

Actemra[®] Pre-filled Pen (ACTPen)

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 pre-filled pen for subcutaneous (under the skin) injection.

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 for subcutaneous injection is used to treat active moderate to

severe rheumatoid arthritis (RA) and giant cell arteritis (GCA) in adults.

Some of the signs and symptoms of RA, GCA and pJIA 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 these conditions. For patients with RA, Actemra can also prevent damage occurring to your joints.

There are different types of medicines used to treat RA, GCA and pJIA. 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 use Actemra

When you must not use 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 use Actemra, talk to your doctor.

Before you use 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
- 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 are planning to have a vaccination or have recently had a vaccination

Certain types of vaccines should not be given while using Actemra.

4. 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.

5. 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.

6. 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 given as a subcutaneous injection to patients below 18 years of with conditions other than pJIA has not been established. Actemra given as subcutaneous injection in pJIA 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 to use Actemra

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Use Actemra exactly as your doctor has prescribed.

How much to inject

Adult patients with RA and GCA

The recommended dose of Actemra to treat RA and GCA is 162 mg injected once a week. For GCA, your doctor may prescribe a lower dose of 162 mg every 2 weeks.

Actemra must be used on the same day each week. Choose the day of the week that best fits your schedule,

The pen is designed to deliver 162 mg per injection when used according to the instructions in this leaflet.

Your doctor will test your blood to help guide your treatment. If you experience certain changes in your blood tests, your doctor may decide to reduce the frequency of dosing to 162 mg every 2 weeks.

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

For GCA, Actemra is initially given in combination with a glucocorticoid medicine (such as prednisone). Over the period of treatment, depending on your response to Actemra, your doctor will adjust the dose of the glucocorticoid with the aim to reduce it over time

Children and adolescents with pJIA (aged 2 and over)

The usual dose of Actemra depends on the patient's weight.

- If the patient weighs less than 30 kg: the dose is 162 mg (the contents of 1 pre-filled pen), once every 3 weeks
- If the patient weighs 30 kg or more: the dose is 162 mg (the content of 1 pre-filled pen), once every 2 weeks

The increasing body weight of a child initially under 30kg should be checked regularly. This is because there is a risk of underdose for this medicine if the frequency of administration does not increase from every 3 weeks to every 2 weeks as the child grows from under to over 30 kg body weight

How to inject Actemra

Actemra is administered by subcutaneous injection. This means it is injected with a short needle into the fatty tissue just under the skin.

Serious allergic reactions can occur with Actemra injections.

At least the first injection of Actemra will be given under the supervision of your healthcare provider in a healthcare facility that can manage these reactions. After your first injection, your doctor may discuss with you whether it would be appropriate for you to inject the next Actemra injection yourself at home, in which case, you or a caregiver would be instructed on how to give the injection and what to do if you experience symptoms of an allergic reaction.

Directions for self-injection

You should read these directions from beginning to end before starting to inject so that you are familiar with each step of the procedure. These instructions must be carefully followed. Consult with your healthcare provider if you require further instructions. These instructions do not replace the instructions from your healthcare provider.

Your healthcare provider should show you how to prepare and inject properly before you inject for the first time. Ask them any questions you may have.

Do not attempt to administer an injection until you are sure that you understand how to self-inject.

It is important to remain under your doctor's care while using Actemra. It is recommended you have someone else present when you self-inject Actemra in case you experience any symptoms of a serious allergic reaction described under 'While you are using Actemra, Things you must do'.

The pen is for single use only and should be safely discarded after use.

How to inject using the pen

The ACTpen components:

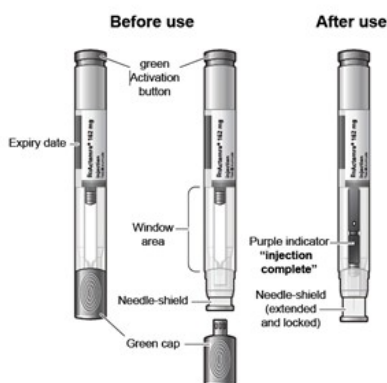


Figure A

Do not remove the pre-filled pen cap until you are ready to inject Actemra.

