NEW ZEALAND DATA SHEET

1 PRODUCT NAME

ILARIS® 150 mg Powder for Injection

ILARIS® 150 mg/mL Solution for injection vial

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

A reconstituted single-use vial delivers 150 mg canakinumab per 1 mL.

Active ingredient:	Canakinumab
	Canakinumab is a high-affinity human anti-human-IL-1β monoclonal antibody that belongs to the IgG1/κ isotype subclass. It is expressed in a murine myeloma SP2/0 cell line.
Chemical name:	Immunoglobulin G1, anti-(human interleukin-1beta (IL-1β)) human monoclonal ACZ885; (1Glu>Glp)-γ1 heavy chain (221-214')-disulfide with kappa light chain, dimer (227-227":230-230")-bisdisulfide
CAS number:	402710-25-2 (variable heavy γ1 chain)
	402710-27-4 (variable light κ chain)
Molecular weight:	Approximately 145.157kDa
Structure:	Canakinumab comprises two 447(or 448)-residue heavy chains and two 214-residue light chains.

For the full list of excipients, see section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Powder for solution for injection

Ilaris is a sterile, white, lyophilised powder that is reconstituted with water for injections and administered as a subcutaneous (SC) injection.

Solution for injection

Ilaris is a colourless to slightly brownish yellow solution, in a 2 mL colourless glass vial with grey rubber stopper and green flip off cap and administered as a SC injection.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Ilaris is indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and children aged 2 years and older including:

- Familial Cold Autoinflammatory Syndrome (FCAS) /Familial Cold Urticaria (FCU)
- Muckle-Wells Syndrome (MWS)

- Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA).

4.2 Dose and method of administration

Treatment should be initiated and supervised by a specialist physician experienced in the diagnosis and treatment of CAPS.

The recommended starting dose of Ilaris for CAPS patients is:

Adults and children ≥4 years of age:

- 150 mg with body weight >40 kg
- 2 mg/kg with body weight ≥15 kg and ≤40 kg
- 4 mg/kg with body weight ≥7.5 kg and <15 kg

Children 2 to <4 years of age:

- 4 mg/kg for patients with body weight ≥7.5 kg

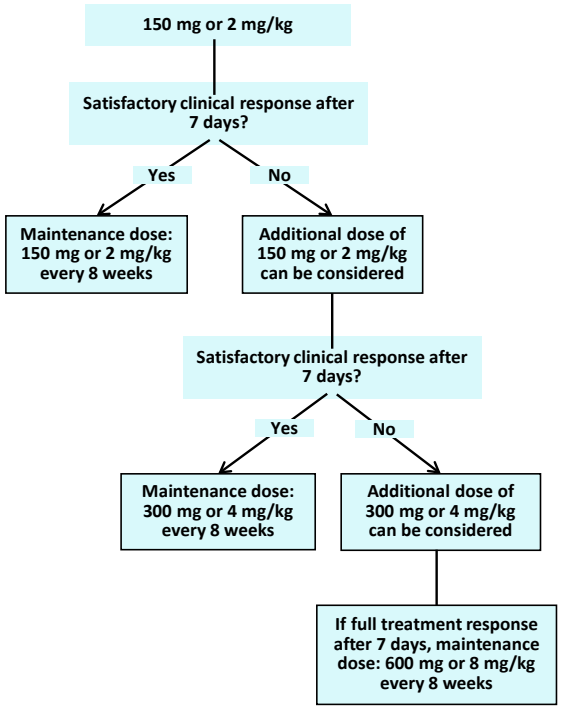
This is administered every eight weeks as a single dose via subcutaneous injection.

For patients with a starting dose of 150 mg or 2 mg/kg, if a satisfactory clinical response (resolution of rash and other generalised inflammatory symptoms) has not been achieved 7 days after treatment start, a second dose of ILARIS at 150 mg or 2 mg/kg can be considered. If a full treatment response is subsequently achieved, the intensified dosing regimen of 300 mg or 4 mg/kg every 8 weeks should be maintained. If a satisfactory clinical response has not been achieved 7 days after this increased dose, a third dose of ILARIS at 300 mg or 4 mg/kg can be considered. If a full treatment response is subsequently achieved, maintaining the intensified dosing regimen of 600 mg or 8 mg/kg every 8 weeks should be considered.

