

Package leaflet: Information for the user

RoActemra® 162 mg solution for injection in pre-filled syringe

tocilizumab



Children and adolescents with pJIA (aged 2 and over) The usual dose of RoActemra depends on the patient's weight.

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

RoActemra is given by injection under the skin (subcutaneously). At the start, your doctor or nurse may inject RoActemra. However, your doctor may decide that you may inject RoActemra yourself. In this case you will get training on how to inject RoActemra yourself. Parents and carers will get training on how to inject RoActemra for patients who cannot inject themselves, such as children.

Talk to your doctor if you have any questions about giving yourself or a child patient you look after an injection. You will find detailed "Instructions for administration" at the end of this leaflet.

If you use more RoActemra than you should
Because RoActemra is given in one pre-filled syringe, it is unlikely that you will receive too much. However, if you are worried, talk to your doctor, pharmacist or nurse.

If an adult with RA or GCA or a child or adolescent with sJIA misses or forgets a dose
It is very important to use RoActemra exactly as prescribed by your doctor. Keep track of your next dose.

- If you miss your weekly dose within 7 days, take your dose on the next scheduled day.
- If you miss your once every 2 weeks dose within 7 days, inject a dose as soon as you remember and take your next dose at your regular scheduled time.
- If you miss your dose by more than 7 days, or you are not sure when to inject RoActemra, call your doctor or pharmacist.

If a child or adolescent with pJIA misses or forgets a dose
It is very important to use RoActemra exactly as prescribed by the doctor. Keep track of the next dose.

- If a dose is missed within 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 more than 7 days, or you are not sure when to inject RoActemra, call the doctor or pharmacist.

If you stop using RoActemra

You should not stop using RoActemra without discussing with your doctor first.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, RoActemra can cause side effects, although not everybody gets them. Side effects could occur 3 months or more after your last dose of RoActemra.

Possible serious side effects:
Tell your doctor **immediately** if you experience any of the following side effects:
These are common: they may affect up to 1 in every 10 people

- Allergic reactions during or after injection:
 - difficulty with breathing, chest tightness or light-headedness
 - rash, itching, hives, swelling of the lips, tongue or face

Signs of serious infections:

- fever and chills
- skin infection (cellulitis) sores with fever and chills
- stomach ache

Signs and symptoms of liver toxicity

These are rare: may affect up to 1 in 1,000 people

- tiredness
- abdominal pain,
- jaundice (yellow discolouration of skin or eyes)

List of other possible side effects

If you notice any of these, tell your doctor as soon as possible.

Very common side effects:

- These may affect 1 in 10 people or more
 - upper respiratory tract infections with typical symptoms such as cough, blocked nose, runny nose, sore throat and headache.
 - high blood fat (cholesterol) levels
 - injection site reactions.

Common side effects:

- These may affect up to 1 in 10 people
 - lung infection (pneumonia)
 - shingles (herpes zoster)
 - cold sores (oral herpes simplex), blisters
 - skin infection (cellulitis) sores with fever and chills
 - rash and itching, hives
 - allergic (hypersensitivity) reactions
 - eye infection (conjunctivitis)
 - headache, dizziness, high blood pressure
 - mouth ulceration, stomach pain
 - fluid retention (oedema) in the lower legs, weight increase
 - cough, shortness of breath
 - low white blood cell counts shown by blood tests (neutropenia, leucopenia)
 - abnormal liver function tests (increased transaminases)
 - increased bilirubin shown by blood tests
 - low fibrinogen levels in the blood (a protein involved in blood clotting).

Uncommon side effects:

- These may affect up to 1 in every 100 people
 - diverticulitis (fever, nausea, diarrhoea, constipation, stomach pain)
 - red swollen areas in the mouth
 - high blood fat (triglycerides)
 - kidney stones
 - underactive thyroid.

