

ACTEMRA DOSING

1

Calculate the appropriate dose

ACTEMRA dosing is calculated based on the individual patient's weight. Verify the patient's weight and then locate it on the chart to find the corresponding dose and recommended vial combination.

If the dose has been previously calculated, check the patient's weight to make sure a dosage change is not needed. If there has been a significant change in weight, please consult the provider.

2

Choose the vial combination of ACTEMRA that best matches your patient's needs

ACTEMRA is available in 3 different dosing vials:

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

ACTEMRA is administered as a 1-hour, single-drip IV infusion.

Infusion Reactions

During the infusion, watch the patient carefully for any hypersensitivity reactions. If you believe the patient is experiencing a reaction to the infusion, immediately stop the infusion and call their physician.

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

8 mg / kg dose				
Weight (kg)	Weight (lbs)	Dose (mg)	Dose (mL)	Vial Combinations
10	22	80	4	80 mg (4 mL)
12	26.4	96	4.8	80 mg (4 mL) + 16 mg (4 mL)
14	30.8	112	5.6	80 mg (4 mL) + 32 mg (8 mL)
16	35.2	128	6.4	80 mg (4 mL) + 48 mg (12 mL)
18	39.6	144	7.2	80 mg (4 mL) + 64 mg (16 mL)
20	44	160	8	80 mg (4 mL) + 80 mg (8 mL)
22	48.4	176	8.8	200 mg (10 mL)
24	52.8	192	9.6	200 mg (10 mL)
26	57.2	208	10.4	80 mg (4 mL) + 120 mg (12 mL)
28	61.6	224	11.2	80 mg (4 mL) + 160 mg (16 mL)
30	66	240	12	80 mg (4 mL) + 200 mg (20 mL)
32	70.4	256	12.8	200 mg (10 mL) + 56 mg (5.6 mL)
34	74.8	272	13.6	200 mg (10 mL) + 72 mg (7.2 mL)
36	79.2	288	14.4	80 mg (4 mL) + 200 mg (20 mL) + 8 mg (4 mL)
38	83.6	304	15.2	80 mg (4 mL) + 240 mg (24 mL)
40	88	320	16	80 mg (4 mL) + 280 mg (28 mL)
42	92.4	336	16.8	200 mg (10 mL) + 136 mg (13.6 mL)
44	96.8	352	17.6	200 mg (10 mL) + 152 mg (15.2 mL)
46	101.2	368	18.4	400 mg (20 mL)
48	105.6	384	19.2	400 mg (20 mL)
50	110	400	20	400 mg (20 mL)
52	114.4	416	20.8	200 mg (10 mL) + 216 mg (21.6 mL)
54	118.8	432	21.6	200 mg (10 mL) + 232 mg (23.2 mL)
56	123.2	448	22.4	400 mg (20 mL) + 48 mg (4.8 mL)
58	127.6	464	23.2	400 mg (20 mL) + 64 mg (6.4 mL)
60	132.0	480	24.0	400 mg (20 mL) + 80 mg (8 mL)

8 mg / kg dose				
Weight (kg)	Weight (lbs)	Dose (mg)	Dose (mL)	Vial Combinations
62	136.4	496	24.8	400 mg (20 mL) + 96 mg (9.6 mL)
64	140.8	512	25.6	400 mg (20 mL) + 112 mg (11.2 mL)
66	145.2	528	26.4	400 mg (20 mL) + 128 mg (12.8 mL)
68	149.6	544	27.2	400 mg (20 mL) + 144 mg (14.4 mL)
70	154.0	560	28.0	400 mg (20 mL) + 160 mg (16 mL)
72	158.4	576	28.8	400 mg (20 mL) + 176 mg (17.6 mL)
74	162.9	592	29.6	400 mg (20 mL) + 192 mg (19.2 mL)
76	167.2	608	30.3	400 mg (20 mL) + 208 mg (20.8 mL)
78	171.6	624	31.2	400 mg (20 mL) + 224 mg (22.4 mL)
80	176.0	640	32.0	400 mg (20 mL) + 240 mg (24 mL)
82	180.4	656	32.8	400 mg (20 mL) + 256 mg (25.6 mL)
84	184.9	672	33.6	400 mg (20 mL) + 272 mg (27.2 mL)
86	189.2	688	34.4	400 mg (20 mL) + 288 mg (28.8 mL)
88	193.6	704	35.2	400 mg (20 mL) + 304 mg (30.4 mL)
90	198.0	720	36.0	400 mg (20 mL) + 320 mg (32 mL)
92	202.4	736	36.8	400 mg (20 mL) + 336 mg (33.6 mL)
94	206.9	752	37.6	400 mg (20 mL) + 352 mg (35.2 mL)
96	211.2	768	38.4	400 mg (20 mL) + 368 mg (36.8 mL)
98	215.6	784	39.2	400 mg (20 mL) + 384 mg (38.4 mL)
100	220.0	800	40.0	400 mg (20 mL) + 400 mg (40 mL)
102	224.4	816	40.8	400 mg (20 mL) + 416 mg (41.6 mL)
104	228.8	832	41.6	400 mg (20 mL) + 432 mg (43.2 mL)
106	233.2	848	42.4	400 mg (20 mL) + 448 mg (44.8 mL)
108	237.6	864	43.2	400 mg (20 mL) + 464 mg (46.4 mL)
110	242.0	880	44.0	400 mg (20 mL) + 480 mg (48 mL)
112	246.4	896	44.8	400 mg (20 mL) + 496 mg (49.6 mL)

Dosing calculation: Patient's weight (kg) X 8 (mg/kg) = ACTEMRA dose

ACTEMRA Important Safety Information

Therapeutic indications

ACTEMRA, in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe active rheumatoid arthritis (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.