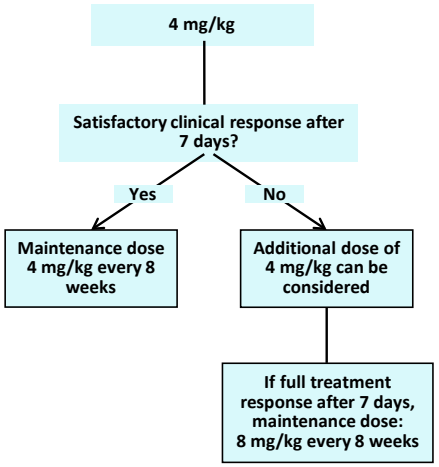
For patients with a starting dose of 4 mg/kg, if a satisfactory clinical response has not been achieved 7 days after treatment start, a second dose of ILARIS 4 mg/kg can be considered. If a full treatment response is subsequently achieved, maintaining the intensified dosing regimen of 8 mg/kg every 8 weeks should be considered.

Clinical experience with dosing at intervals of less than 4 weeks or at doses above 600 mg or 8 mg/kg is limited.

Adults and children ≥4 years of age ≥15 kg



Children 2-<4 years of age or children ≥4 years of age ≥7.5 kg and <15 kg



Renal and Hepatic Impairment

No dose adjustment is needed in patients with renal impairment. However, clinical experience in such patients is limited.

Ilaris has not been studied in patients with hepatic impairment.

Paediatric Patients

Ilaris is not indicated for use in children below age 2 years or with body weight below 7.5 kg.

CAPS: Limited data on patients with CAPS under 2 years are available (see section 5.1 Pharmacodynamic Properties, Clinical Trials).

Geriatric Patients

No dose adjustment is required in geriatric patients. However, clinical experience in such patients is limited.

Method of Administration

Subcutaneous injection.

After proper training in injection technique, patients may self-inject Ilaris if their physician determines that it is appropriate and with medical follow-up as necessary.

For instructions on reconstitution of the product before administration, see section 6.6 Special precautions for handling and disposal.

4.3 Contraindications

Confirmed hypersensitivity to the active substance or to any of the excipients (see section 4.4 Special warnings and precautions for use and section 4.8 Undesirable effects).

4.4 Special warnings and precautions for use

Infections

Ilaris is associated with an increased incidence of serious infections. Physicians should exercise caution when administering Ilaris to patients with infections, a history of recurring infections or underlying conditions which may predispose them to infections. Treatment with Ilaris should not be initiated or continued in patients with active infection requiring medical intervention.

Isolated cases of unusual or opportunistic infections (including aspergillosis, atypical mycobacterial infections, herpes zoster) have been reported during Ilaris treatment. A causal relationship of Ilaris to these events cannot be excluded.

Concomitant use of Ilaris with tumour necrosis factor (TNF) inhibitors is not recommended because this may increase the risk of serious infections (see section 4.5 Interactions with Other Medicines).

In approximately 12% of CAPS patients tested with a PPD skin test in clinical trials, follow-up testing yielded a positive test result while treated with Ilaris without clinical evidence of a latent or active tuberculosis infection.

It is unknown whether the use of IL-1 inhibitors such as Ilaris increases the risk of reactivation of tuberculosis. Before initiation of therapy, all patients must be evaluated for both active and latent tuberculosis infection. Particularly in adult patients, this evaluation should include a detailed medical history. Appropriate screening tests e.g. tuberculin skin test, Interferon-Gamma-Release-Assay (IGRA) or chest X-ray should be performed in all patients according to local recommendations. Patients must be monitored closely for signs and symptoms of tuberculosis during and after treatment with Ilaris. All patients should be instructed to seek medical device if signs or symptoms suggestive of tuberculosis (e.g. persistent cough, weight loss, subfebrile temperature) appear during Ilaris therapy. In the event of conversion from a negative to a positive PPD test, especially in high-risk patients, alternative means of screening for a tuberculosis infection should be considered.