Rare side effects:

- These may affect up to 1 in every 1,000 people
 - Stevens-Johnson syndrome (skin rash, which may lead to severe blistering and peeling of the skin)
 - fatal allergic reaction (anaphylaxis)
 - inflammation of the liver (hepatitis), jaundice

Very rare side effects:

- These may affect up to 1 in every 10,000 people
 - low counts for white blood cells, red blood cells and platelets in blood tests.
 - liver failure

Side effects in children and adolescents with sJIA or pJIA
Side effects in children and adolescents with sJIA or 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store RoActemra

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pre-filled syringe label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C). Do not freeze. Once removed from the refrigerator, the pre-filled syringe can be stored up to 2 weeks at or below 30 °C.

Keep the pre-filled syringes in the outer carton in order to protect from light and moisture.

Do not use if the medicine is cloudy or contains particles, is any colour besides colourless to yellowish, or any part of the pre-filled syringe appears to be damaged.

The syringe should not be shaken. After removing the cap the injection must be started within 5 minutes to prevent the medicine from drying out and blocking the needle. If the pre-filled syringe is not used within 5 minutes of cap removal, you must dispose of it in a puncture resistant container and use a new pre-filled syringe.

If following insertion of the needle, you cannot depress the plunger, you must dispose of the pre-filled syringe in a puncture resistant container and use a new pre-filled syringe.

6. Contents of the pack and other information

What RoActemra contains

- The active substance is tocilizumab.
- Each pre-filled syringe contains 162 mg tocilizumab in 0.9 mL.

The other ingredients are L-Histidine, L-Histidine monohydrochloride monohydrate, L-Arginine hydrochloride, L-Methionine, Polysorbate 80 and Water for injections. (see section 2: RoActemra contains polysorbate). May contain L-Arginine.

What RoActemra looks like and contents of the pack
RoActemra is a solution for injection. The solution is colourless to slightly yellowish.

RoActemra is supplied as a 0.9 mL pre-filled syringe containing 162 mg tocilizumab solution for injection.

Each pack contains 4 pre-filled syringes with multipacks containing 12 (3 packs of 4) pre-filled syringes. Not all pack sizes may be marketed.

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What do I need to know to use my RoActemra pre-filled syringe safely?
It is important to read, understand and follow these instructions so that you or your caregiver uses the RoActemra syringe correctly. These instructions do not replace training from your healthcare provider. Your healthcare provider should show you how to prepare and inject properly before you use the RoActemra syringe for the first time. Ask your healthcare provider any questions you may have. Do not attempt to administer an injection until you are sure that you understand how to use the RoActemra syringe.

Please also read the Patient Leaflet that comes with the RoActemra syringe for the most important information you need to know about the medicine. It is important to remain under your healthcare provider's care while using RoActemra.

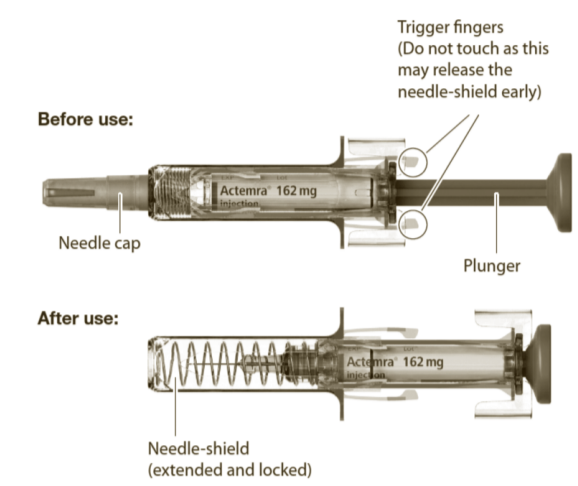
Important Information:

- Do not use the syringe if it appears to be damaged
- Do not use if medicine is cloudy, hazy, discoloured or contains particles
- Do not try to take apart the syringe at any time
- Do not remove the needle-cap until you are ready to inject
- Do not inject through clothing covering the skin
- Never re-use the same syringe
- Do not touch the syringe trigger fingers as this may damage the syringe

Storage:

Keep the RoActemra syringe and all medicines out of the sight and reach of children. Always store the syringe in a refrigerator or a temperature of 2 °C – 8 °C. Once removed from the refrigerator, the pre-filled syringe can be stored for a total time of up to 2 weeks at or below 30 °C, but not exceeding the original expiry date (EXP). Mark the relevant date on the carton. The pre-filled syringe must always be kept in the carton. Protect the syringe from freezing and from light. Keep the syringes dry.

