Actemra® Intravenous (IV) Infusion

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.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using Actemra?

Actemra contains the active ingredient tocilizumab. Actemra IV is used to treat certain types of rheumatoid arthritis (RA), COVID-19 in some patients who are in hospital, patients with some types of cytokine release syndrome (CRS), children with active systemic juvenile idiopathic arthritis (sJIA) and active moderate to severe polyarticular juvenile idiopathic arthritis (pJIA).

For more information, see Section 1. Why am I using Actemra? in the full CMI.

2. What should I know before I use Actemra?

Do not use if you have ever had an allergic reaction to Actemra 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 Actemra? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Actemra or it may interfere with other medicines. 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 Actemra?

- You will receive Actemra as an infusion into a vein (intravenous infusion), usually over one hour.
- The dose of Actemra is dependent on your weight and the timing of your infusions depends on what you are being treated for.

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

5. What should I know while using Actemra?

Things you should do	• Tell your doctor immediately or go to accident and emergency if you develop symptoms of an allergic reaction. • Tell your doctor immediately if you develop an infection or have symptoms of an infection while you are being treated with Actemra. • Tell your doctor if you become pregnant or if you are breast-feeding while taking Actemra • If you are a woman of childbearing potential, you should use adequate contraception during and for several months after treatment with Actemra.
Driving or using machines	• Be careful driving or operating machinery until you know how Actemra affects you.

Looking after your medicine	• As your healthcare professional will administer this to you, the medicine will be stored at the place you receive your medicine

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

6. Are there any side effects?

Serious side effects include the following: **Allergic reactions** such as chest tightness, wheezing, difficulty breathing, severe dizziness or light-headedness, swelling of the face, lips, tongue, throat with difficulty breathing, skin rash, itching or hives (raised red patches of skin that are often very itchy), **signs of an infection with or without fever**, **signs of tears of the stomach or intestines**, **liver disease, hepatitis and/or jaundice, signs of pancreatitis.**

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.

▼ This medicine is subject to additional monitoring due to the approval of an extension of indications. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Actemra (pronounced Act-tem-ra)

Active ingredient: *tocilizumab (rch)*

This medicine has **provisional approval** in Australia for the treatment of coronavirus disease 2019 (COVID-19) in adults who have been hospitalised and are receiving corticosteroids and require a machine that helps with their breathing (ventilator). This approval has been granted based on short term effectiveness and safety evidence. Longer-term evidence from ongoing trials continues to be gathered and assessed.

Consumer Medicine Information (CMI)

This leaflet provides important information about using Actemra. **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 Actemra.**

Where to find information in this leaflet:

1. Why am I using Actemra?

Actemra contains the active ingredient tocilizumab.

Actemra belongs to a group of medicines called monoclonal antibodies.

Monoclonal antibodies are proteins which specifically recognise and bind to other unique proteins in the body.

Actemra is used to treat active moderate to severe rheumatoid arthritis (RA).

Actemra has **provisional approval** to be used for the treatment of coronavirus disease 2019 (COVID-19) in adults who have been hospitalised and are receiving corticosteroids and require supplemental oxygen or a machine that helps with their breathing (ventilator).

Actemra is used to treat adults and children 2 years of age and older with severe or life-threatening cytokine release syndrome (CRS), a side-effect in patients treated with chimeric antigen receptor (CAR) T-cell therapies used to treat certain types of cancer.

Actemra is also used to treat active systemic juvenile idiopathic arthritis (sJIA) and active moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) in children

over 2 years of age. Some of the signs and symptoms of RA, pJIA and sJIA are caused by the actions of a protein called interleukin-6 receptor (IL-6R).

Actemra works by binding and blocking IL-6R thereby helping to relieve some of the signs and symptoms of RA, pJIA, sJIA, CRS and COVID-19. For RA, Actemra can also prevent damage occurring to your joints.

There are many different types of medicines used to treat RA, pJIA and sJIA. Your doctor, however, may have prescribed Actemra for another purpose.

Ask your doctor if you have any questions about why Actemra has been prescribed for you.

Actemra is not addictive.

This medicine is available only with a doctor's prescription. For pJIA and sJIA Actemra should be prescribed by a doctor experienced in the management of these conditions.