Contraindications

Hypersensitivity to the active substance or to any of the excipients.

Active, severe infections.

Infections

ACTEMRA treatment should not be initiated in patients with active infections. Administration of ACTEMRA should be interrupted if a patient develops a serious infection until the infection is controlled. Healthcare professionals should exercise caution when considering the use of ACTEMRA in patients with a history of recurring or chronic infections or with underlying conditions (eg, diverticulitis, diabetes) which may predispose patients to infections.

Vigilance for the timely detection of serious infections is recommended for patients receiving biological treatments for moderate to severe RA as signs and symptoms of acute inflammation may be lessened, associated with suppression of the acute phase reaction. The effects of ACTEMRA on C-reactive protein (CRP), neutrophils and signs and symptoms of infection should be considered when evaluating a patient for a potential infection. Patients should be instructed to contact their healthcare professional immediately when any symptoms suggesting infection appear, in order to assure rapid evaluation and appropriate treatment.

Tuberculosis

As recommended for other biological treatments in RA, patients should be screened for latent tuberculosis (TB) infection prior to starting ACTEMRA therapy. Patients with latent TB should be treated with standard anti-mycobacterial therapy before initiating ACTEMRA.

Complications of diverticulitis

Events of diverticular perforations as complications of diverticulitis have been reported uncommonly with ACTEMRA. ACTEMRA should be used with caution in patients with previous history of intestinal ulceration or diverticulitis. Patients presenting with symptoms potentially indicative of complicated diverticulitis, such as abdominal pain, haemorrhage and/or unexplained change in bowel habits with fever should be evaluated promptly for early identification of diverticulitis which can be associated with gastrointestinal perforation.

Hypersensitivity reactions

Serious hypersensitivity reactions have been reported in association with infusion of ACTEMRA in approximately 0.3% of patients. Appropriate treatment should be available for immediate use in the event of an anaphylactic reaction during administration of ACTEMRA.

Active hepatic disease and hepatic impairment

Treatment with ACTEMRA, particularly when administered concomitantly with MTX, may be associated with elevations in hepatic transaminases. Therefore, caution should be exercised when considering treatment of patients with active hepatic disease or hepatic impairment, as the safety of ACTEMRA in these patients has not been adequately studied.

Hepatic transaminase elevations

In clinical trials, transient or intermittent mild and moderate elevations of hepatic transaminases have been reported commonly with ACTEMRA treatment, without progression to hepatic injury. An increased frequency of these elevations was observed when potentially hepatotoxic drugs (eg, MTX) were used in combination with ACTEMRA.

Caution should be exercised when considering initiation of ACTEMRA treatment in patients with elevated alanine aminotransferase (ALT) or aspartate aminotransferase (AST) > 1.5 x upper limit of normal (ULN). In patients with baseline ALT or AST > 5 x ULN, treatment is not recommended.

ALT and AST levels should be monitored every 4 to 8 weeks for the first 6 months of treatment followed by every 12 weeks thereafter. For ALT or AST elevations > 3-5 x ULN, confirmed by repeat testing, ACTEMRA treatment should be interrupted. Once the patient's hepatic transaminases are below 3 x ULN, treatment with ACTEMRA may recommence at 4 or 8 mg/kg.

Haematological abnormalities

Decreases in neutrophil and platelet counts have occurred following treatment with ACTEMRA 8 mg/kg in combination with MTX. There may be an increased risk of neutropenia in patients who have previously been treated with a TNF antagonist.

Caution should be exercised when considering initiation of ACTEMRA treatment in patients with a low neutrophil or platelet count (ie, absolute neutrophil count (ANC) < 2 x 10⁹/L or platelet count below 100 x 10⁹/L). In patients with an ANC < 0.5 x 10⁹/L or a platelet count < 50 x 10⁹/L treatment is not recommended.

Neutrophils and platelets should be monitored 4 to 8 weeks after start of therapy and thereafter according to standard clinical practice.

Lipid parameters

Elevations in lipid parameters including total cholesterol, low-density lipoprotein (LDL), high-density lipoprotein (HDL) and triglycerides were observed in patients treated with ACTEMRA. In the majority of patients, there was no increase in atherogenic indices, and elevations in total cholesterol responded to treatment with lipid lowering agents.

Assessment of lipid parameters should be performed 4 to 8 weeks following initiation of ACTEMRA therapy. Patients should be managed according to local clinical guidelines for management of hyperlipidaemia.

Neurological disorders

Physicians should be vigilant for symptoms potentially indicative of new-onset central demyelinating disorders. The potential for central demyelination with ACTEMRA is currently unknown.

Malignancy

The risk of malignancy is increased in patients with RA. Immunomodulatory medicinal products may increase the risk of malignancy.

Vaccinations

Live and live attenuated vaccines should not be given concurrently with ACTEMRA as clinical safety has not been established.

Cardiovascular risk

RA patients have an increased risk for cardiovascular disorders and should have risk factors (eg, hypertension, hyperlipidaemia) managed as part of usual standard of care.

Combination with TNF antagonists

There is no experience with the use of ACTEMRA with TNF antagonists or other biological treatments for RA. ACTEMRA is not recommended for use with other biological agents.

Sodium

This medicinal product contains 1.17 mmol (or 26.55 mg) sodium per maximum dose of 1200 mg. To be taken into consideration by patients on a controlled sodium diet. Doses below 1025 mg of this medicinal product contain less than 1 mmol sodium (23 mg), i.e. essentially 'sodium free'.

Undesirable effects

The most commonly reported adverse drug reactions (occurring in ≥5% of patients treated with ACTEMRA monotherapy or in combination with DMARDs) were upper respiratory tract infections, nasopharyngitis, headache, hypertension and increased ALT.

ACTEMRA[®]
tocilizumab

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