

# RoActemra® (tocilizumab) intravenous (IV) dosing for Polyarticular Juvenile Idiopathic Arthritis (pJIA)

This educational material is provided by Roche Products Limited and is mandatory as a condition of the Marketing Authorisation in order to minimise important selected risks

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

RoActemra IV is available in three different dosing vials:

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

	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	+	

# RoActemra IV is available in 3 different dosing vials.

 400 mg (20 ml) vials

 200 mg (10 ml) vials

 80 mg (4 ml) vials

## pJIA

### 1. Calculate the appropriate dose

RoActemra IV dosing should be calculated based on the patient's body weight at each administration. Verify the patient's weight, then locate it on the chart to find the corresponding dose and recommended vial combination.

Dosing in pJIA patients is based on the following formulae:

#### For patients weighing <30 kg

Patient's weight (kg) x 10 = RoActemra dose (mg)

#### For patients weighing ≥30 kg

Patient's weight (kg) x 8 = RoActemra dose (mg)

Dosing should take place at 4-week intervals. The dose should be calculated based on the patient's body weight at each administration. A change in dose should only be based on a consistent change in the patient's body weight over time.

### 2. Choose the vial combination of RoActemra that best matches your patient's needs

RoActemra IV is available in three different dosing vials:

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

RoActemra for pJIA is administered as a 60-minute, IV infusion at 4-week intervals.

#### Infusion reactions

During the infusion, watch the patient closely for any signs and symptoms of hypersensitivity, including anaphylaxis. If an anaphylactic reaction or other serious hypersensitivity reaction occurs, administration of RoActemra should be stopped immediately, appropriate therapy initiated and RoActemra permanently discontinued.

## sJIA

### 1. Calculate the appropriate dose

RoActemra IV dosing should be calculated based on the patient's body weight at each administration. Verify the patient's weight, then locate it on the chart to find the corresponding dose and recommended vial combination.

Dosing in sJIA patients is based on the following formulae:

#### For patients weighing <30 kg

Patient's weight (kg) x 12 = RoActemra dose (mg)

#### For patients weighing ≥30 kg

Patient's weight (kg) x 8 = RoActemra dose (mg)

Dosing should take place at 4-week intervals. The dose should be calculated based on the patient's body weight at each administration. A change in dose should only be based on a consistent change in the patient's body weight over time.

### 2. Choose the vial combination of RoActemra that best matches your patient's needs

RoActemra IV is available in three different dosing vials:

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

RoActemra for sJIA is administered as a 60-minute, IV infusion at 2-week intervals.

#### Infusion reactions

During the infusion, watch the patient closely for any signs and symptoms of hypersensitivity, including anaphylaxis. If an anaphylactic reaction or other serious hypersensitivity reaction occurs, administration of RoActemra should be stopped immediately, appropriate therapy initiated and RoActemra permanently discontinued.

Full prescribing information can be found in the RoActemra IV Summary of Product Characteristics (SmPC) via the electronic Medicines Compendium (eMC) website: [www.medicines.org.uk](http://www.medicines.org.uk).

If you have any further questions relating to RoActemra please contact Roche Medical Information on +44(0)1707 361010 or email: [medinfo.uk@roche.com](mailto:medinfo.uk@roche.com).



Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Reporting forms and information can be found at [www.medicinesauthority.gov.uk/adrportal](http://www.medicinesauthority.gov.uk/adrportal). Adverse events should also be reported to Roche Products Ltd. Please contact Roche Drug Safety Centre by emailing [welwyn.uk\\_dsc@roche.com](mailto:welwyn.uk_dsc@roche.com) or calling +44(0)1707 367554.

As RoActemra is a biological medicine, healthcare professionals should report adverse reactions by brand name and batch number.

# Roactemra® (tocilizumab) intravenous (IV) dosing for Systemic Juvenile Idiopathic Arthritis (sJIA)

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Roactemra IV, 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 non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Roactemra IV can be given as monotherapy (in case of intolerance to methotrexate [MTX] or where treatment with MTX is inappropriate) or in combination with MTX.

Roactemra IV is available in three different dosing vials:

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

Weight (kg)	Weight (lbs)	Dose (mg)	Dose (ml)	Vial combinations
10	22.0	120	6.0	 + 
12	26.4	144	7.2	 + 
14	30.8	168	8.4	
16	35.2	192	9.6	
18	39.6	216	10.8	 + 
20	44.0	240	12.0	 + 
22	48.4	264	13.2	 + 
24	52.8	288	14.4	 + 
26	57.2	312	15.6	 + 
28	61.6	336	16.8	 + 
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	 + 
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66	145.2	528	26.4	 + 
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70	154.0	560	28.0	 + 
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74	162.8	592	29.6	 + 
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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	 + 

8 mg/kg

12 mg/kg