Actemra
DOSING GUIDE

A guide to assist healthcare professionals with the dose preparation and administration of Actemra therapy in patients with:

- Rheumatoid Arthritis [Intravenous or subcutaneous]
- Giant Cell Arteritis [Subcutaneous]
- Polyarticular Juvenile Idiopathic Arthritis (also referred to as Juvenile Idiopathic Polyarthritis) [Intravenous or subcutaneous]
- Systemic Juvenile Idiopathic Arthritis [Intravenous or subcutaneous

This document is approved by The Executive Directorate of Pharmacovigilance, at Saudi Food and Drug Authority [SFDA].

Contents

This Actemra Dosing Guide contains important safety information that you need to be aware of when administering Actemra, This Actemra Dosing Guide must be read together with the Actemra Healthcare Professional and Patient Brochures and the Actemra Labeling/Summary of Product Characteristics that comes with Actemra as it contains important information about Actemra.

Please read this information carefully before administering the product.

Actemra IV (Actemra 20 mg/ml concentrate for solution for infusion):

Actemra, in combination with methotrexate (MTX), is indicated for:

- The treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX.
- The treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying antirheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.
- In these patients, Actemra can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.
- Actemra has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with methotrexate.

Actemra is indicated for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older, who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids. Actemra can be given as monotherapy (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX.

Actemra in combination with methotrexate (MTX) is indicated for the treatment of juvenile idiopathic polyarthritis (pJIA; rheumatoid factor positive or negative) in patients 2 years of age and older, who have responded inadequately to previous therapy with MTX. Actemra can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

Actemra SC (Actemra 162 mg solution for injection in **pre-filled syringe)**:

Actemra is indicated for the treatment of Rheumatoid Arthritis (RA) in adult patients:

In combination with methotrexate (MTX), Actemra is indicated for

- The treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX.
- The treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.

- In these patients, Actemra can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.
- Actemra has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with methotrexate.

Actemra is indicated for the treatment of Giant Cell Arteritis (GCA) in adult patients.

Actemra is indicated for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 1 year of age and older, who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids. Actemra can be given as monotherapy (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX..

Actemra in combination with methotrexate (MTX) is indicated for the treatment of juvenile idiopathic polyarthritis (pJIA; rheumatoid factor positive or negative) in patients 2 years of age and older, who have responded inadequately to previous therapy with MTX.

Actemra can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

Patients who transition from tocilizumab IV therapy to SC administration should administer the first SC dose at the time of the next scheduled IV dose under the supervision of a qualified health care professional.

All patients treated with Actemra should be given the Patient Alert Card.

Suitability of the patient or parent/guardian for subcutaneous home use should be assessed and patients or their parent/guardian should be instructed to inform a healthcare professional before administering the next dose if they experience symptoms of an allergic reaction. Patients should seek immediate medical attention if developing symptoms of serious allergic reactions.

Prior to starting treatment with Actemra:

- It is important that you review the pre-administration checklist found in the Patient Brochure: ***Before starting treatment with Actemra® (tocilizumab)*** with your patient, the patient's parents/guardians, or both.
- Allow ample time to discuss any questions your patient, the patient's parents/guardians, or both may have.
- It is important that you review the information contained within the *Healthcare Professional Brochure* for Actemra® (tocilizumab) intravenous (IV) and subcutaneous (SC) formulations and the Patient Brochure: ***Before starting treatment with Actemra® (tocilizumab)*** with your patient, the patient's parents/guardians, or both. These will help them understand what they may expect from the treatment of the patient's condition with Actemra.

For full information, see the Summary of Product Characteristics (SmPC) and the Actemra Package Leaflet:

Actemra Patient Brochures and other information can be requested from your sales representative.

PART I – INTRAVENOUS (IV) ADMINISTRATION OF ACTEMRA BY INFUSION

This guide will walk you through the Actemra infusion process in 6 steps

1 WEIGH PATIENT AND CALCULATE ACTEMRA DOSE BASED ON INDICATION

Actemra dosing is calculated based on each patient's weight and the indication for which they are treated. The treatment frequency varies by indication. Verify the patient's weight and indication, then locate it on the chart to find the corresponding dose and recommended vial combination.

