

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 moderate to severe rheumatoid arthritis (RA).

ACTEMRA is also used to treat active systemic juvenile idiopathic arthritis (sJIA) in children over 2 years of age.

Some of the signs and symptoms of RA and sJIA are caused by the actions of a

protein called interleukin-6 receptor (IL-6R).

For RA ACTEMRA can also prevent damage occurring to your joints and improve your ability to do your normal daily activities.

ACTEMRA works by binding and blocking IL-6R thereby helping to relieve some of the signs and symptoms of RA or sJIA.

There are many different types of medicines used to treat RA 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.

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:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

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).

2. you have any other health problems, especially the following:

- liver disease such as viral hepatitis
- tuberculosis
- diverticulitis or intestinal ulcers
- a low white blood cell count or a low platelet count
- diabetes
- cancer
- raised blood pressure
- high cholesterol or triglycerides
- kidney disease

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

The safety and efficacy of ACTEMRA in patients below 18 years of age with conditions other than sJIA have not been established. 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 used to treat RA or sJIA, including *infliximab*, *adalimumab*, *etanercept*, *anakinra*, *abatacept* and *rituximab*. 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
- 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

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

The infusion usually takes one hour.

For RA ACTEMRA is usually given in combination with methotrexate (MTX) or other arthritis medications. However you may receive ACTEMRA on its own if your doctor determines that MTX is inappropriate.

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

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 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.

How long is ACTEMRA given

For RA 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.

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

Tell your doctor immediately if you experience allergic reactions such as chest tightness, wheezing, severe dizziness or light-headedness, swelling of the lips or skin rash during or after receiving ACTEMRA.

Tell your doctor immediately if you develop an infection while you are being treated with ACTEMRA.

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 may test your blood to help guide your treatment.

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.

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 or sJIA 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 if you notice any of the following and they worry you:

- fever and chills
- high blood pressure (symptoms may include headache, dizziness, ringing in the ears)
- rashes or itching
- headache
- cough
- blocked or runny nose
- sore throat
- dizziness
- nausea or indigestion
- stomach pain
- constipation
- diarrhoea

- cold sores
- mouth or skin blisters
- mouth ulcers
- skin infection (redness, pain and/or swelling)

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

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

- difficulty breathing, chest tightness or wheezing
- severe light-headedness
- severe skin rash, itching, hives
- swelling of the face, lips, mouth
- signs of serious infection such as fever and chills, stomach ache or persistent headaches
- bleeding from the stomach or intestines. Signs and symptoms may include severe stomach pain, vomiting blood or material that looks like coffee grounds, bleeding from your rectum, black sticky motions, bloody diarrhoea.

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

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 - 8°C. It should not be frozen.

ACTEMRA should be stored away from light.

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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.

(*not available in New Zealand)

Australian Registration Numbers

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

This leaflet was prepared on 17 January 2012.

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:

Actemra® CMI 120117
PI 111219