin and eyes (hyperbilirubinaemia).

Uncommon (may affect up to 1 in 100 people):
- Heartburn (gastro-oesophageal reflux disease).
- Drop in level of blood cells which help prevent bleeding (platelets).

Tell your doctor or your child's doctor immediately if you notice any of these symptoms.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ilaris

Keep this medicine out of the sight and reach of children.

Do not use this medicine:
- if the liquid contains visible particles or is distinctly brown.
- after the expiry date which is stated on the carton or on the pen label after "EXP". The expiry date refers to the last day of that month.
  - if the product has been out of the refrigerator (below 30°C) for longer than 14 days.
- if the safety seal has been broken.
- if the pen looks damaged.
- if the pen has been dropped with the cap removed.

Keep the pen in the original carton until ready to use in order to protect from light.

Store in a refrigerator (2°C - 8°C). Do not freeze. Do not shake.

If necessary, Ilaris boxed pen may be stored below 30°C for up to 14 days.

This medicine is for single use only.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ilaris contains
- The active substance is canakinumab. Each pre-filled pen contains 150 mg canakinumab in 1 ml of solution.
- The other ingredients are mannitol, histidine, histidine hydrochloride monohydrate, polysorbate 80 (E 433) (see section 2), water for injections.

What Ilaris looks like and contents of the pack
- Ilaris is supplied as a solution for injection in a pre-filled pen.
- The solution is a clear to opalescent liquid. It is colourless to slightly brownish-yellow. Do not use if the liquid contains visible particles or is distinctly brown.
- Ilaris is available in packs containing 1 pre-filled pen.

Marketing Authorisation Holder and Manufacturer
Novartis Pharmaceuticals UK Limited
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Novartis Pharmaceuticals UK Ltd.
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This leaflet was last revised in January 2025.

Instructions for use of the Ilaris 150 mg SensoReady pen

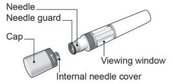
canakinumab

Read ALL the way through these instructions before injecting.

These instructions are to help you to inject correctly using the Ilaris 150 mg SensoReady pen.

It is important not to try to inject yourself until you have been trained properly by your doctor, nurse or pharmacist.

Your Ilaris 150 mg SensoReady pen:



Ilaris 150 mg SensoReady pen shown with the cap removed. **Do not** remove the cap until you are ready to inject.

Store your boxed pen in a refrigerator between 2°C and 8°C and keep out of the sight and reach of children.

After removing Ilaris boxed pen from the refrigerator, use it within 14 days, (but not later than the expiry date stated on the carton) and do not store it above 30°C. Write the date the Ilaris boxed pen is removed from the refrigerator in the date field on the carton.

- **Do not** use the pen if the product has been out of the refrigerator (below 30°C) for longer than 14 days.
- **Do not** use the pen if the product has been stored above 30°C.
- **Do not** freeze the pen.
- Keep the pen in the original carton until ready to use in order to protect from light.
- **Do not** shake the pen.
- **Do not** use the pen if it has been dropped with the cap removed.
- **Do not** use the pen if you are sensitive to latex.

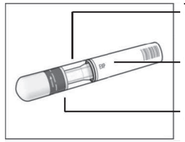
Remove the carton containing the pen from the refrigerator and leave it unopened for 30 minutes to reach room temperature (below 30°C).

What you need for your injection:

Included in the carton:
- A new and unused Ilaris 150 mg SensoReady pre-filled pen

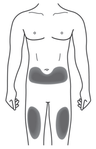
Not included in the carton:
- Alcohol swab.
- Cotton ball or gauze.
- Sharps disposal container.

Before your injection

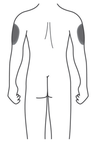


1. Important safety checks before you inject:
- The liquid needs to be clear to opalescent. Its colour may vary from colourless to slightly brownish-yellow.
- **Do not use** the pen if the liquid contains visible particles or is distinctly brown. You may see a small air bubble, which is normal.
- **Do not** use the pen if the expiry date has passed.
- **Do not** use the pen if it has been out of the refrigerator for longer than 14 days.
- **Do not** use the pen if the safety seal has been broken.
- **Do not** use the pen if it looks damaged.

Contact your pharmacist if the pen fails any of these checks.



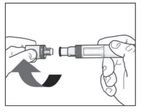
2a. Choose your injection site:
- The recommended site is the front of the thighs. You may also use the lower abdomen, but **not** the area 5 centimetres around the navel (belly button).
- Choose a different site each time you give yourself an injection.
- **Do not** inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks.



2b. Caregivers and healthcare professionals only:
- If a caregiver or healthcare professional is giving you your injection, they may also inject into your outer upper arm.

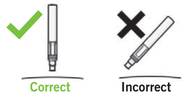
Your injection

3. Cleaning your injection site:
- Wash your hands with soap and hot water.
- Using a circular motion, clean the injection site with the alcohol swab. Leave it to dry before injecting.
- **Do not** blow on or touch the cleaned area again before injecting.



4. Removing the cap:
- Only remove the cap when you are ready to use the pen.
- Twist off the cap in the direction of the arrow.
- Once removed, throw away the cap. **Do not** try to re-attach the cap.
- Use the pen within 5 minutes of removing the cap.
- You may see a few drops of solution come out of the needle. This is normal.

5. Holding your pen:
- Hold the pen at 90 degrees to the cleaned injection site.



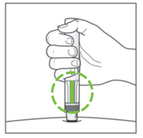
YOU MUST READ THIS BEFORE INJECTING.

During the injection you will hear 2 loud clicks.

The 1st click indicates that the injection has started. Several seconds later a 2nd click will indicate that the injection is almost finished.

You must keep holding the pen firmly against your skin until you see a green indicator fill the window and stop moving.

6. Starting your injection:
- Press the pen firmly against the skin to start the injection.
- The **1st click** indicates the injection has started.
- **Keep holding** the pen firmly against your skin.
- The **green indicator** shows the progress of the injection.



7. Completing your injection:
- Listen for the **2nd click**. This indicates the injection is **almost** complete.
- Check the **green indicator** fills the window and has stopped moving.
- The pen can now be removed.

After your injection

8. Check the green indicator fills the window:
- This means the medicine has been delivered. Contact your doctor if the green indicator is not visible.
- There may be a small amount of blood at the injection site. You can press a cotton ball or gauze over the injection site and hold it for 10 seconds. **Do not** rub the injection site. You may cover the injection site with a small adhesive plaster, if needed.

9. Disposing of your Ilaris 150 mg pre-filled pen:
- Dispose of the used pen in a sharps disposal container (i.e. a puncture-resistant closable container, or similar).
- Never try to reuse your pen.