Malignancies

Malignancy events have been reported in patients treated with Ilaris. The risk for the development of malignancies with anti-interleukin (IL)-1 therapy is unknown. A potential risk cannot be excluded in patients treated with Ilaris.

Hypersensitivity Reactions

Hypersensitivity reactions with Ilaris therapy have been reported. The majority of these events were mild in severity. During clinical development of Ilaris, no anaphylactoid or anaphylactic reactions attributable to treatment with secukinumab have been reported. However, the risk for severe hypersensitivity reactions, which is not uncommon for injectable proteins, cannot be excluded (see section 4.3 Contraindications and section 4.8 Undesirable Effects).

Vaccinations

Live vaccines should not be given concurrently with Ilaris (see section 4.5 Interactions with Other Medicines).

Neutropenia

Neutropenia has been observed with medicinal products that inhibit IL-1, including Ilaris. Treatment with Ilaris should not be initiated in patients with neutropenia. It is recommended that neutrophil counts be assessed prior to initiating treatment (see section 4.8 Undesirable Effects).

Effects on Laboratory Tests

Haematology

During clinical trials with Ilaris in CAPS patients, mean values for haemoglobin increased and for white blood cell, neutrophils and platelets decreased.

Hepatic transaminases

Elevations of transaminases have been observed rarely in CAPS patients.

Bilirubin

Asymptomatic and mild elevations of serum bilirubin have been observed in CAPS patients treated with canakinumab without concomitant elevations of transaminases.

4.5 Interaction with other medicines and other forms of interaction

Interactions between Ilaris and other medicinal products have not been investigated in formal studies.

The expression of hepatic CYP450 enzymes may be suppressed by the cytokines that stimulate chronic inflammation, such as IL-1 beta. Thus, CYP450 expression may be normalised when potent cytokine inhibitory therapy, such as canakinumab, is introduced. This is clinically relevant for CYP450 substrates with a narrow therapeutic index where the dose is individually adjusted. On initiation of canakinumab in patients being treated with this type of medicinal product, therapeutic monitoring of the effect or of the active substance concentration should be performed and the individual dose of the medicinal product adjusted as necessary.

In clinical studies, Ilaris has been safely administered with urate lowering therapies (ULT).

An increased incidence of serious infections has been associated with administration of another IL-1 blocker in combination with TNF inhibitors. Use of Ilaris with TNF inhibitors is not recommended because this may increase the risk of serious infections.

No data are available on either the effects of live vaccination or the secondary transmission of infection by live vaccines in patients receiving Ilaris. Therefore, live vaccines should not be given concurrently with Ilaris. It is recommended that, if possible, paediatric and adult patients should complete all immunisations in accordance with current immunisation guidelines prior to initiating Ilaris therapy.

The results of a study in healthy adult subjects demonstrated that a single dose of ILARIS 300 mg did not affect the induction and persistence of antibody responses after vaccination with influenza and glycosylated protein based meningococcus vaccines.

The results of a 56-week, open label study in CAPS patients aged 4 years and younger demonstrated that all patients who received non-live, standard of care childhood vaccinations developed protective levels of antibody.

The results of a study in healthy adult subjects demonstrated that a single dose of Ilaris 300mg does not affect the induction and persistence of antibody responses after vaccination with influenza and glycosylated protein based meningococcus vaccines.

4.6 Fertility, pregnancy and lactation

Effects on fertility

Formal studies of the potential effect of Ilaris on human fertility have not been conducted.

Canakinumab had no effect on male fertility parameters in marmoset (*C. jacchus*). A murine anti-murine IL-1 beta antibody had no undesirable effects on fertility in male or female mice. The high dose (150 mg/kg) in the mouse study was in excess of the maximally effective dose in terms of IL-1 beta suppression and activity.

Use in Pregnancy (Category B3)

There is limited amount of data from literature and post-marketing reports on the use of canakinumab in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see Animal data). The risk for the foetus/mother is unknown. Because animal reproduction studies are not always predictive of the human response, canakinumab should be given to a pregnant woman only if clearly needed.