If the patient's dose has been calculated prior to the infusion date, take his or her weight to make sure that it has not changed from the time of the original calculation to require a change in dose. If the patient's weight has changed, contact the prescriber to discuss whether a dosing change is needed. Refer to the chart to check whether a dosing adjustment is necessary.

Once the dose is calculated, choose the vial combination of Actemra that best matches the patient's needs. Actemra is available in three different dosing vials:

 400 mg (20 ml) vials 200 mg (10 ml) vials  80 mg (4 ml) vials

Inspect the vials for particulate matter and discoloration. Only solutions which are clear to opalescent, colourless to pale yellow and free of visible particles should be used.

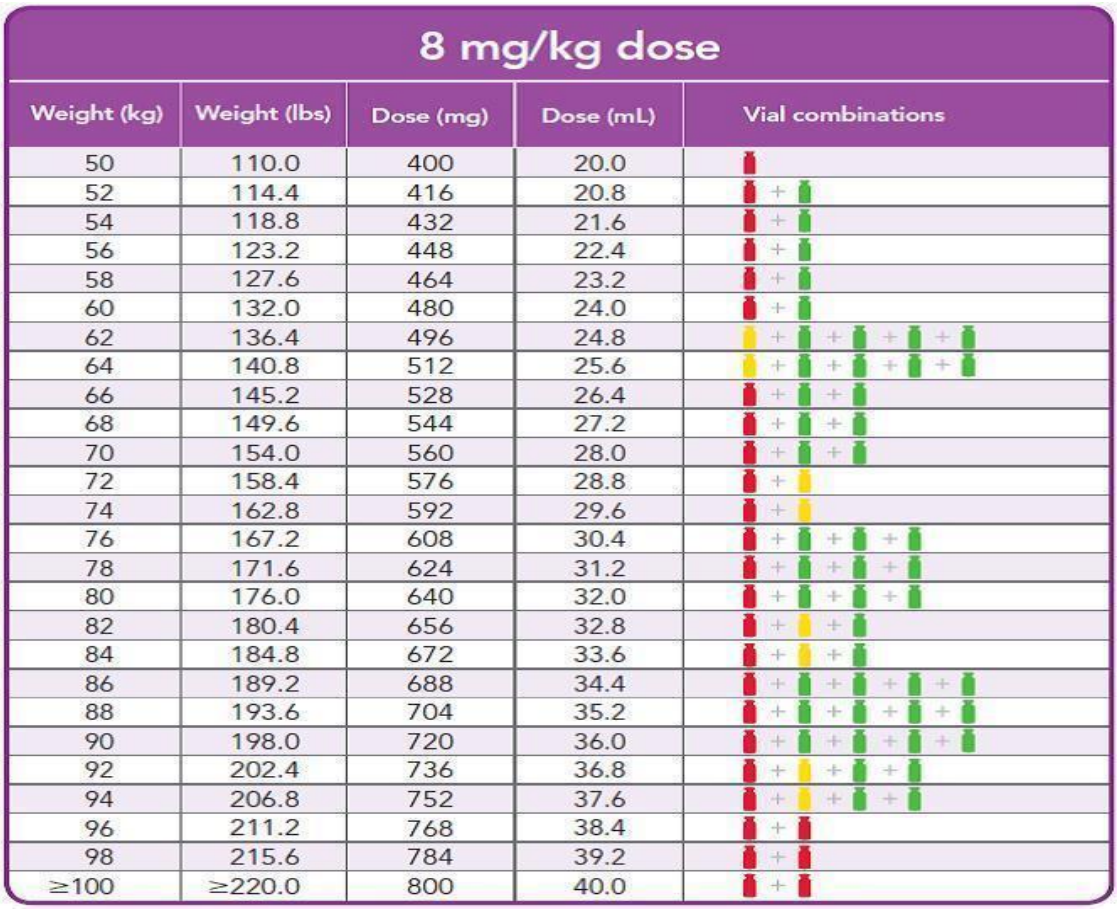
RA: Dosing Preparation and Administration Guide with Actemra IV

Dosing should take place at 4-week intervals.

Actemra IV dosing in RA patients is calculated based on each patient's weight as follows:

For the 8 mg/kg dose: Patient weight (kg) x 8 (mg/kg) = Actemra …. Mg dose

For individuals whose body weight is more than 100 kg, doses exceeding 800 mg per infusion are not recommended.