2. What should I know before I use Actemra?

Warnings

Do not use Actemra if:

1. **you are allergic to:**

Actemra, any of the ingredients listed at the end of this leaflet, or any other recombinant human or humanised antibodies or proteins that are of hamster origin

Always check the ingredients to make sure you can use this medicine.

- Symptoms of an allergic reaction may include:
  - chest tightness, wheezing or difficulty breathing
  - severe dizziness or light-headedness
  - swelling of the face, lips, tongue, throat or other parts of the body with difficulty breathing
  - skin rash, itching or hives (raised red
  - patches of skin that are often very itchy)

or

2. **you have an active, severe infection**

Actemra can reduce your body's ability to respond to infections and may make an existing infection worse or increase the chance of getting a new infection. This may be important if you have diabetes or diverticulitis (which increase your risk of infection).

If Actemra is being used to treat COVID-19, Actemra should not be given if you have a serious active infection other than COVID-19.

Tell your doctor if you think you have an infection or have symptoms of an infection. Signs of an infection, with or without fever include:

- sweating or chills,
- feeling very tired

- cough
- shortness of breath
- muscle aches
- weight loss
- warm, red, or painful skin or sores on your body
- blood in phlegm
- diarrhoea or stomach ache
- persistent headaches
- burning when you urinate or urinating more often than normal.

Check with your doctor if:

- **you have any other health problems, especially the following**:
  - liver disease such as viral hepatitis or other liver problems

    Your doctor will monitor your liver function closely before and during your treatment with Actemra.
- HIV or AIDs
- tuberculosis
- diverticulitis or ulcers in your intestine
- a low white blood cell count (white blood cells that help the body fight off infections)
- a low platelet count (blood cells that help with blood clotting and stop bleeding)
- diabetes
- cancer
- heart problems

- raised blood pressure
- high cholesterol or triglycerides
- kidney disease
- have a condition which affects your nervous system, such as multiple sclerosis or
- neuropathy

  MAS is a complication of sJIA. If you have a history of MAS your doctor will decide if you can still be given Actemra.

- **you are planning to have a vaccination or have recently had a vaccination**

  Certain types of vaccines should not be given while receiving Actemra. It is particularly recommended that sJIA patients receive all necessary vaccinations prior to receiving Actemra.

- **you are on a controlled sodium diet**

  Actemra contains a small amount of sodium.

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

- **Tell your doctor if you are pregnant or intend to become pregnant.**

  Women of childbearing potential should be advised to use adequate contraception during and for several months after treatment with Actemra. Actemra should not be used during pregnancy as Actemra may harm

your unborn baby. However if there is a need to take Actemra when you are pregnant, your doctor will discuss the benefits and risks to you and the unborn baby.

- **Tell your doctor if you are breast-feeding or plan to breast-feed**

  It is not known whether Actemra passes into breast milk. It is recommended that you discontinue breast-feeding while you are treated with Actemra.

Use in Children

- Actemra given as an intravenous injection in patients below 18 years of age with conditions other than pJIA, sJIA and CRS has not been studied. There is only limited data available for Actemra use in children with pJIA who are under 4 years of age. The use of Actemra in children under the age of 2 has not been studied.

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.

These medicines **increase your risk of side effects** with Actemra:

- **other biological medicines for RA**. e.g. infliximab, adalimumab, etanercept, certolizumab pegol, golimumab anakinra, abatacept, rituximab.

  It is unknown how Actemra interacts with these medicines. You may have an increased risk of infection. You should not use Actemra with other biological medicines for RA.

- **vaccines**

  Certain types of vaccines should not be given while receiving Actemra. You may have an increased risk of infection.

Actemra may **reduce the amount of some medicines that require close monitoring** to ensure drug levels are maintained. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you. E.g.:

- warfarin, a medicine used to prevent blood clots
- cyclosporin, a medicine used after organ transplants
- atorvastatin and simvastatin, medicines used to reduce cholesterol levels
- calcium channel blockers, such as amlodipine, which are used to treat raised blood pressure
- theophylline, a medicine used to treat asthma
- phenytoin, a medicine used to treat convulsions
- benzodiazepines, such as diazepam, which are used to treat anxiety

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

4. How do I use Actemra?

How will I receive Actemra

Actemra is given by infusion into a vein (intravenous infusion). It will go slowly into your bloodstream through a needle. This will be done by your doctor or nurse.