Do not try to take apart the pre-filled pen at any time.

Do not reuse the same pre-filled pen.

Do not use the pre-filled pen through clothing.

Do not leave the pre-filled pen unattended.

Keep out of the reach of children.

Gather what you will need:

Included in the pack:

- Pre-filled pen

Not included in the pack:

- Alcohol pad
- Sterile cotton ball or gauze
- Puncture-resistant container (also called a "sharps" container) for safe disposal of the pre-filled pen cap and used pre-filled pen.



Figure B

STEP 1. Preparing for a Actemra Injection

Find a comfortable space with a clean, flat, working surface.

Take the box containing the pre-filled pen out of the refrigerator.

If you are opening the box for the first time, check to make sure that it is properly sealed. Do not use the pre-filled pen if the box looks like it has already been opened.

Check that the pre-filled pen box is not damaged. Do not use pre-filled pen if the box looks damaged.

Check the expiration date on the pre-filled pen box.

Do not use the pre-filled pen if the expiration date has passed because it may not be safe to use.

Open the box, and remove 1 single-use pre-filled pen from the box.

Return any remaining pre-filled pens in the box to the refrigerator.

Check the expiration date on the pre-filled pen (See Figure A).

Do not use it if the expiration date has passed because it may not be safe to use. If the expiration date has passed, safely dispose of the pre-filled pen in a sharps container and get a new one.

Check the pre-filled pen to make sure it is not damaged.

Do not use the pre-filled pen if it appears to be damaged or if you have accidentally dropped the pre-filled pen.

Place the pre-filled pen on a clean, flat surface and let the pre-filled pen warm up for 45 minutes to allow it to reach room temperature. If the pre-filled pen does not reach room temperature, this could cause your injection to feel uncomfortable and it could take longer to inject.

Do not speed up the warming process in any way, such as using the microwave or placing the pre-filled pen in warm water.

Do not leave the pre-filled pen to warm up in direct sunlight.

Do not remove the green cap while allowing your Actemra pre-filled pen to reach room temperature.

Hold your pre-filled pen with the green cap pointing down (See Figure C).

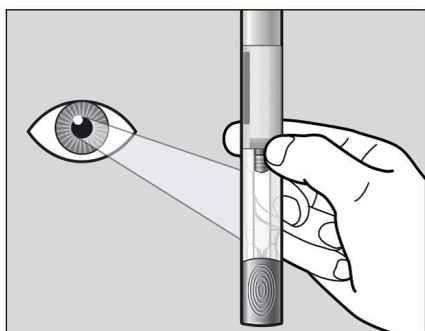


Figure C

Look in the clear Window area. Check the liquid in the pre-filled pen (See Figure C). It should be clear and colourless to pale yellow.

Do not inject Actemra if the liquid is cloudy, discoloured, or has lumps or particles in it because it may not be safe to use.

Safely dispose of the pre-filled pen in a sharps container and get a new one.

Wash your hands well with soap and water.

Step 2. Choose and Prepare an Injection Site

Choose an Injection Site

The front of your thigh or your abdomen except for the 2-inch (5cm) area around your navel are the recommended injection sites (See Figure D).

The outer area of the upper arms may also be used only if the injection is being given by a caregiver. Do not attempt to use the upper arm area by yourself (See Figure D).

Rotate Injection Site

Choose a different injection site for each new injection at least 1 inch (2.5cm) from the last area you injected.

Do not inject into moles, scars, bruises, or areas where the skin is tender, red, hard or not intact.

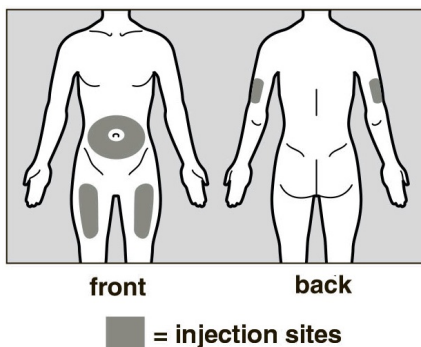


Figure D

Prepare the Injection Site

Wipe the injection site with an alcohol pad in a circular motion and let it air dry to reduce the chance of getting an infection. Do not touch the injection site again before giving the injection.

