

# RoACTEMRA DOSING

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## Calculate the appropriate dose




RoACTEMRA 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.

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

RoACTEMRA is available in 3 different dosing vials:













































































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

RoACTEMRA 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.

## 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	 + 

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

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

## RoACTEMRA® (tocilizumab) Important Safety Information

### Therapeutic indications

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

RoACTEMRA 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.

### Contraindications

Hypersensitivity to the active substance or to any of the excipients. Active, severe infections.

### Infections

RoACTEMRA treatment should not be initiated in patients with active infections. Administration of RoACTEMRA 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 RoACTEMRA 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 infection 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 RoACTEMRA 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 RoACTEMRA therapy. Patients with latent TB should be treated with standard anti-mycobacterial therapy before initiating RoACTEMRA.

### Viral reactivation

Viral reactivation (eg, hepatitis B virus) has been reported with biologic therapies for rheumatoid arthritis. In clinical studies with tocilizumab, patients who screened positive for hepatitis were excluded.

### Complications of diverticulitis

Events of diverticular perforations as complications of diverticulitis have been reported uncommonly with RoACTEMRA. RoACTEMRA 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 RoACTEMRA in approximately 0.3% of patients. Appropriate treatment should be available for immediate use in the event of an anaphylactic reaction during administration of RoACTEMRA.

### Active hepatic disease and hepatic impairment

Treatment with RoACTEMRA, 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.

### Hepatic transaminase elevations

In clinical trials, transient or intermittent mild and moderate elevations of hepatic transaminases have been reported commonly with RoACTEMRA 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 RoACTEMRA.

Caution should be exercised when considering initiation of RoACTEMRA 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, RoACTEMRA treatment should be interrupted.

### Haematological abnormalities

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

Caution should be exercised when considering initiation of RoACTEMRA treatment in patients with a low neutrophil or platelet count (ie, absolute neutrophil count (ANC) <2 x 10<sup>9</sup>/L or platelet count below 100 x 10<sup>9</sup>/μL). In patients with an ANC <0.5 x 10<sup>9</sup>/L or a platelet count <50 x 10<sup>9</sup>/μL treatment is not recommended.

Severe neutropenia may be associated with an increased risk of serious infections, although there has been no clear association between decreases in neutrophils and the occurrence of serious infections in clinical trials with RoACTEMRA to date.

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 RoACTEMRA. 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 RoACTEMRA 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 RoACTEMRA 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 RoACTEMRA 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 RoACTEMRA with TNF antagonists or other biological treatments for RA. RoACTEMRA 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), ie, essentially 'sodium free'.

### Pregnancy

There are no adequate data from the use of RoACTEMRA in pregnant women. A study in animals has shown an increased risk of spontaneous abortion/embryo-foetal death at a high dose. The potential risk for humans is unknown. Women of childbearing potential must use effective contraception during and up to 3 months after treatment.

RoACTEMRA should not be used during pregnancy unless clearly necessary.

### Lactation

It is unknown whether RoACTEMRA is excreted in human breast milk. The excretion of RoACTEMRA in milk has not been studied in animals. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with RoACTEMRA should be made taking into account the benefit of breast-feeding to the child and the benefit of RoACTEMRA therapy to the woman.

### Undesirable effects

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

 **RoACTEMRA**<sup>®</sup>  
tocilizumab

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