Clinical considerations

Monoclonal antibodies such as canakinumab actively cross the placenta and are detectable in the foetus, predominantly in the second and third trimesters of pregnancy. Based on limited human data, canakinumab levels were detected in cord and neonatal blood. The clinical impact of this is unknown. However, administration live vaccines to newborn infants exposed to canakinumab *in utero* is not recommended for 16 weeks following the mother's last dose of Ilaris before childbirth.

Animal data

Studies on embryofoetal development were performed in marmoset monkeys dosed with canakinumab. There was no evidence of maternal toxicity, embryotoxicity, or teratogenicity when administred throughout organogenesis. In addition, canakinumab did not elicit adverse effects on foetal or neonatal growth when administered throughout late gestation.

Reproductive studies in mice using a murine anti-murine IL-1 beta antibody have shown no undersirable effects. No effects on labour and delivery were observed. The high dose used in these studies was in excess of the maximally effective dose in terms of IL-1 beta suppression and activity.

Use in Lactation

It is not known whether canakinumab is transferred into breast milk. There are no data on the effects of Ilaris on the breastfed child or milk production. Animal studies have shown that a murine anti-murine IL-l beta antibody had no undesirable effects on development of nursing mouse pups.

Breast-feeding is not recommended during treatment with Ilaris.

Paediatric use

The safety and efficacy of ILARIS in CAPS patients under two years of age have not been established. Limited data on patients under two years are available (see 'Clinical Trials'). No dosage recommendation can be made.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

In blinded and open-label clinical trials in patients with CAPS, the most frequently reported adverse drug reactions were infections, predominantly of the upper respiratory tract. The majority of the events were mild to moderate although serious infections were observed. No impact on the type or frequency of adverse drug reactions was seen with longer-term treatment.

Hypersensitivity reactions have been reported in patients treated with Ilaris (see section 4.3 Contraindications and section 4.4 Special warnings and precautions for use).

Opportunistic infections have been reported in patients treated with Ilaris (see section 4.4 Special warnings and precautions for use).

A total of 211 adult and paediatric CAPS patients (including FCAS/FCU, MWS, and NOMID/CINCA) have received Ilaris in clinical trials. The safety of canakinumab compared with placebo was investigated in a pivotal phase III trial that consisted of an 8-week, open-label period (Part I), followed by a 24-week, randomised, double-blind and placebo-controlled withdrawal period (Part II), and a 16-week open label period on canakinumab treatment (Part III). All patients were treated with Ilaris 150 mg subcutaneous or 2 mg/kg if body weight was ≥15 kg and ≤40 kg (see section 5.1 Pharmacodynamic properties > Clinical Trials).

Table 1 Tabulated summary of reported adverse drug reactions from pivotal CAPS clinical trial

	Phase III trial			
	Part I	**Part II**		**Part III**
	Ilaris N=35 n(%)	**Ilaris N=15 n(%)**	**Placebo N=16 n(%)**	**Ilaris N=31 n(%)**
Infections and infestations				
Nasopharyngitis	4 (11.4%)	5 (33.3%)	3 (18.8%)	4 (12.9%)
Urinary tract infection	0	2 (13.3%)	0	1 (3.2%)
Upper respiratory tract infection	1 (2.9%)	1 (6.7%)	1 (6.3%)	1 (3.2%)
Viral infection	3 (8.6%)	2 (13.3%)	3 (18.7%)	1 (3.2%)
General disorders and administration site conditions				
Injection site reaction	3 (8.6%)	2 (13.4%)	1 (6.3%)	1 (3.2%)
Nervous system disorders				
Dizziness/vertigo	3 (8.6%)	0	0	3 (9.7%)

In the long-term, open label studies with dose-escalation, events of infections (gastroenteritis, respiratory tract infection, and upper respiratory tract infection), vomiting and dizziness were more frequently reported in the 600 mg or 8 mg/kg dose group than in other dose groups.