8 mg/kg dose

Weight (kg)	Weight (lbs)	Dose (mg)	Dose (mL)	Vial combinations
50	110.0	400	20.0	
52	114.4	416	20.8	
54	118.8	432	21.6	
56	123.2	448	22.4	
58	127.6	464	23.2	
60	132.0	480	24.0	
62	136.4	496	24.8	
64	140.8	512	25.6	
66	145.2	528	26.4	
68	149.6	544	27.2	
70	154.0	560	28.0	
72	158.4	576	28.8	
74	162.8	592	29.6	
76	167.2	608	30.4	
78	171.6	624	31.2	
80	176.0	640	32.0	
82	180.4	656	32.8	
84	184.8	672	33.6	
86	189.2	688	34.4	
88	193.6	704	35.2	
90	198.0	720	36.0	
92	202.4	736	36.8	
94	206.8	752	37.6	
96	211.2	768	38.4	
98	215.6	784	39.2	
≥100	≥220.0	800	40.0	

pJIA: Dosing Preparation and Administration Guide with Actemra IV

Dosing should take place at 4-week intervals.

A change in dose of 8mg/kg or 10 mg/kg should only be based on a consistent change in the patient's body weight over time (e.g., within 3 weeks). If the patient's weight has changed, contact the prescriber to discuss whether a dosing change is needed. Refer to the chart to check whether a dosing adjustment is necessary.

Actemra IV dosing in pJIA patients is calculated based on each patient's weight as follows:

For patients weighing <30 kg: Patient's weight (kg) x 10 mg/kg = Actemra dose

For patients weighing ≥30 kg: Patient's weight (kg) x 8 mg/kg = Actemra dose

	Weight (kg)	Weight (lbs)	Dose (mg)	Dose (ml)	Vial combinations
10 mg/kg	10	22.0	100	5.0	
	12	26.4	120	6.0	
	14	30.8	140	7.0	
	16	35.2	160	8.0	
	18	39.6	180	9.0	
	20	44.0	200	10.0	
	22	48.4	220	11.0	
	24	52.8	240	12.0	
	26	57.2	260	13.0	
	28	61.6	280	14.0	
8 mg/kg	30	66.0	240	12.0	
	32	70.4	256	12.8	
	34	74.8	272	13.6	
	36	79.2	288	14.4	
	38	83.6	304	15.2	
	40	88.0	320	16.0	
	42	92.4	336	16.8	
	44	96.8	352	17.6	
	46	101.2	368	18.4	
	48	105.6	384	19.2	
	50	110.0	400	20.0	
	52	114.4	416	20.8	
	54	118.8	432	21.6	
	56	123.2	448	22.4	
	58	127.6	464	23.2	
	60	132.0	480	24.0	
	62	136.4	496	24.8	
	64	140.8	512	25.6	
	66	145.2	528	26.4	
	68	149.6	544	27.2	
	70	154.0	560	28.0	
	72	158.4	576	28.8	
	74	162.8	592	29.6	
	76	167.2	608	30.4	
	78	171.6	624	31.2	
	80	176.0	640	32.0	
	82	180.4	656	32.8	
	84	184.8	672	33.6	
	86	189.2	688	34.4	
	88	193.6	704	35.2	
	90	198.0	720	36.0	
	92	202.4	736	36.8	
	94	206.8	752	37.6	
	96	211.2	768	38.4	
	98	215.6	784	39.2	
	≥100	≥220.0	800	40.0	

sJIA: Dosing Preparation and Administration Guide with Actemra IV

Dosing should take place at 2-week intervals.

A change in dose of 8mg/kg or 12 mg/kg should only be based on a consistent change in the patient's body weight over time (e.g., within 3 weeks). If the patient's weight has changed, contact the prescriber to discuss whether a dosing change is needed. Refer to the chart to check whether a dosing adjustment is necessary.