Do not fan or blow on the clean area.

Step 3. Inject Actemra

Hold the Actemra pre-filled pen firmly with one hand. Twist and pull off the green cap with the other hand (See Figure E). The green cap contains a loose fitting metal tube.

If you cannot remove the green cap you should ask a caregiver for help or contact your healthcare provider.

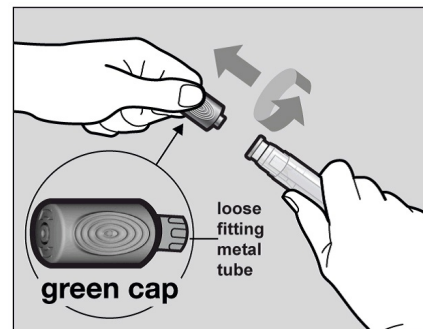


Figure E

Do not touch the needle shield which is located at the tip of the Autoinjector below the Window area (see Figure A), to avoid accidental needle stick injury.

Throw away the green cap in a sharps container.

After you remove the green cap, the pre-filled pen is ready for use. If the pre-filled pen is not used within 3 minutes of the cap removal, the pre-filled pen should be disposed of in the sharps container and a new pre-filled pen should be used.

Never reattach the green cap after removal.

Hold the pre-filled pen comfortably in 1 hand by the upper part, so that you can see the Window area of the pre-filled pen (See Figure F).

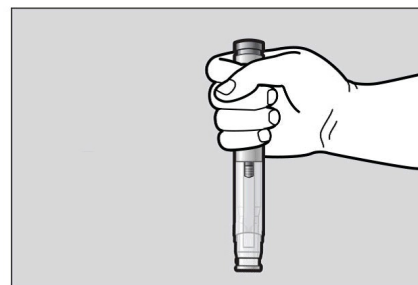


Figure F

Use your other hand to gently pinch the area of skin you cleaned, to prepare a firm injection site (See Figure G). The pre-filled pen requires a firm injection site to properly activate.

Pinching the skin is important to make sure that you inject under the skin (into fatty tissue) but not any deeper (into muscle). Injection into muscle could cause the injection to feel uncomfortable.



Figure G

Do not press the green activation button yet.

Place the needle-shield of the pre-filled pen against your pinched skin at a 90° angle (See Figure H).

It is important to use the correct angle to make sure the medicine is delivered under the skin (into fatty tissue), or the injection could be painful and the medicine may not work.

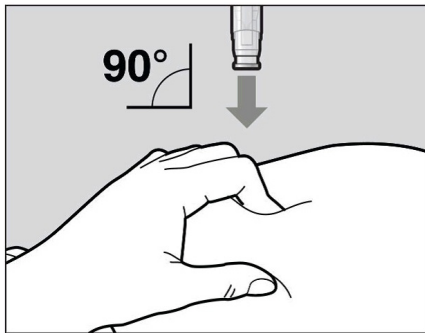


Figure H

To use the pre-filled pen, you first have to unlock the green Activation button.

To unlock it, press the pre-filled pen firmly against your pinched skin until the needle-shield is completely pushed in (See Figure I).

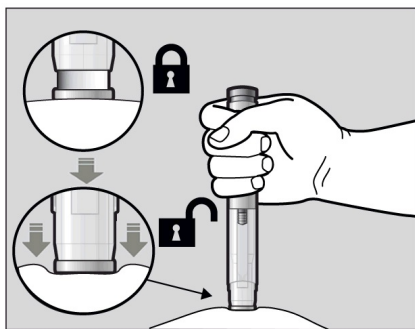


Figure I

Continue to keep the needle-shield pushed in.

If you don't keep the needle-shield completely pushed against the skin, the green Activation button will not work.