Pre-filled syringe parts



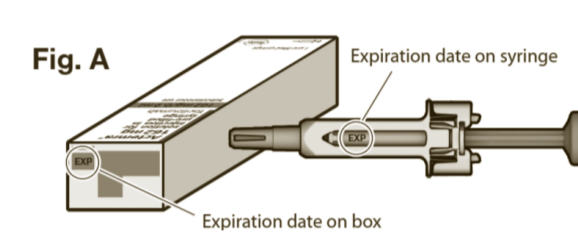
You will need the following to give your injection:
Included in the box:
Pre-filled Syringe

Not included in the box:

- Alcohol pad
- Sterile cotton ball or gauze
- Puncture-resistant container or sharps container for safe disposal of needle-cap and used syringe

A place to prepare your supplies:
• Find a well-lit, clean, flat surface such as a table

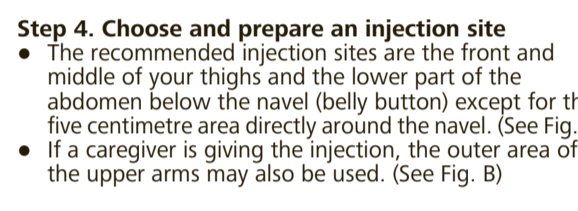
- **Step 1. Visually check the syringe**
 - Take the box containing the syringe out of the refrigerator and open the box. Do not touch the trigger fingers on the syringe as this may damage the syringe.
 - Remove the syringe from the box and visually examine the syringe, as well as the medicine in the syringe. This is important to ensure that the syringe and medicine are safe to use.
 - Check the expiry date on the box and syringe (See Fig. A) to make sure that it has not passed (expired). Do not use the syringe if the expiry date has passed. This is important to ensure that the syringe and medicine are safe to use.



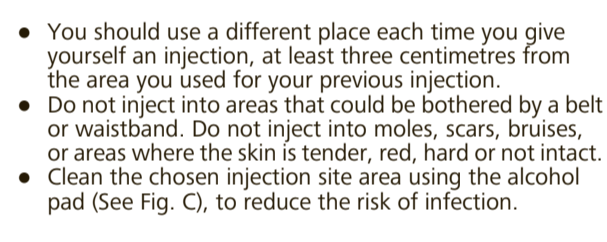
- **Step 2. Allow the syringe to adjust to room temperature**
 - Do not remove the needle-cap on your syringe until Step 5. Early removal of the needle-cap can cause the medication to dry out and block the needle.
 - Place the syringe on a clean flat surface and allow the syringe to come to room temperature (18 °C – 28 °C) for about 25-30 minutes to warm up. Not allowing the syringe to come to room temperature could result in an uncomfortable injection and it may be difficult to depress the plunger.
 - Do not warm up the syringe in any other way.

- **Step 3. Clean your hands**
 - Wash your hands with soap and water.

- **Step 4. Choose and prepare an injection site**
 - The recommended injection sites are the front and middle of your thighs and the lower part of the abdomen below the navel (belly button) except for the five-centimetre area directly around the navel. (See Fig. B)
 - If a caregiver is giving the injection, the outer area of the upper arms may also be used. (See Fig. B)

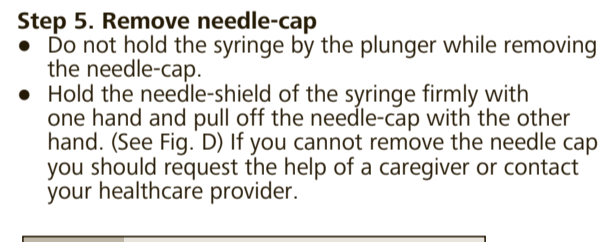


- You should use a different place each time you give yourself an injection, at least three centimetres from the area you used for your previous injection.
- Do not inject into areas that could be bothered by a belt, waistband. Do not inject into moles, scars, bruises, or areas where the skin is tender, red, hard or not intact.
- Clean the chosen injection site area using the alcohol pad (See Fig. C), to reduce the risk of infection.