Actemra dosing in sJIA patients is calculated based on each patient's weight as follows:

For patients weighing <30 kg: Patient's weight (kg) x 12 mg/kg = Actemra dose

For patients weighing ≥30 kg: Patient's weight (kg) x 8 mg/kg = Actemra dose

	Weight (kg)	Weight (lbs)	Dose (mg)	Dose (ml)	Vial combinations
12 mg/kg	10	22.0	120	6.0	1 + 1
	12	26.4	144	7.2	1 + 1
	14	30.8	168	8.4	1
	16	35.2	192	9.6	1
	18	39.6	216	10.8	1 + 1 + 1
	20	44.0	240	12.0	1 + 1 + 1
	22	48.4	264	13.2	1 + 1
	24	52.8	288	14.4	1 + 1 + 1 + 1
	26	57.2	312	15.6	1 + 1 + 1 + 1
	28	61.6	336	16.8	1 + 1 + 1
8 mg/kg	30	66.0	240	12.0	1 + 1 + 1
	32	70.4	256	12.8	1 + 1
	34	74.8	272	13.6	1 + 1
	36	79.2	288	14.4	1 + 1 + 1 + 1
	38	83.6	304	15.2	1 + 1 + 1 + 1
	40	88.0	320	16.0	1 + 1 + 1 + 1
	42	92.4	336	16.8	1 + 1 + 1
	44	96.8	352	17.6	1 + 1 + 1
	46	101.2	368	18.4	1
	48	105.6	384	19.2	1
	50	110.0	400	20.0	1
	52	114.4	416	20.8	1 + 1 + 1 + 1
	54	118.8	432	21.6	1 + 1 + 1 + 1
	56	123.2	448	22.4	1 + 1
	58	127.6	464	23.2	1 + 1
	60	132.0	480	24.0	1 + 1
	62	136.4	496	24.8	1 + 1 + 1 + 1 + 1
	64	140.8	512	25.6	1 + 1 + 1 + 1 + 1
	66	145.2	528	26.4	1 + 1 + 1
	68	149.6	544	27.2	1 + 1 + 1
	70	154.0	560	28.0	1 + 1 + 1
	72	158.4	576	28.8	1 + 1
	74	162.8	592	29.6	1 + 1
	76	167.2	608	30.4	1 + 1 + 1 + 1
	78	171.6	624	31.2	1 + 1 + 1 + 1
	80	176.0	640	32.0	1 + 1 + 1 + 1
	82	180.4	656	32.8	1 + 1 + 1
	84	184.8	672	33.6	1 + 1 + 1
	86	189.2	688	34.4	1 + 1 + 1 + 1 + 1
	88	193.6	704	35.2	1 + 1 + 1 + 1 + 1
	90	198.0	720	36.0	1 + 1 + 1 + 1 + 1
	92	202.4	736	36.8	1 + 1 + 1 + 1
	94	206.8	752	37.6	1 + 1 + 1 + 1
	96	211.2	768	38.4	1 + 1
	98	215.6	784	39.2	1 + 1
	≥100	≥220.0	800	40.0	1 + 1

2 GATHER ALL NECESSARY SUPPLIES

You will need:

- Actemra, at room temperature
- Syringes and large-bore needles
- One primary infusion set
- One 100 ml or 50 ml (for patients <30kg) bag of 0.9% (9 mg/mL) sterile,non-pyrogenic sodium chloride solution for injection
- One intravenous (IV) catheter
- Gauze
- Tourniquet
- Gloves
- Alcohol/cleansing wipes

3 TAKE BASELINE ASSESSMENTS

Take baseline assessments to ensure the patient is healthy enough to receive the infusion.

Vital signs may include:

- Blood pressure
- Temperature
- Pulse

Follow the recommended baseline patient questions as described in the Actemra Healthcare Professional Brochure (Section 15 – General Recommendation) as well as the Summary of Product Characteristics (Section 4.4 – Warnings and Precautions).

4 PREPARE THE PATIENT FOR THE INFUSION

Review the Patient Brochure: ***Before starting treatment with Actemra® (tocilizumab)*** with the patient. Answer any questions he or she might have

Actemra does not require premedication

5 PREPARE THE ACTEMRA INFUSION

Actemra is a ready-mix solution and requires no reconstitution. The expiry date should always be checked before use. The Actemra concentrate for IV infusion should be diluted by a healthcare professional using aseptic technique.