Continue to pinch the skin while you keep the pre-filled pen in place.

Press the green Activation button to start the injection. A "click" sound indicates the start of the injection. Keep the green button pressed in and continue holding the pre-filled pen pressed firmly against your skin (See Figure J). If you cannot start the injection you should ask for help from a caregiver or contact your healthcare provider.

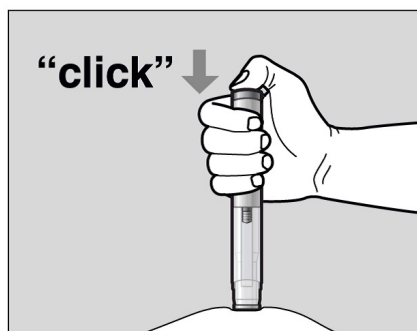


Figure J

The purple indicator will move along the Window area during the injection (See Figure K).

Watch the purple indicator until it stops moving to be sure the full dose of medication is injected.

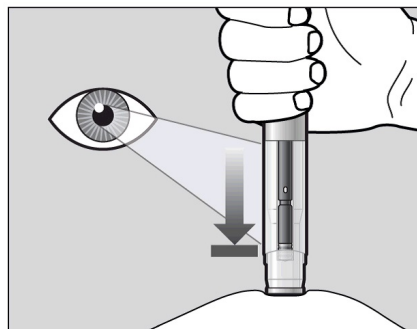


Figure K

The injection may take up to 10 seconds.

You may hear a second "click" during the injection but you should continue to hold the pre-filled pen firmly against your skin until the purple indicator stops moving.

When the purple indicator has stopped moving, release the green button. Lift the pre-filled pen straight

off of the injection site at a 90° angle to remove the needle from the skin. The needle shield will then move out and lock into place covering the needle (See Figure L).

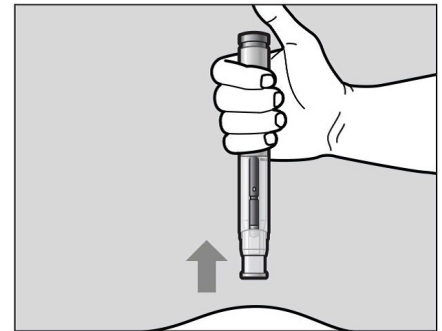


Figure L

Check the Window area to see that it is filled with the purple indicator (See Figure L).

If the Window area is not filled by the purple indicator then:

- The needle-shield may not have locked. Do not touch the needle-shield of the pre-filled pen, because you may stick yourself with the needle. If the needle is not covered, carefully place the pre-filled pen into the sharps container to avoid any injury with the needle.
- You may not have received your full dose of Actemra. Do not try to re-use the pre-filled pen. Do not repeat the injection with another pre-filled pen. Call your healthcare provider for help.

After the Injection

There may be a little bleeding at the injection site. You can press a cotton ball or gauze over the injection site.

Do not rub the injection site.

If needed, you may cover the injection site with a small bandage.

Step 4. Dispose of the pre-filled pen

The Actemra pre-filled pen should not be reused.

Put the used pre-filled pen into your sharps container (see "How do I dispose of used pre-filled pens?")

Do not put the cap back on the pre-filled pen.

If your injection is given by another person, this person must also be

careful when removing the pre-filled pen and disposing of it to prevent accidental needle stick injury and passing infection.

How do I dispose of used pre-filled pens?

Put your used Actemra pre-filled pen and green cap in a sharps disposal container right away after use (See Figure M).

Do not throw away (dispose of) the pre-filled pen and the green cap in your household trash and do not recycle them.



Figure M

Dispose of the full container as instructed by your healthcare provider or pharmacist.

Always keep the puncture-resistant container out of the sight and reach of children.

Keep the Actemra pre-filled pen and disposal container out of the reach of children.

Record your Injection

Write the date, time, and specific part of your body where you injected yourself. It may also be helpful to write any questions or concerns about the injection so you can ask your healthcare provider.