- Let the skin dry for approximately 10 seconds.
- Be sure not to touch the cleaned area prior to the injection. Do not fan or blow on the clean area.

- **Step 5. Remove needle-cap**
 - Hold the syringe comfortably by the plunger while removing the needle-cap.
 - Hold the needle-shield of the syringe firmly with one hand and pull the needle-cap with the other hand. (See Fig. D) If you cannot remove the needle cap you should request the help of a caregiver or contact your healthcare provider.

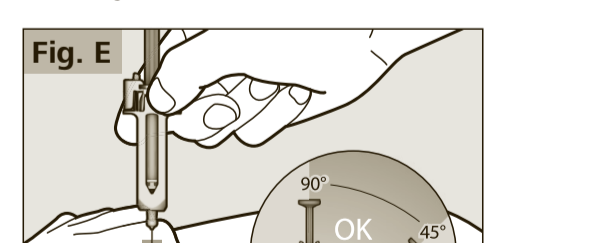


- Do not touch the needle or let it touch any surface.
- There may be a small air bubble in the RoActemra pre-filled syringe. You do not need to remove it.
- You may see a drop of liquid at the end of the needle. This is normal.
- Throw away the needle-cap in the puncture resistant container or sharps container.

NOTE: Once the needle-cap is removed, the syringe must be used immediately.

- If it is not used within 5 minutes of cap removal, the syringe must be disposed of in the puncture resistant container or sharps container and a new syringe must be used. If the needle cap is removed for more than 5 minutes, it may be more difficult to perform an injection as the medicine can dry out and block the needle.
- Never reattach the needle-cap after removal.

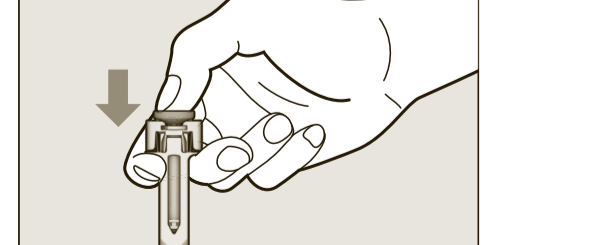
- **Step 6. Give the injection**
 - To be sure the needle can be inserted correctly under the skin, pinch a fold of loose skin at the clean injection site with your free hand. Pinching the skin is important to ensure that you inject under the skin (into fatty tissue) but not any deeper (into muscle). Injection into muscle could result in an uncomfortable injection.
 - Do not hold or push on the plunger while inserting the needle.
 - Insert the needle all the way into the pinched skin at an angle between 45° to 90° with a quick, firm action. (See Fig. E).



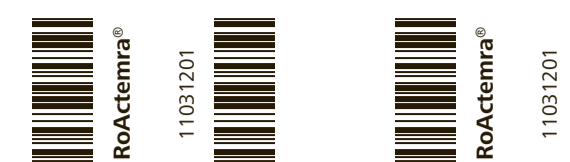
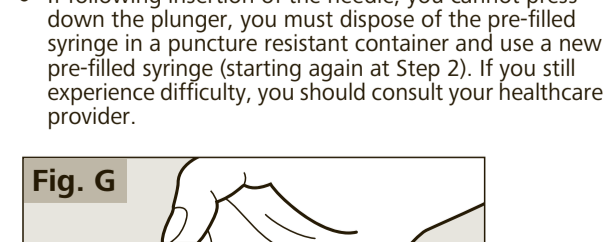
It is important to choose the correct angle to ensure the medication is delivered under the skin (into fatty tissue), otherwise the injection could be painful and the medication may not work.

- Then keep the syringe in position and let go of the pinch of skin.
- Slowly inject all of the medicine by gently pushing the plunger all the way down. (See Fig. F). You must press the plunger all the way down to ensure that you get the full dose of medication and to ensure the trigger fingers are completely pushed to the side. If the plunger is not fully depressed the needle shield will not extend to cover the needle when it is removed. If the needle is not covered proceed carefully, and place the syringe into the puncture resistant container to avoid injury with the needle.