Paediatric Population

There were 80 paediatric patients with an age range from 2 to 17 years in the CAPS studies. Overall, there were no clinically meaningful differences for the safety and tolerability profile of Ilaris in paediatric patients compared to the overall CAPS population (comprised of adult and paediatric patients, N=211) including the overall frequency and severity of infectious episodes. However, the risk of infection in younger children (aged <11 years) is higher than in older children and adolescents. Infections of the upper respiratory tract were the most frequently reported infection events.

Additionally, 6 paediatric patients under the age of 2 years were evaluated in a small open-label clinical study. The safety profile of Ilaris appeared similar to that in patients aged 2 years and above.

Geriatric Population

There is no significant difference in safety profile observed in patients aged 65 years or older.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/

4.9 Overdose

There is limited experience with overdosage. In early clinical trials, patients and healthy volunteers received doses as high as 10mg/kg administered intravenously or subcutaneously without evidence of acute toxicity. In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions or effects and appropriate symptomatic treatment instituted as necessary.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group, ATC

Interleukin inhibitors; ATC code: L04AC08

Mechanism of action

Canakinumab is a human monoclonal anti-human interleukin-1beta (IL-1beta) antibody of the IgG1/kappa isotype. Canakinumab binds with high affinity to human IL-1beta and neutralises the biological activity of human IL-1beta by blocking its interaction with IL-1 receptors, thereby preventing IL-1beta-induced gene activation and the production of inflammatory mediators such as interleukin-6 or cyclooxygenase-2. Canakinumab is therefore suited to treat diseases and pathologies characterised by local or systemic overproduction of IL-1beta.

Pharmacodynamics

Excess production of IL-1beta in inflammatory diseases leads to local or systemic inflammation, increased production of the inflammatory markers C-reactive protein (CRP) or serum amyloid A (SAA), and fever.

Cryopyrin-Associated Periodic Syndromes (CAPS) patients who have uncontrolled overproduction of IL-1beta (manifest as fever, fatigue, skin rash, arthritis, intense leukocytosis, high platelet count, and acute phase protein elevation) show a rapid response to therapy with canakinumab. Following canakinumab treatment, CRP and SAA levels, leukocytosis and high platelet count rapidly returned to normal.

Clinical Trials

The efficacy and safety of canakinumab have been demonstrated in patients with varying degrees of disease severity and different CAPS phenotypes including:

- Familial Cold Autoinflammatory Syndrome (FCAS) /Familial Cold Urticaria (FCU)
- Muckle-Wells Syndrome (MWS) and
- Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA).

In the Phase I/II study, treatment with canakinumab had a rapid onset, with disappearance or clinically significant improvement of symptoms within one day after dosing. Laboratory parameters such as high CRP and SAA, high neutrophils and platelet counts normalised rapidly within days of canakinumab injection.

The pivotal study consisted of a 48-week three-part multicentre study, i.e. a 8-week open-label period (Part I), a 24-week randomised, double-blind, placebo-controlled withdrawal period (Part II), followed by a 16-week open-label period (Part III). The aim of the study was to assess efficacy, safety, and tolerability of canakinumab in patients with CAPS.

- Part I: A complete clinical and biomarker response to canakinumab (defined as composite of: physician's global assessment on autoinflammatory and on skin disease ≤ minimal and CRP or SAA values <10 mg/L) to canakinumab was observed in 97% of patients and appeared within 7 days of initiation of treatment. Significant improvements were seen in physician's clinical assessment of autoinflammatory disease activity: global assessment of autoinflammatory disease activity, assessment of skin disease (urticarial skin rash), arthralgia, myalgia, headache/migraine, conjunctivitis, fatigue/malaise, assessment of other related symptoms and patient's assessment of symptoms.
- Part II: In the withdrawal period of the pivotal study, the primary endpoint was defined as disease relapse/flare: none (0%) of the patients randomized to canakinumab flared, compared with 81% of the patients randomized to placebo.
- Part III: Patients treated with placebo in Part II who entered the open-label extension on canakinumab, again showed a significant clinical and serological improvement of disease activity, comparable to patients continuously treated with canakinumab.

