

# Actemra

# DOSING GUIDE

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

- Rheumatoid Arthritis [Intravenous]
- Polyarticular Juvenile Idiopathic Arthritis (also referred to as Juvenile Idiopathic Polyarthritis) [Intravenous]
- Systemic Juvenile Idiopathic Arthritis [Intravenous]

*Dosing Guide for Actemra® (tocilizumab) (IV) for RA, pJIA and sJIA*

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This Actemra Dosing Guide is a requirement of the Actemra product license and 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 [available online at [www.pharm.am](http://www.pharm.am) and the Actemra Labeling/Summary of Product Characteristics that comes with Actemra (and is also available on [www.pharm.am](http://www.pharm.am) 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 and extended oligoarthritis) 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.

**Prior to starting treatment with Actemra:**

- It is important that you review the pre-administration checklist found in the Patient Brochure: *What You Should Know About Actemra* with your patient, the patient's parents/guardians, or both.
- Allow sample time to discuss any questions your patient, the patient's parents/guardians, or both may have.

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- It is important that you review the information contained within the *Important Efficacy and Safety Information for Healthcare Professionals* for Actemra® (tocilizumab) intravenous (IV) formulations and the Patient Brochure: *What You Should Know About Actemra* 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.

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For full information, see the Summary of Product Characteristics (SmPC) and the Actemra Package Leaflet: Information for the user, which can be found on the site of “Scientific Centre of Drug and Medical Technology Expertise after academician E.Gabrielyan” CJSC website: [www.pharm.am](http://www.pharm.am). There also available Patient Information Leaflet and Summary of Product Characteristics. In case of any question you may contact via the phone: (+374 10) 20 05 05 l (+374 96) 22 05 05.

Actemra Patient Brochures and other information can be requested from company representative. If you have questions or concerns, please call +374 91796688 to Gayane Ghazaryan or 37491721153, Nune Karapetyan.

## **1. PART I – INTRAVENOUS (IV) ADMINISTRATION OF ACTEMRA BY INFUSION**

**1 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:

**1.1.2**  **100 mg (20 ml) vials**      **2**  **mg (10 ml) vials**      **80 m**  **4 ml) vials**

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

#### **1.1.2.1 RA: Dosing Preparation and Administration Guide with Actemra IV**

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

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

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

## Dosing Guide for Actemra® (tocilizumab) (IV) for RA, pJIA and sJIA

8 mg/kg dose				
Weight (kg)	Weight (lbs)	Dose (mg)	Dose (mL)	Vial combinations
50	110.0	400	20.0	1 red vial
52	114.4	416	20.8	1 red vial + 1 green vial
54	118.8	432	21.6	1 red vial + 1 green vial
56	123.2	448	22.4	1 red vial + 1 green vial
58	127.6	464	23.2	1 red vial + 1 green vial
60	132.0	480	24.0	1 red vial + 1 green vial
62	136.4	496	24.8	1 yellow vial + 1 green vial + 1 green vial + 1 green vial + 1 green vial
64	140.8	512	25.6	1 yellow vial + 1 green vial + 1 green vial + 1 green vial + 1 green vial
66	145.2	528	26.4	1 red vial + 1 green vial + 1 green vial
68	149.6	544	27.2	1 red vial + 1 green vial + 1 green vial
70	154.0	560	28.0	1 red vial + 1 green vial + 1 green vial
72	158.4	576	28.8	1 red vial + 1 yellow vial
74	162.8	592	29.6	1 red vial + 1 yellow vial
76	167.2	608	30.4	1 red vial + 1 green vial + 1 green vial + 1 green vial
78	171.6	624	31.2	1 red vial + 1 green vial + 1 green vial + 1 green vial
80	176.0	640	32.0	1 red vial + 1 green vial + 1 green vial + 1 green vial
82	180.4	656	32.8	1 red vial + 1 yellow vial + 1 green vial
84	184.8	672	33.6	1 red vial + 1 yellow vial + 1 green vial
86	189.2	688	34.4	1 red vial + 1 green vial + 1 green vial + 1 green vial + 1 green vial
88	193.6	704	35.2	1 red vial + 1 green vial + 1 green vial + 1 green vial + 1 green vial
90	198.0	720	36.0	1 red vial + 1 green vial + 1 green vial + 1 green vial + 1 green vial
92	202.4	736	36.8	1 red vial + 1 yellow vial + 1 green vial + 1 green vial
94	206.8	752	37.6	1 red vial + 1 yellow vial + 1 green vial + 1 green vial
96	211.2	768	38.4	1 red vial + 1 red vial
98	215.6	784	39.2	1 red vial + 1 red vial
≥100	≥220.0	800	40.0	1 red vial + 1 red vial