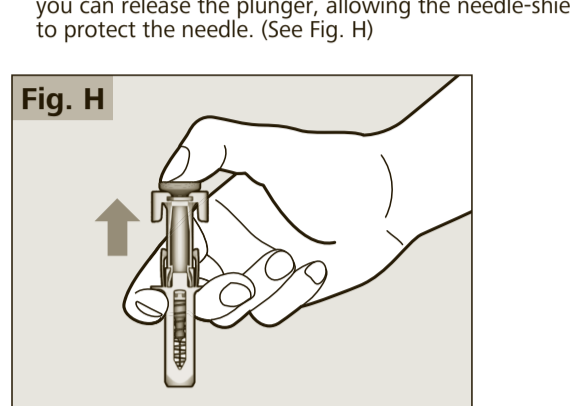
- Once the plunger is pushed all the way down, keep pressing down on the plunger to be sure all of the medicine is injected before taking the needle out of the skin.
- Keep pressing down on the plunger while you take the needle out of the skin at the same angle as inserted. (See Fig. G)
- If following insertion of the needle, you cannot press down the plunger, you must dispose of the pre-filled syringe in a puncture resistant container and use a new pre-filled syringe (starting again at Step 2). If you still experience difficulty, you should consult your healthcare provider.



- Once the plunger is pushed all the way down, keep pressing down on the plunger to be sure all of the medicine is injected before taking the needle out of the skin.
- Keep pressing down on the plunger while you take the needle out of the skin at the same angle as inserted. (See Fig. G)
- If following insertion of the needle, you cannot press down the plunger, you must dispose of the pre-filled syringe in a puncture resistant container and use a new pre-filled syringe (starting again at Step 2). If you still experience difficulty, you should consult your healthcare provider.



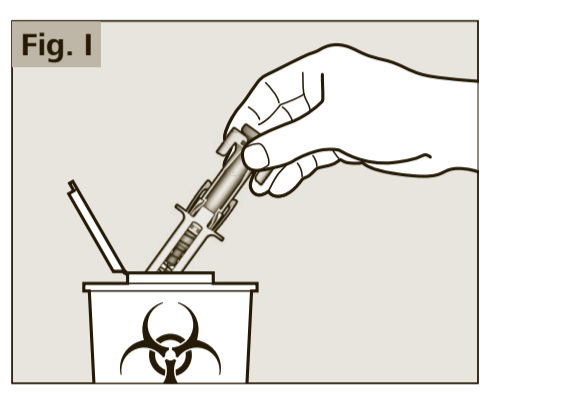
- Once the needle is removed completely from the skin, you can release the plunger, allowing the needle-shield to protect the needle. (See Fig. H)



- If you see drops of blood at the injection site, you can press a sterile cotton ball or gauze over the injection site for approximately 10 seconds.
- Do not rub the injection site.

Step 7. Dispose of the syringe

- Do not try to re-cap your syringe.
- Throw away used syringes in a puncture-resistant container or sharps container. Ask your healthcare provider or pharmacist for information about where you can get a "sharps" container or what other types of puncture-resistant containers you can use to safely dispose of your used syringes, if you do not have one. (See Fig. I)



Check with your healthcare provider for instructions about the right way to throw away used syringes. There may be local or state laws about how to throw away used syringes.

Do not throw away used syringes or the puncture resistant container in household trash and do not recycle them.

- 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.

Patient advice regarding hypersensitivity reactions (also known as anaphylaxis, if severe)
If you develop symptoms such as, but not limited to skin rash, itching, chills, swelling of face, lips, tongue or throat, chest pain, wheezing, difficulty breathing or swallowing or feeling dizzy or faint at any time while not at the clinic, during or following an RoActemra injection you should seek emergency care immediately.

Patient advice regarding early recognition and treatment to limit risk of a serious infection

- Be alert for the first signs of infection such as:
 - body aches, fever, chills
 - cough, chest discomfort/tightness, shortness of breath
 - redness, heat, unusual swelling of skin or joint
 - abdominal pain/tenderness and/or change in bowel function

Call your doctor and seek medical attention without delay if you think you might be developing an infection.

If you have any concerns or questions about your syringe, contact your healthcare provider or pharmacist for assistance.