The infusion usually takes one hour. For pJIA, sJIA, CRS and COVID-19, Actemra should be given in a hospital setting.

How much Actemra is given

The dose of Actemra is dependent on your weight. Your doctor will prescribe an amount of Actemra that is right for you.

For RA and COVID-19, the normal dose of Actemra is 8 milligrams for every 1 kilogram you weigh.

For pJIA the normal dose of Actemra is 8 milligrams for every 1 kilogram you weigh if you weigh 30 kg or more, or 10 milligrams for every 1 kilogram you weigh if you weigh less than 30 kg.

For sJIA the normal dose of Actemra is 8 milligrams for every 1 kilogram you weigh if you weigh 30 kg or more, or 12 milligrams for every 1 kilogram you weigh if you weigh less than 30 kg.

For CRS the normal dose of Actemra is 8 milligrams for every 1 kilogram you weigh if you weigh 30 kg or more, or 12 milligrams for every 1 kilogram you weigh if you weigh less than 30 kg.

When you will be given Actemra

For RA and pJIA you will be treated with Actemra once every 4 weeks.

For sJIA you will be treated with Actemra once every 2 weeks.

The number of infusions you will receive depends on how you are responding to treatment. Your doctor will discuss this with you.

Continue receiving Actemra until your doctor tells you to stop.

For CRS and COVID-19 you will receive a single dose of Actemra, and if needed additional doses.

If you forget to receive Actemra

Contact your doctor or nurse to schedule another infusion as soon as possible. Do not wait for your next scheduled infusion.

Your doctor or nurse will decide when you should be given your next dose of Actemra.

If you are given too much Actemra

If you think that you have had too much Actemra, you may need urgent medical care. **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 Actemra?

Things you should do

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if:

you experience symptoms of a **serious allergic reaction** during or after receiving Actemra such as;

- chest tightness, wheezing or difficulty breathing
- severe dizziness or light-headedness
- swelling of the face, lips, tongue, throat or other parts of the body with difficulty breathing
- skin rash, itching or hives (raised red patches of skin that are often very itchy).

Your doctor or nurse will monitor you for 30 minutes afteryour Actemra infusion, to check for any signs or symptoms of an allergic reaction.

Tell your doctor immediately if:

1. You develop an infection or have symptoms of an **infection** while you are being treated with Actemra. **Signs of an infection**, with or without fever include:

- sweating or chills,
- feeling very tired
- cough
- shortness of breath
- muscle aches
- weight loss
- warm, red, or painful skin or sores on your body
- blood in phlegm
- diarrhoea or stomach ache
- persistent headaches
- burning when you urinate or urinating more often than normal.

2. you develop **severe blisters and bleeding in the lips, eyes, mouth, nose and genitals** while you are being treated with Actemra.

Skin cancer monitoring:

if you are at increased risk for skin cancer:

- Regular skin examination is recommended if you are at increased risk for skin cancer.

- Exposure to sunlight and UV light should be limited by wearing protective clothing and using sunscreen with a high protection factor.
- Immunosuppressive medication (a medicine that reduces the activity of your immune system), such as Actemra, have an increased risk of developing skin cancer (melanoma and non-melanoma).

Tell all doctors, dentists and pharmacists who are treating you that you are receiving Actemra.

Tell your doctor if you become pregnant while taking Actemra.

Tell your doctor if you are breast-feeding while being treated with Actemra.

Tell your doctor if you feel Actemra is not helping your condition.

