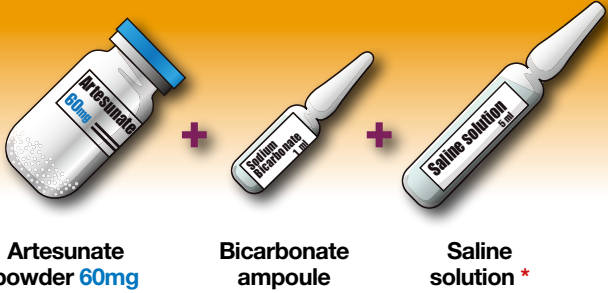


GUIDELINES FOR ADMINISTRATION OF INJECTABLE ARTESUNATE FOR SEVERE MALARIA



PRODUCT DESCRIPTION ¹

Dose: For children < 20 kg: 3.0 mg/kg
For children > 20 kg and adults: 2.4 mg/kg

Can be given by intravenous route (IV) or intramuscular route (IM). IV is the preferred route of administration. Please refer to the patient information leaflet for more information.

*** Water for injection is not an appropriate dilutant**

1 WEIGH THE PATIENT

2 DETERMINE THE NUMBER OF VIALS NEEDED

Weight	less than 25 kg	26-50 kg	51-75 kg	76-100 kg
60 mg vial	1	2	3	4

3 RECONSTITUTE

■ Activate the drug: artesunate powder + bicarbonate ampoule (immediately before use)

A

Artesunate powder + bicarbonate ampoule

B

Inject full contents of bicarbonate ampoule (1 ml) into artesunate vial.

C

Shake until dissolved. Solution will be cloudy.

D

The reconstituted solution will clear in about 2 mins. Discard if not clear.

4 DILUTE

■ Reconstituted artesunate + saline solution (or dextrose 5%)

■ Volume for dilution

	IV	IM
Bicarbonate solution volume	1 ml	1 ml
Saline solution volume	5 ml	2 ml
Total volume	6 ml	3 ml
Artesunate 60 mg solution concentration	10 mg/ml	20 mg/ml

IMPORTANT

Water for injection is not an appropriate dilutant

A

Artesunate reconstituted + saline solution

B

Withdraw all the air from the vial.

C

Inject required volume of saline into the reconstituted solution.

D

Artesunate solution is now ready for use.

5 CALCULATE THE DOSE

■ Calculate and withdraw the required dose in ml according to route of administration:

For intravenous route (IV)

Concentration: 10 mg/ml

3.0 mg x body weight (kg)

IV artesunate solution concentration **10 mg/ml**

Round up to the next whole number

Example:

Dose needed (ml) for 8 kg child:

$$\frac{3.0 \times 8}{10} = 2.4 \text{ ml}$$

2.4 ml rounded up to **3 ml**

Weight kg	Dose	
	mg	ml
6 - 7	20	2
8 - 10	30	3
11 - 13	40	4
14 - 16	50	5
17 - 20	60	6

For intramuscular route (IM)

Concentration: 20 mg/ml

3.0 mg x body weight (kg)

IM artesunate solution concentration **20 mg/ml**

Round up to the next whole number

Example:

Dose needed (ml) for 8 kg child:

$$\frac{3.0 \times 8}{20} = 1.2 \text{ ml}$$

1.2 ml rounded up to **2 ml**

Weight kg	Dose	
	mg	ml
6 - 7	20	1
8 - 10	30	2
11 - 13	40	2
14 - 16	50	3
17 - 20	60	3

Concentration: 10 mg/ml

2.4 mg x body weight (kg)

IV artesunate solution concentration **10 mg/ml**

Round up to the next whole number

Example:

Dose needed (ml) for 26 kg child:

$$\frac{2.4 \times 26}{10} = 6.24 \text{ ml}$$

6.24 ml rounded up to **7 ml**

Weight kg	Dose	
	mg	ml
20 - 25	60	6
26 - 29	70	7
30 - 33	80	8
34 - 37	90	9
38 - 41	100	10
42 - 45	110	11
46 - 50	120	12
51 - 54	130	13
55 - 58	140	14
59 - 62	150	15
63 - 66	160	16
67 - 70	170	17
71 - 75	180	18
76 - 79	190	19
80 - 83	200	20
84 - 87	210	21
88 - 91	220	22
92 - 95	230	23
96 - 100	240	24

Concentration: 20 mg/ml

2.4 mg x body weight (kg)

IM artesunate solution concentration **20 mg/ml**

Round up to the next whole number

Example:

Dose needed (ml) for 26 kg child:

$$\frac{2.4 \times 26}{20} = 3.12 \text{ ml}$$

3.12 ml rounded up to **4 ml**

Weight kg	Dose	
	mg	ml
20 - 25	60	3
26 - 29	70	4
30 - 33	80	4
34 - 37	90	5
38 - 41	100	5
42 - 45	110	6
46 - 50	120	6
51 - 54	130	7
55 - 58	140	7
59 - 62	150	8
63 - 66	160	8
67 - 70	170	9
71 - 75	180	9
76 - 79	190	10
80 - 83	200	10
84 - 87	210	11
88 - 91	220	11
92 - 95	230	12
96 - 100	240	12

6 ADMINISTER

IV: slow bolus 3-4 ml per minute.

IM: Inject slowly. Spread the doses of more than 2 ml over different sites for babies and 5 ml for adults.

7 DOSING SCHEDULE

- Give **3 parenteral doses** over 24 hours as indicated in the opposite table
 - Give **parenteral doses** for a minimum of 24 hours once started irrespective of the patients ability to tolerate oral treatment earlier.
- Day 1** Dose 1: on admission (0 Hours)
Dose 2: 12 hours later
 - Day 2** Dose 3: 24 hours after first dose
- When the patient can take oral medication, prescribe a full 3-day course of recommended first line oral Artemisinin Combination Therapy (ACT). The first dose of ACT should be taken **between 8 and 12 hours** after the last injection of artesunate.
 - Until the patient is able to take oral medication, continue parenteral treatment (one dose a day) **for a maximum of 7 days.**
 - A course of injectable artesunate should always be followed by a 3-day course of ACT.
- Evaluate the patient's progress regularly.

IMPORTANT

- Prepare a fresh solution for each administration.
- Discard any unused solution after use.

This document is intended to demonstrate to health workers how to prepare and administer injectable artesunate, a treatment for severe malaria. It is not intended to provide personal medical advice. The responsibility for the interpretation and use of this material lies with the reader. In no event shall MMV be liable for damages arising from its use.

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1. World Health Organization (WHO) List of Prequalified Medicinal Products (<http://apps.who.int/prequal/query/ProductRegistry.aspx?list=ma>): artesunate injectable, reference N° MA051, prequalified on 05-Nov-2010.

2. World Health Organization, Management of Severe Malaria - A practical handbook - Third edition - April 2013 - (<http://www.who.int/malaria/publications/atoz/9789241548526/en/index.html>)

Remark: the upper limit for each weight band is 0.9 kg e.g. 14 - 16 kg covers 14 - 16.9 kg.