Two open-label, uncontrolled, long-term phase III studies were performed. One was a safety, tolerability, and efficacy study of canakinumab in patients with CAPS. The total treatment duration ranged from 6 months to 2 years. The other was an open-label study with canakinumab to evaluate the efficacy and safety in Japanese CAPS patients for 24 weeks with an extension phase up to 48 weeks. The primary objective was to assess the proportion of patients who were free of relapse at week 24 including those patients whose dose was increased.

In the pooled efficacy analysis for these two studies (n=185), 65.6% of patients who had not previously been treated with canakinumab achieved complete response at 150 mg or 2 mg/kg, while 85.2% of patients achieved complete response at any dose. Of the patients treated with 600 mg or 8 mg/kg (or even higher), 43.8% achieved complete response. Fewer patients aged 2 to <4 years achieved complete response (57.1%) than older pediatric and adult patients. Of the patients who had achieved a complete response, 89.3% maintained response without relapsing.

Experience from individual patients who achieved a complete response following dose escalation to 600 mg (8 mg/kg) every eight weeks suggests that a higher dose may be beneficial in patients not achieving complete response or not maintaining complete response with the recommended doses (150 mg or 2 mg/kg for patients ≥15 kg and ≤40 kg). An increased dose was administered more frequently to patients aged 2 to <4 years and patients with NOMID/CINCA symptoms compared with FCAS or MWS.

The CAPS trials with canakinumab included a total of 80 paediatric patients with an age range from 2 to 17 years. Overall, there were no clinically meaningful differences for the efficacy, safety and tolerability profile of canakinumab in paediatric patients compared to the overall CAPS population (comprised of adult and paediatric patients, N=211). The majority of paediatric patients achieved improvement in clinical symptoms and objective markers of inflammation (e.g. SAA and CRP).

A 56 week, open-label study was conducted to assess the efficacy, safety and tolerability of ILARIS in paediatric CAPS patients ≤ 4 years of age. Seventeen patients (including 6 patients under the age of 2 years) were evaluated, using weight-based starting doses of 2-8mg/kg. The study also evaluated the effect of canakinumab on the development of antibodies to standard childhood vaccines. No differences in safety or efficacy were observed in patients under the age of 2 years compared with patients aged 2 years and above. All patients who received non-live, standard of care childhood vaccinations (N=7) developed protective levels of antibody.

5.2 Pharmacokinetic properties

The peak serum canakinumab concentration (C_{max}) occurred approximately 7 days following single subcutaneous administration of 150 mg in adult CAPS patients. The mean terminal half-life was 26 days. Based on a population pharmacokinetic analysis in the CAPS population including children from 2 years of age, the absolute bioavailability of subcutaneous administration of canakinumab was estimated to be 66%. The clearance (CL) and distribution volume (Vss) of canakinumab varied according to body weight and were estimated to be0.17 L/day and6.2 L, respectively, in a typical CAPS patient of body weight 70 kg. The expected accumulation ratio was 1.3-fold following 6 months of subcutaneous administration of 150 mg canakinumab every 8 weeks (see section 4.2 Dosage and method of administration). Exposure parameters (such as AUC and C_{max}) increased in proportion to dose over the dose range of 0.30 to 10.0 mg/kg given as intravenous infusion or from 150 to 600 mg

as subcutaneous injection. There was no indication of accelerated clearance or time-dependent change in the pharmacokinetic properties of canakinumab following repeated administration. No gender or age-related pharmacokinetic differences were observed after correction for body weight.

Paediatric population:

Peak concentrations of canakinumab occurred between 2 to 7 days following single subcutaneous administration of canakinumab 150 mg or 2 mg/kg in paediatric patients 4 years of age and older. The terminal half-life ranged from 22.9 to 25.7 days, similar to the pharmacokinetic properties observed in adults. Based on the population PK modelling analysis, the pharmacokinetics of canakinumab in children 2 to <4 years of age were similar to patients 4 years of age and older. An additional pharmacokinetics analysis showed that the pharmacokinetics of canakinumab in 6 paediatric CAPS patients under the age of 2 years were similar to the pharmacokinetics in patients aged 2 years and above.