Be sure to keep all of your appointments and get follow-up blood tests done as ordered by **your doctor so that your progress can be checked.**

Blood tests/monitoring:

- Liver enzymes:
  - If you have rheumatoid arthritis (RA) or giant cell arteritis (GCA), your doctor should do blood tests every 4 to 8 weeks for the first 6 months of treatment followed by every 12 weeks. Your doctor will then decide on the frequency.
  - If you have polyarticular juvenile idiopathic arthritis (pJIA) or systemic juvenile idiopathic arthritis (sJIA), your doctor should do blood test at the time of

second administration and every 4 to 8 weeks for pJIA and 2 to 4 weeks for sJIA.
    - If you are hospitalised with COVID-19, your doctor will determine the frequency of testing.
- Blood count:
    - If you have rheumatoid arthritis (RA) or giant cell arteritis (GCA), your doctor should do blood tests every 4 to 8 weeks after the start of therapy. Your doctor will then decide on the frequency.
    - If you have polyarticular juvenile idiopathic arthritis (pJIA) or systemic juvenile idiopathic arthritis (sJIA), your doctor should do blood tests at the time of second administration and every 4 to 8 weeks for pJIA and 2 to 4 weeks for sJIA.
    - If you are hospitalised with COVID-19, your doctor should do blood test levels according to the current clinical guidelines.
- Cholesterol:
    - If you have RA and sJIA, your doctor will decide on the frequency of testing.
    - If you have pJIA, your cholesterol levels should be tested every 3 months while on Actemra.

Remind any doctor, dentist or pharmacist you visit that you are using Actemra.

Driving or using machines

Be careful driving or operating machinery until you know how Actemra affects you.

Actemra has not been shown to impair the ability to drive or operate machinery. However if you experience dizziness, a reported side effect, then you should not drive or operate machinery until it has resolved.

Looking after your medicine

As a healthcare professional will administer Actemra Infusion to you, the medicine will be stored in the place you receive the medicine.

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.

Less serious side effects

Less serious side effects	What to do
Blood pressure related: • high blood pressure or hypertension (symptoms may include headache, dizziness, ringing in the ears) **Stomach related:**	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• constipation **General:** • anxiety • difficulty sleeping • low potassium levels shown by blood tests	

Serious side effects

Serious side effects	What to do
Allergic reaction related: • chest tightness, wheezing or difficulty breathing, • severe dizziness or light-headedness • swelling of the face, lips, tongue, throat or other parts of your body with difficulty breathing • skin rash, itching or (raised red • patches of skin that are often very itchy). • severe blisters and bleeding in the lips,	**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.** **Call your doctor straight away** if you notice any of these serious side effects. **Call your doctor straight away** if you notice any of these serious side effects.

Serious side effects	What to do
eyes, mouth, nose and genitals. **Infections:** • signs of an infection, with or without fever: sweating or chills, feeling very tired, cough, shortness of breath, muscle aches, weight loss, warm, red, or painful skin or sores on your body, blood in phlegm, diarrhoea or stomach ache, persistent headaches, burning when you urinate or urinating more often than normal. **Stomach and gut:** • signs of tears (perforation) of the stomach or intestines such as fever and pain in the stomach area that does not go away, vomiting blood or material that looks like coffee grounds, bleeding from your rectum, and	**Call your doctor straight away** if you notice any of these serious side effects. **Make sure you get all your follow-up blood tests done as ordered by your doctor.**

Serious side effects	What to do
a change in your bowel habits • signs of inflamed pancreas (pancreatitis) including: upper stomach pain, abdominal pain that may spread to the back, generally feeling unwell/ sick **Liver:** • signs of liver disease, hepatitis and/or jaundice including: nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine. **Laboratory tests:** • low white blood cell and platelet counts. • increase in certain liver function tests. • raised blood fat (cholesterol) levels.	

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 Actemra contains

Active ingredient **(main ingredient)**	tocilizumab (rch)
Other ingredients **(inactive ingredients)**	• polysorbate 80 • sucrose

	• dibasic sodium phosphate dodecahydrate • monobasic sodium phosphate dihydrate • water for injections

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

What Actemra looks like

Actemra is a clear to opalescent, colourless to pale yellow liquid for intravenous infusion.

Australian Registration Numbers:

80 mg/4 mL AUST R 149403

200 mg/10 mL AUST R 149404

400 mg/20 mL AUST R 149402

Who distributes Actemra

Roche Products Pty Limited
ABN 70 000 132 865
Level 8, 30-34 Hickson Road

Sydney NSW Australia

How to contact us

You can contact us at www.medinfo.roche.com/australia or by scanning the below code:

You can also call us on 1800 233 950.

This leaflet is for people in Australia only. If you are not in Australia, you can contact Roche/Genentech in your country at www.medinfo.roche.com.

This leaflet was prepared in August 2022.