If you have any questions or concerns about your Actemra Autoinjector, talk to your healthcare provider familiar with Actemra.

How long to use Actemra

The duration of treatment depends on how you are responding to the medicine. Your doctor will discuss this with you.

Continue to use Actemra until your doctor tells you to stop.

If an adult with RA/GCA forgets to use Actemra

It is very important to use Actemra exactly as prescribed by your doctor. Keep track of your next dose.

If you inject Actemra weekly and it is within 7 days of the dose you missed, you should skip the missed dose. Inject your next dose as you would normally on the next scheduled day.

Do not give yourself two injections to make up for the injection that you missed.

If you inject Actemra every 2 weeks and it is within 7 days of the dose you missed, you should inject the missed dose as soon as you remember. Inject the next dose as you would on the next scheduled day.

Do not give yourself two injections to make up for the injection that you missed.

If you inject Actemra weekly or every 2 weeks and it has been more than 7 days since you missed your dose, contact your healthcare provider for advice.

If you are not sure when to inject your next dose, contact your healthcare provider for advice.

If a child or adolescent with pJIA forgets to use Actemra

It is very important to use Actemra exactly as prescribed by the doctor. Keep track of the next dose.

If a dose is missed by less than 7 days, inject a dose as soon as you remember and give the next dose at the regular scheduled time.

If a dose is missed by 7 days or more, or you are not sure when to inject your next dose, contact your healthcare provider for advice. Overdose

If you think that you or anyone else may have used too much Actemra, immediately telephone your doctor or Poisons

Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

While you are using 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 using 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.

The reaction can occur even after multiple doses of Actemra. If you have experienced any allergic reaction symptoms after using Actemra, do not take the next dose until you have informed your doctor AND your doctor has told you it is safe to take the next dose.

Tell your doctor immediately if you develop an infection while you are using Actemra. Signs of serious infection include fever and chills, stomach ache or persistent headaches.

Tell your doctor immediately if you develop severe blisters and bleeding in the lips, eyes, mouth,

nose and genitals while you are using Actemra.

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

Tell your doctor if you become pregnant while using Actemra.

Tell your doctor if you are breast-feeding while using 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.

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 using Actemra.

Actemra helps many patients with RA, GCA and pJIA 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 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
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals.

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
- 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)
- injection site reactions, such as pain, redness and itch
- 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.

Side effects in children and adolescents with pJIA

Side effects in children and adolescents with pJIA are generally similar to those in adults. Some side effects are seen more often in children and adolescents: inflamed nose and throat, headache, feeling sick (nausea) and lower white blood cell counts.

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 using Actemra

Storage

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

Store the pens in the carton to protect them from light and to keep them dry.

Once removed from the refrigerator, Actemra must be used within 8 hours and should not be kept above 30°C.

Do not use Actemra after the expiry date which is stated on the carton and pen labels after 'EXP'. The expiry date refers to the last day of that month.

Disposal

The pen is intended for single use only and must be discarded after the injection.

Dispose of the pens in a sharps container as instructed by your doctor, nurse or pharmacist.

Do not put the used pens in your normal household rubbish.

If your doctor tells you to stop using Actemra, or the product has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

- arginine
- arginine hydrochloride
- methionine
- water for injections

Distributor

Actemra (ACTPen) is distributed in Australia by:

Roche Products Pty Limited

ABN 70 000 132 865

Level 8, 30-34 Hickson Road

Sydney NSW 2000 Australia

Medical enquiries: 1800 233 950

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

Australian Registration Numbers

- 162mg/0.9mL pre-filled pens (ACTPen) AUST R 296808

This leaflet was prepared on 19 November 2018.

Product description

Availability

Actemra (ACTPen) is available as pre-filled pens (162mg/0.9mL) in packs of 1 and 4 pens.

Actemra is also available as a concentrated solution for intravenous infusion.

What Actemra looks like

Actemra is a clear to opalescent, colourless to pale yellow solution.

Ingredients

Active ingredient - tocilizumab (rch)

Inactive ingredients

- polysorbate 80
- histidine
- histidine hydrochloride