Geriatric population:

No change in pharmacokinetic parameters based on clearance or volumes of distribution were observed between geriatric patients and adult patients below 65 years of age.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on cross-reactivity, repeated dose, immunotoxicity, reproductive and juvenile toxicity studies performed with canakinumab or a murine anti-murine IL-1 beta antibody.

Carcinogenicity

Carcinogenicity studies have not been conducted with canakinumab.

Immunogenicity

No anaphylactic reactions were observed in patients treated with Ilaris.

Antibodies against ILARIS were observed in approximately 1.5% of the patients treated with ILARIS for CAPS.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Powder for solution for injection: Sucrose, histidine, histidine hydrochloride monohydrate, polysorbate 80, dilute hydrochloric acid.

Solution for injection: Mannitol, L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80, water for injection.

6.2 Incompatibilities

Incompatibilities were either not assessed or not identified as part of the registration of this medicine. In the absence of compatibility studies, this medicines must not be mixed with other medicines.

6.3 Shelf life

36 months from date of manufacture when stored at 2° to 8°C (refrigerate).

After reconstitution, if not used within 60 minutes of reconstitution, the solution should be stored in the refrigerator (2°C to 8°C) and used within 24 hours.

6.4 Special precautions for storage

Do not freeze. Protect from light.

For storage conditions after reconstitution of the medicine, see section 6.3 Shelf life.

6.5 Nature and contents of container

Powder for solution for injection:

- A pack containing 1 or 4 single-use vials of 150 mg sterile, lyophilised powder.

Solution for injection:

- A pack containing 1 vial of 150 mg/mL solution for injection.

Not all presentations may be available.

6.6 Special precautions for handling and disposal

Instructions for Use and Handling (powder for solution for injection)

Vials

Reconstitute each vial of Ilaris by slowly injecting 1.0 mL water for injections with a 1 mL syringe and a 18 G x 2" needle. Swirl the vial slowly at an angle of about 45° for approximately 1 minute and allow to stand for 5 minutes. Then gently turn the vial upside down and back again ten times. If possible, avoid touching the rubber stopper with your fingers. Allow to stand for about 15 minutes at room temperature. Do not shake. Do not use if particles are present in the solution.

Tap the side of the vial to remove any residual liquid from the stopper. The solution should be essentially free of visible particles and clear to opalescent. The solution should be colourless or may have a slight brownish-yellow tint. If not used within 60 minutes of reconstitution, the solution should be stored in the refrigerator (2°C to 8°C) and used within 24 hours.

Carefully withdraw the required volume depending on the dose to be administered and subcutaneously inject using a 27 G x 0.5" needle.

Injection into scar-tissue should be avoided as this may result to insufficient exposure to Ilaris.

Ilaris 150 mg/mL powder for injection is supplied in a single-use vial. Ilaris 150mg/mL powder for injection is for single use in one patient only. Any unused product or waste material should be disposed of in accordance with local requirements.

Instructions for Use and Handling (solution for injection)

Ilaris 150 mg/1 mL solution for injection is supplied in a single-use vial for individual use. Any unused product or waste material should be disposed of in accordance with local requirements.

Bring the vial to room temperature. The solution should be practically free of visible particles and clear to opalescent. The solution should be colourless or may have a slight brownish-yellow tint. Do not use if particles are present in the solution.

Carefully withdraw the required volume depending on the dose to be administered using an appropriate size needle and a 1 ml syringe and subcutaneously inject using a 27 G x 0.5" needle. Once the vial is pierced, use the solution immediately.

Injection into scar-tissue should be avoided as this may result in insufficient exposure to Ilaris.

7 MEDICINE SCHEDULE

Prescription Medicine

8 SPONSOR

Novartis New Zealand Limited
PO Box 99102
Newmarket
Auckland 1149

Telephone: 0800 354 335
® = Registered Trademark

9 DATE OF FIRST APPROVAL

28 April 2011

10 DATE OF REVISION OF THE TEXT

3 February 2023

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
6.5, 6.6	Removal of deregistered convenience kit

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