Actemra® Infusion

pronounced (Act-tem-ra)

contains the active ingredient tocilizumab (rch)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Actemra infusion.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Actemra against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Actemra is used for

Actemra contains the active ingredient tocilizumab.

Actemra belongs to a group of medicines called anti-rheumatic agents. There are many different classes of anti-rheumatic agents. Actemra belongs to a class 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 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 and CRS. 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.

Before you are given Actemra

When you must not be given Actemra

Do not use Actemra if:

1. **you have had an allergic reaction to Actemra or any ingredients listed at the end of this leaflet**

   Some of the 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
   - rash, itching or hives on the skin

2. **you have had an allergic reaction to any other recombinant human or humanised antibodies or proteins that are of hamster origin**
3. **you have an active, severe infection**
4. **the package is torn or shows signs of tampering**
5. **the expiry date (EXP) printed on the pack has passed.**

   If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should be given Actemra, talk to your doctor.

Before you are given Actemra

Tell your doctor if:

1. **you have or develop any kind of 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).

   Your doctor will perform blood tests before you are given Actemra to determine if you have low white blood cell or platelet counts, or high liver enzymes.

2. **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 intestinal ulcers
- a low white blood cell count or a low platelet count
- diabetes
- cancer
- heart problems
- raised blood pressure
- high cholesterol or triglycerides
- kidney disease
- nerve disease such as neuropathy

3. **you have a history of macrophage activation syndrome (MAS)**

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

4. **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.

5. **you are pregnant or plan to become pregnant**

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

6. **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.

7. **you are on a controlled sodium diet**

   Actemra contains a small amount of sodium.

8. **you are allergic to any other medicines, foods, dyes or preservatives**

If you have not told your doctor about any of the above, tell him or her before you start taking 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.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you have bought from a pharmacy, supermarket or health food shop.

Do not use Actemra with other biological medicines including infliximab, adalimumab, etanercept, anakinra, abatacept, rituximab, certolizumab pegol and golimumab. It is unknown how Actemra interacts with these medicines.

Actemra may interfere with some medicines. These include:

- warfarin, a medicine used to prevent blood clots
- cyclosporin, a medicine used after organ transplants
- some vaccines
- 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

These medicines may be affected by Actemra, or may affect how well the medicine works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Actemra.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How Actemra is given

How Actemra is given

Actemra is given by infusion into a vein (intravenous infusion) by a health care professional.

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

For RA and pJIA Actemra is usually given in combination with methotrexate (MTX). However you may receive Actemra on its own if your doctor determines that initial treatment with MTX is inappropriate or unsuccessful.

For sJIA Actemra can be given on its own or in combination with MTX.

For CRS Actemra can be given alone or in combination with corticosteroids.

How much is given

For RA the normal dose of Actemra is 8 mg per kilogram (kg) of your body weight. Your doctor will prescribe an amount of Actemra that is right for you.

For pJIA the normal dose of Actemra is 8 mg per kg of your body weight if you weigh 30 kg or more, or 10 mg per kg of your body weight if you weigh less than 30 kg. Your doctor will prescribe amount of Actemra that is right for you.

For sJIA the normal dose of Actemra is 8 mg per kg of your body weight if you weigh 30 kg or more, or 12 mg per kg of your body weight if you weigh less than 30 kg. Your doctor will prescribe an amount of Actemra that is right for you.

For CRS the normal dose of Actemra is 8 mg per kg of your body weight if you weigh 30 kg or more, or 12 mg per kg of your body weight if you weigh less than 30 kg. Your doctor will prescribe an amount of Actemra that is right for you.

How long is Actemra given

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.

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

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.

If you miss a dose

As Actemra is given to you under the supervision of your doctor, you are unlikely to miss a dose. However, if you do then your doctor will decide when you should be given your next dose of Actemra.

Overdose

As Actemra is given to you under the supervision of your doctor it is unlikely that you will be given too much. However, if you experience any side effects after being given Actemra, tell your doctor immediately.

While you are receiving Actemra

Things you must do

When using Actemra, there is a risk of serious allergic reaction which needs immediate medical attention. 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**
- **rash, itching or hives on the skin.**

Tell your doctor immediately if 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
- diarrohea or stomach ache
- persistent headaches
- burning when you urinate or urinating more often than normal.

Tell your doctor immediately if you develop severe blisters and bleeding in the lips, eyes, mouth, nose and genitals while you are being treated with Actemra.

When using immunosuppressive medication (lowers resistance to disease): such as Actemra, there is an increased risk of developing skin cancer (melanoma and non-melanoma). 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.

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 with your doctor so that your progress can be checked.

Your doctor will perform blood tests at regular intervals during your treatment to determine if you have low white blood cell or platelet counts, or high liver enzymes or cholesterol.

For pJIA your doctor will check your cholesterol at 3 monthly intervals.

Things you must not do

You should not breast-feed your infant during treatment with Actemra.

It is not known whether Actemra crosses into human milk.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Things to be careful of

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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving Actemra.

Actemra helps many patients with RA, pJIA, sJIA and CRS but it may have unwanted side effects.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- 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
- rash, itching or hives on the skin
- signs of an infection, with or without fever
- 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 a change in your bowel habits
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals.
- 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.

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor if you notice any of the following and they worry you:

- high blood pressure (symptoms may include headache, dizziness, ringing in the ears)
- headache
- upper respiratory tract infection such as a common cold or sinus infection (cough, blocked or runny nose, sore throat)
- dizziness
- nausea or indigestion
- stomach pain
- constipation
- diarrhoea
- back pain
- cold sores
- mouth or skin blisters
- mouth ulcers
- skin infection (redness, pain and/or swelling)
- low white blood cell and platelet counts shown by blood tests
- raised blood fat (cholesterol) levels

These are the more common side effects of Actemra. Mostly these are mild.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After receiving Actemra

Storage

Actemra should be stored in the pharmacy or on the hospital ward.

The concentrated solution for infusion should be kept in a refrigerator at 2°C to 8°C. It should not be frozen.

Actemra should be stored away from light.

Product description

Availability

Actemra is available as 80 mg/4 mL, 200 mg/10 mL and 400 mg/20 mL single dose vials

Actemra comes in packs of 1 vial for each of the 80 mg, 200 mg or 400 mg presentations.

Actemra is also available as a solution for subcutaneous injection.

What Actemra looks like

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

Ingredients

Active ingredient - tocilizumab (rch)

Inactive ingredients

- polysorbate 80
- sucrose
- dibasic sodium phosphate dodecahydrate
- monobasic sodium phosphate dihydrate
- water for injections

Distributor

Actemra is distributed in Australia by:

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

Sydney NSW Australia

Medical enquiries: 1800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Numbers

- 80 mg/4 mL AUST R 149403
- 200 mg/10 mL AUST R 149404
- 400 mg/20 mL AUST R 149402

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