- Actemra should be refrigerated for storage. However, the fully diluted Actemra solution should be allowed to reach room temperature before it is infused.
- The fully diluted Actemra solutions for infusion may be stored at 2°C–8°C or room temperature (if diluted under controlled and validated aseptic conditions) for up to 24 hours and should be protected from light.
- Actemra solutions do not contain preservatives; therefore, unused product remaining in the vials should not be used.
- **Weight-/indication-based dosing:**
    - **For RA , sJIA (>30 kg), and pJIA (>30 kg):** From a 100 ml infusion bag withdraw a volume of 0.9% (9 mg/ml) sterile, non-pyrogenic sodium chloride solution for injection equal to the volume of the Actemra solution required for the patient's dose.
    - **For sJIA and pJIA patients < 30 kg:** Use a 50ml infusion bag withdraw a volume of 0.9% (9 mg/ml) sterile, non-pyrogenic sodium chloride solution for injection equal to the volume of the Actemra solution required for the patient's dose.
- Actemra should not be infused concomitantly in the same IV line with other medications. No physical or biochemical compatibility studies have been conducted to evaluate the co-administration of Actemra with other medications.

- Slowly add Actemra concentrate for IV infusion from each vial into the infusion bag. To mix the solution, gently invert the bag to avoid foaming.
- Parenteral medicinal products should be inspected visually for particulate matter and discolouration prior to administration. Only solutions which are clear to opalescent, colourless to pale yellow and free of visible particles should be diluted.
- Dispose of needle and syringe in sharps containers when finished.

6 BEGIN THE ACTEMRA INFUSION

The infusion should be administered over 60 minutes. It must be administered with an infusion set and should never be administered as an IV push or bolus.

- Prior to the infusion, inform the patient that serious allergic reactions including anaphylaxis have been reported in association with Actemra. Such reactions may be more severe, and potentially fatal, in patients who have experienced allergic reactions during previous treatment with Actemra even if they have received premedication with steroids and antihistamines. Most allergic reactions occur during infusion or within 24 hours of Actemra administration, although allergic reactions can occur at any time.
- If an anaphylactic reaction or other serious hypersensitivity reaction occurs, administration of Actemra should be stopped immediately, appropriate therapy initiated and Actemra should be permanently discontinued. Fatal anaphylaxis has been reported after marketing authorisation during treatment with IV Actemra.
- Instruct the patient to **seek immediate medical attention** if they notice any of the following signs or symptoms of systemic allergic reactions after receiving Actemra:
    - Rash, itching or hives
    - Shortness of breath or trouble breathing
    - Swelling of the lips, tongue or face
    - Chest pain
    - Feeling dizzy or faint
    - Severe stomach pain or vomiting
    - Hypotension

Once the infusion is completed, remove the catheter and dispose of all supplies properly, bandage the infusion site and check the patient’s vital signs.

PART II - DOSING ADMINISTRATION GUIDE WITH ACTEMRA SC USING EITHER THE PRE-FILLED SYRINGE.

The pre-filled syringe is used in the RA, GCA, pJIA, and sJIA indications only.

This guide will walk you through the Actemra SC injection process in 7 steps

1 GATHER ALL NECESSARY SUPPLIES

You will need:

- One Actemra pre-filled syringe
- A well-lit, clean, flat surface
- Puncture-resistant container/sharps container for
- disposal
- Alcohol/cleansing wipes
- Sterile cotton ball or gauze
- Clock or watch

Actemra Pre-filled Syringe

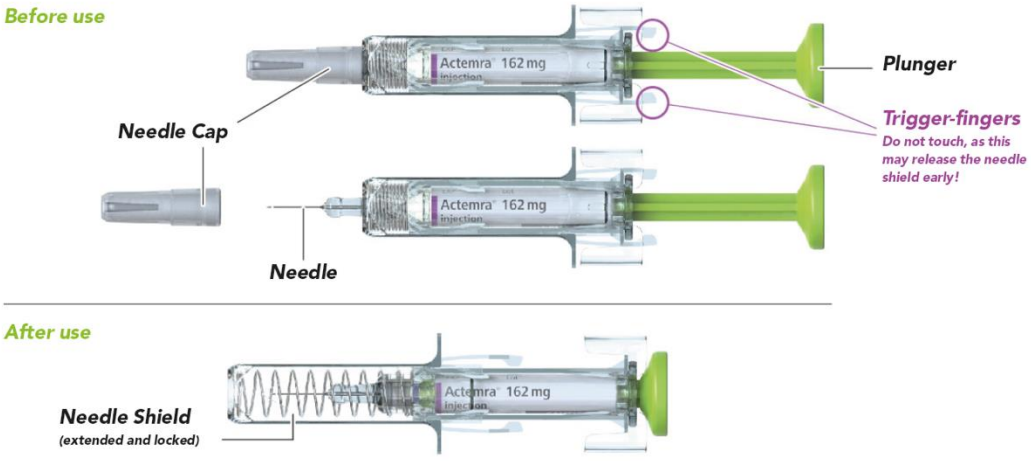


Figure A

2 TAKE BASELINE ASSESSMENTS

The first injection using the Actemra device should be performed under the supervision of a qualified health care professional

