

Easier to prepare
Faster to reconstitute and
Safer to administer

Argesun[®], the first injectable artesunate presented with a single solvent system



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Argesun[®], the new generation Artesunate for injection

The Conventional Injectable Artesunate



Upgraded

The New Injectable Artesunate



Artesun[®]
Artesunate for Injection

Argesun[®]
Artesunate for Injection

Children < 20kg: 3.0mg/kg BW/dose
Children and adults ≥ 20kg: 2.4mg/kg BW/dose

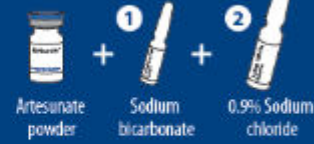
Reconstitution steps

Artesunate concentration to be prepared

Reconstitution time

Volume to be injected

2 steps



IV: 10mg/ml
IM: 20mg/ml

00:03:00
3 minutes

E.g. Body weight = 25kg
IV = 6ml / IM = 3ml



Different volume for IV and IM

1 step



IV & IM: 20mg/ml

00:01:00
1 minute

E.g. Body weight = 25kg
IV* & IM = 3ml
*Half the volume of conventional injectable Artesunate



Same volume for IV and IM

Without affecting Safety, Efficacy and Reliability...

- Argesun[®] combines the 2-step reconstitution and dilution into only **1-step**
- Argesun[®] allows **one volume for both IV and IM** administration
- Short reconstitution time: **1 minute** to get a clear solution
- **Fewer syringes** per administration

Argesun[®]
Artesunate for Injection

Treating of severe *P. falciparum* malaria with Argesun®

Step 1

IV = Intravenous route
IM = Intramuscular route

Weigh the patient & Check vials needed

Weight Strength	kg	less than 6	6-10	11-20	21-25	26-37	38-50	51-62	63-75	76-87	88-100
30 mg	IV/IM	1	1	2	2	3	4	5	6	7	8
60 mg	IV/IM	1	1	1	1	2	2	3	3	4	4
120 mg	IV/IM	1	1	1	1	2	1	2	2	2	2
180 mg	IV/IM	1	1	1	1	1	1	1	1	2	2

Product description

- Artesunate powder in 4 different strengths:

30 mg 60 mg 120 mg 180mg

Dose

Can be given by intravenous route (IV) or intramuscular route (IM)

- for children < 20kg: 3.0mg/kg BW/dose
- for children and adults ≥ 20kg: 2.4mg/kg BW/dose



Artesunate powder

+



Argesun® new solvent

Dosing of Argesun[®]

Step 2 Reconstitute

Artesunate powder + New solvent ampoule



Artesunate powder

Argesun[®] new solvent

- Follow sterile procedures for all steps.
- Reconstitute the correct number of vials needed.
- Use full content of bicarbonate vial.
- Shake slowly.
- Reconstitute immediately before use.
- Label with date and time.
- Discard if solution does not clear.



1 Inject contents of Argesun[®] new solvent into artesunate vial.



2 Shake the mixture and wait for a minute until the solution to be clear.



3 Artesunate solution is now ready for use.

Strength	30mg	60mg	120mg	180mg
New solvent volume (ml)	1.5	3	6	9
Artesunate concentration	20mg/ml			

Step 3 Administer

For Intravenous and Intramuscular route
(IV & IM)

- Prepare the correct size syringe to withdraw the correct mls from the vial/vials.
- Double check dose and required(mls) for patient's weight (kg) before injecting.
- Inject immediately after preparation.
- Discard any solution not used within 1 hour.
- Prepare a fresh solution for each administration.

For children < 20kg: 3.0 mg/kg BW/dose
For Both routes (IV & IM)

$$\frac{3.0 \text{ mg/kg} \times \text{body weight (kg)}}{\text{IV \& IM artesunate solution concentration 20 mg/ml}}$$

IV & IM artesunate solution concentration 20 mg/ml

Round up to the next whole number



IV

Intravenous route

Slow injection 3-4 ml per minute.

For children and adults ≥ 20kg:
3.0 mg/kg BW/dose
For Both routes (IV & IM)

$$\frac{2.4 \text{ mg/kg} \times \text{body weight (kg)}}{\text{IV \& IM artesunate solution concentration 20 mg/ml}}$$

IV & IM artesunate solution concentration 20 mg/ml

Round up to the next whole number



IM

Intramuscular route

Inject in an appropriate IM site.
Use a different site for each dose greater than 3-5 ml.

Argesun[®] is bioequivalent to the conventional injectable artesunate

A randomized, Open-Label, Single-Dose, Cross-Over Study to Evaluate the Bioequivalence of a New Parenteral Formulation of Artesunate (Argesun[®]) with the Currently Used Formulation (Artesun[®]) in Healthy Adult Thai Subjects¹

- Study population**

Normal, healthy, male and female adult subjects with BMI within the range of 18.1 to 24.9 kg/m² were screened as per inclusion/exclusion criteria. A total of 75 subjects were enrolled in this study.

- Conclusions**

- ✓ Bioequivalence was demonstrated for the new parenteral formulation to the currently used parenteral formulation for the combined exposure to ARS and DHA when study drug was administered IV and IM.
- ✓ The IM or IV administration of the new parenteral formulation of ARS was generally safe and well tolerated and showed no additional safety signals compared with the currently used parenteral formulation.

For combined ARS and DHA when ARS formulations were administered IV:

Parameter	Test IV	Reference IV	% Ratio of geometric means	CV (%)	BIOEQUIV
AUC _{0-last} (h*ng/mL)	8747.183	9191.323	95.17	35.960	YES
C _{max} (ng/mL)	19874.140	22920.685	86.71	26.438	YES

For combined ARS and DHA when ARS formulations were administered IM:

Parameter	Test IM	Reference IM	% Ratio of geometric means	CV (%)	BIOEQUIV
AUC _{0-last} (h*ng/mL)	8930.502	8474.945	105.38	26.336	YES
C _{max} (ng/mL)	5290.739	4754.096	111.29	25.981	YES

Source:

1. Clinical Study Report PHARMA1702 - Bioequivalence study of a New Formulation of Artesunate (Fosun Pharma internal data)

HCP Feedback



Name: Dr K. O

Hospital: AH, Kisumu

Department: Emergency

Feedback :

“On my personal experience, administering Argesun is much easier for me than Artesun (the conventional inj AS). This is based on the administration options. With a single diluent, very little time is needed to prepare the drug for injection. Argesun feels safer for me to administer”

Sampled Health Care Providers	*Summarized Feedbacks from product use
Nurse, Doctors	The 1-step reconstitution has reduced tendency for reconstitution errors
	Same volume for IV and IM removes dosing confusions when a patient’s veins are difficult to find
	Reduced IV volume has allowed for fewer syringes to be used in drug preparation
	Smaller IV volume makes duration for IV drug administration shorter
	Introduction of 180mg helpful for adult population

* Sampled HCP feedback from Kenya and Tanzania

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Thank You