## 1.1.2.4 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

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	Weight (kg)	Weight (lbs)	Dose (mg)	Dose (ml)	Vial combinations
10 mg/kg	10	22.0	100	5.0	100 mg/50 mL
	12	26.4	120	6.0	100 mg/50 mL + 20 mg/10 mL
	14	30.8	140	7.0	100 mg/50 mL + 40 mg/20 mL
	16	35.2	160	8.0	100 mg/50 mL + 60 mg/30 mL
	18	39.6	180	9.0	100 mg/50 mL + 80 mg/40 mL
	20	44.0	200	10.0	100 mg/50 mL + 100 mg/50 mL
	22	48.4	220	11.0	100 mg/50 mL + 120 mg/60 mL
	24	52.8	240	12.0	100 mg/50 mL + 140 mg/70 mL
	26	57.2	260	13.0	100 mg/50 mL + 160 mg/80 mL
	28	61.6	280	14.0	100 mg/50 mL + 180 mg/90 mL
8 mg/kg	30	66.0	240	12.0	100 mg/50 mL + 140 mg/70 mL
	32	70.4	256	12.8	100 mg/50 mL + 156 mg/78 mL
	34	74.8	272	13.6	100 mg/50 mL + 172 mg/86 mL
	36	79.2	288	14.4	100 mg/50 mL + 188 mg/94 mL
	38	83.6	304	15.2	100 mg/50 mL + 204 mg/102 mL
	40	88.0	320	16.0	100 mg/50 mL + 220 mg/110 mL
	42	92.4	336	16.8	100 mg/50 mL + 236 mg/118 mL
	44	96.8	352	17.6	100 mg/50 mL + 252 mg/126 mL
	46	101.2	368	18.4	100 mg/50 mL + 268 mg/134 mL
	48	105.6	384	19.2	100 mg/50 mL + 284 mg/142 mL
	50	110.0	400	20.0	100 mg/50 mL + 300 mg/150 mL
	52	114.4	416	20.8	100 mg/50 mL + 316 mg/158 mL
	54	118.8	432	21.6	100 mg/50 mL + 332 mg/166 mL
	56	123.2	448	22.4	100 mg/50 mL + 348 mg/174 mL
	58	127.6	464	23.2	100 mg/50 mL + 364 mg/182 mL
	60	132.0	480	24.0	100 mg/50 mL + 380 mg/190 mL
	62	136.4	496	24.8	100 mg/50 mL + 396 mg/198 mL
	64	140.8	512	25.6	100 mg/50 mL + 412 mg/206 mL
	66	145.2	528	26.4	100 mg/50 mL + 428 mg/214 mL
	68	149.6	544	27.2	100 mg/50 mL + 444 mg/222 mL
	70	154.0	560	28.0	100 mg/50 mL + 460 mg/230 mL
	72	158.4	576	28.8	100 mg/50 mL + 476 mg/238 mL
	74	162.8	592	29.6	100 mg/50 mL + 492 mg/246 mL
	76	167.2	608	30.4	100 mg/50 mL + 508 mg/254 mL
	78	171.6	624	31.2	100 mg/50 mL + 524 mg/262 mL
	80	176.0	640	32.0	100 mg/50 mL + 540 mg/270 mL
	82	180.4	656	32.8	100 mg/50 mL + 556 mg/278 mL
	84	184.8	672	33.6	100 mg/50 mL + 572 mg/286 mL
	86	189.2	688	34.4	100 mg/50 mL + 588 mg/294 mL
	88	193.6	704	35.2	100 mg/50 mL + 604 mg/302 mL
90	198.0	720	36.0	100 mg/50 mL + 620 mg/310 mL	
92	202.4	736	36.8	100 mg/50 mL + 636 mg/318 mL	
94	206.8	752	37.6	100 mg/50 mL + 652 mg/326 mL	
96	211.2	768	38.4	100 mg/50 mL + 668 mg/334 mL	
98	215.6	784	39.2	100 mg/50 mL + 684 mg/342 mL	
≥100	≥220.0	800	40.0	100 mg/50 mL + 700 mg/350 mL	

### 1.1.2.5 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:



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

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**For patients weighing  $\geq 30$  kg: Patient's weight (kg) x 8 mg/kg = Actemra dose**

**For patients weighing  $\geq 30$  kg: Patient's weight (kg) x 8 mg/kg = RoActemra dose**

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

## **2 GATHER ALL NECESSARY SUPPLIES**

You will need:

Actemra, at room temperature

Syringes and large-bore needles

One primary infusion set

One 100 ml 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

- 1.1.2.6 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: *What You Should Know About Actemra* 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.

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- 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**

**1.1.2.7 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.**

Monitor the patient for infusion related reactions.

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

1.1.4

**7 RECORD YOUR INJECTION****1.1.4.1 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.

**1.1.4.2 Call for reporting**

**1.1.4.3 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.**

**1.1.4.4 You can also report side effects directly via [the national reporting system]. By reporting side effects, you or the patient can help provide more information on the safety of this medicine.**

Please report side-effects or if you If you need additional copies of the Patient or HCP Guides or have information on adverse event you may contact with the Scientific Centre of Drug and Medical Technology Expertise after academician Emil Gabrielyan via

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contacts presented below: address: RA, Yerevan 0051, 49/5 Komitas avenue, tel.: (374 60) 830073, (+374 10) 230896, hot line: (+374 10) 200505; (+374 96) 220505; or email: vigilance@pharm.am; or via website: www.pharm.am.

**1.2 COMPANY CONTACT POINT**

Should you have any questions regarding to this, please contact to Gayane Ghazaryan, Local person for Pharmacovigilance for Hoffmann-La Roche products in Armenia Acti Group LLC., via mob.: +374 91 796688 or email address: gayaneh.ghazaryan@gmail.com; or Nune Karapetyan, Local backup for Pharmacovigilance of Roche Products in Armenia, via mob.: +374 91 721153 or email address: nune.karapetyan.roche@gmail.com.

Also you may contact to Local Safety Responsible, Roche Georgia LLC via tel: +995 322 506284, +995 322 507284 or emailing to georgia.safety@roche.com.

Gayane Ghazaryan *Gayane Ghazaryan*  
Local person for Pharmacovigilance for Hoffmann- La Roche products in Armenia, Acti Group LLC.

Nino Ganugrava *Nino Ganugrava*  
Country Medical Director for Georgia/Armenia, Roche Georgia LLC.

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