The healthcare professional should take baseline assessments to ensure the patient is healthy enough to receive the injection. Vital signs may include:

- Blood pressure
- Temperature
- Pulse

3 PREPARATION FOR INJECTION

- Store the device at 2°C–8°C and should not be frozen.
- Allow the Actemra device to reach room temperature (**18°C to 28°C**) after removing it from the refrigerator. Do not warm up the Actemra device in any other way.
    - **Do not** speed up the warming process in any way, such as using the microwave or placing the Actemra device in warm water.
    - **Do not** leave the Actemra device to warm up in direct sunlight.
- Do not shake the Actemra device.
- Do not reuse the Actemra device.
- Do not try to take apart the Actemra device at any time.
- Do not use the Actemra device through clothing.
- **Before every use:**
    - **Check the Actemra device to make sure it is not damaged.** Do not use the Actemra device if it appears to be damaged or if you have accidentally dropped it.
    - If you are opening the box for the first time, check to make sure that it is properly sealed. **Do not** use the device if the box looks like it has already been opened.
    - Check that the device box is not damaged. **Do not** use device if the box looks damaged.
    - **Check the expiration date on device**. **Do not** use the Actemra device if the expiration date has passed because it may not be safe to use. If the expiration date has passed, safely dispose of the Actemra device in a sharps container and get a new one.
    - Inspect the Actemra device visually for particulate matter and discolouration prior to administration and check the expiration date. Do not use if the medicine is cloudy or contains particles, is any colour besides colourless to slightly yellowish, or if any part of the device appears to be damaged
- Do not leave the Actemra device unattended. Keep out of the reach of children.
- Stop administration of Actemra immediately if an anaphylactic reaction or other serious hypersensitivity reaction occurs. Initiate appropriate therapy and permanently discontinue Actemra.

INJECTION PREPARATION: ACTEMRA PRE-FILLED SYRINGE

Actemra 162 mg is supplied in 0.9 ml of solution for injection as a pack of 4 single-use pre-filled syringes,

They should be kept in the outer carton to protect them from light and should be kept dry. The pre-filled syringes should be kept out of sight and reach of children.

- Allow the pre-filled syringe to reach room temperature and wait for about 25 to 30 minutes before injecting Actemra 162 mg/0.9 ml.
- Start the injection within 5 minutes after removing the cap, to prevent the medicine from drying out and blocking the needle.

4 CHOOSE AND PREPARE AN INJECTION SITE

- Wash your hands well with soap and water
- Clean the chosen injection site area using the alcohol pad to reduce the risk of infection. 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. Let the skin dry for approximately 10 seconds. Do not touch the injection site again before giving the injection
- Do not fan or blow on the clean area.
- **Injection Site for the PFS**
    - **PFS:**
        - 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 centimeter area directly around the navel. (**See Fig. C**)
        - If a caregiver is giving the injection, the outer area of the upper arms may also be used. (**See Fig. C**)

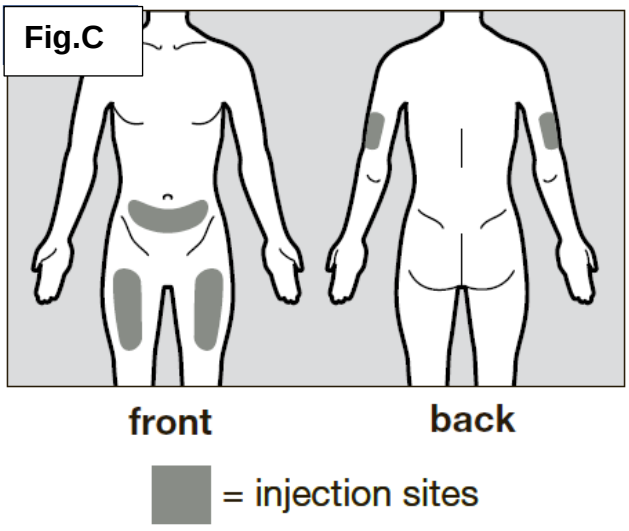


Figure C

- You should use a different place each time you give yourself an injection, at least three centimeters from the area you used for your previous injection.

        - Do not inject into areas that could be bothered by a belt or waistband. Do not inject into moles, scars, bruises, or areas where the skin is tender, red, hard or not intact.

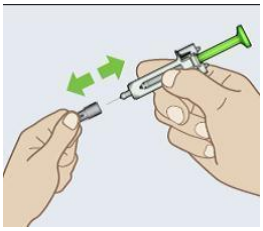
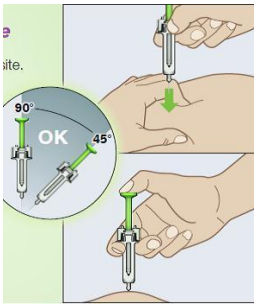
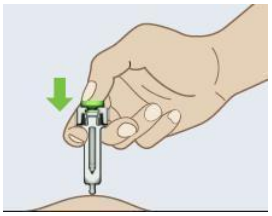
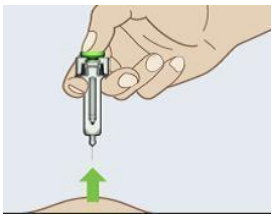
- **Rotate Injection Site**
    - Choose a different injection site for each new injection at least:
    - **PFS: 1.5 inch (3 cm) from the area you used for your previous injection.**
- Do not inject into moles, scars, bruises, or areas where the skin is tender, red, hard or not intact. Do not inject into areas that could be bothered by a belt or waistband.

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. Let the skin dry for approximately 10 seconds. **Do not** touch the injection site again before giving the injection.
- **Do not** fan or blow on the clean area.

5 ADMINISTERING THE INJECTION

ADMINISTRATION: ACTEMRA PRE-FILLED SYRINGE

1. Do not shake the pre-filled syringe. Remove the needle-cap and firmly grip the syringe with one hand. Do not pull or press the plunger. Pull the cap straight off with the other hand. After removing the needle-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 removing the cap, you must dispose of it in a puncture-resistant container and use a new pre-filled syringe. Never re-attach the needle-cap after removal.	
2. Pinch a fold of loose skin at the injection site to provide a firm surface for injection. Insert the needle with a quick, firm action. The needle may be inserted at an angle between 45° to 90°. Insert the needle all the way in. Then keep the syringe in position and let go of the pinched skin.	
3. Slowly inject all the medicine by gently pushing the plunger all the way down. When the plunger is all the way down, keep pressing down to be sure all the medication has been injected. Dispose of the pre-filled syringe in a puncture-resistant container and use a new pre-filled syringe if you cannot depress the plunger after you insert the needle.	
4. Keep the plunger pushed down while you take the needle out of the skin at the same angle it was inserted.	
5. Release the plunger, once the needle is completely removed from the skin, allowing the needle-shield to protect the needle. Throw away the used syringe in a puncture-resistant container or sharps container. 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.	

- 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.

6 DISPOSE OF THE ACTEMRA DEVICE

- **Do not** put the cap back on the Actemra device.
- Put the used uncapped Actemra device directly into the sharps container
    - **Do not throw away (dispose of) the device in your household trash and do not recycle it**
    - Always keep the sharps container and Actemra device out of the sight and reach of children

7 RECORD YOUR INJECTION

Product traceability

In order to improve the traceability of biological medicinal products, the tradename and batch number of the administered product should be clearly recorded (or stated) in the patient file.

Call for reporting

If the patient experiences any side effects, talk to the doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

By reporting side effects, you or the patient can help provide more information on the safety of this medicine.

Please report any suspected adverse reactions associated with the use of Actemra(Tocilizumab) in accordance with the national requirements via the national spontaneous reporting system, to:

Roche Products Saudi Arabia L.L.C.
Direct Tel. +966 12 211 4618
Mobile: +966 56 784 4692
Email: jeddah.drug_safety@roche.com
Local Safety Responsible: doha.samargandi@roche.com
www.roche.com

Or report to:

The National Pharmacovigilance and Drug Safety Centre (NPC)
Land Line: 19999.
Website: https//:ade.sfda.gov.sa
Email: npc.drug@sfda.g

For full information on all possible side effects please see the Actemra Package Leaflet.

[Health Authority Approval Date: XX-XXXX]