

Information For the User

Artesunate (60mg)

Arteslide 60 Injection

Artesunate (60 mg) Injection: Product Information

Brand Name: Artesunate Injection

Generic Name: Artesunate

Strength: 60 mg per vial

Dosage Form: Injectable powder for reconstitution

Indications:

Artesunate 60 mg Injection is indicated for:

- **Treatment of severe malaria**, particularly **severe Plasmodium falciparum malaria** in adults, children, and infants.
- **Emergency management of malaria cases** in situations where oral administration is not possible or rapid response is needed due to the severity of infection.

Artesunate is often administered alongside other antimalarials to reduce the likelihood of drug resistance.

Mechanism of Action:

Artesunate, a **derivative of artemisinin**, works by:

- Generating **reactive oxygen species** within the malaria parasite, which leads to cellular damage and destruction of the parasite.
 - Rapidly reducing the parasite load in the blood, making it highly effective in managing severe cases of malaria.
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Dosage and Administration:

- **Preparation:** Reconstitute the 60 mg vial with the specified volume of diluent (usually sterile water) as per the product instructions to create the desired concentration.

- **Adult and Pediatric Dosage:** The typical dosing is **2.4 mg/kg body weight** administered intravenously or intramuscularly at 0, 12, and 24 hours, followed by once-daily doses until the patient can switch to oral antimalarial therapy or for at least 48 hours.
- **Duration:** Continue Artesunate injection therapy until the patient is stable enough to switch to oral treatment or as per healthcare provider's guidance.

Administration Instructions:

- Administer either by **slow intravenous injection** or **intramuscular injection**.
 - Reconstituted solution should be administered promptly, and any storage instructions for reconstituted solutions should be followed as per the package insert.
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Contraindications:

Artesunate 60 mg Injection is contraindicated in:

- Patients with known **hypersensitivity** to Artesunate, artemisinin derivatives, or any components of the formulation.
 - Use in the **first trimester of pregnancy** is only recommended if the benefits outweigh the risks, as assessed by a healthcare provider.
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Warnings and Precautions:

- **Risk of Delayed Hemolysis:** Artesunate may cause delayed hemolysis, a condition where red blood cells are destroyed after treatment. Monitor hemoglobin levels in the weeks following treatment.
- **Liver and Kidney Function:** Use cautiously in patients with hepatic or renal

impairment; monitor liver and kidney function during and after treatment.

- **Avoid repeated courses** of Artesunate unless necessary, as repeated use has not been extensively studied and may increase toxicity risks.

- Store unopened vials at **room temperature** (15°C to 25°C / 59°F to 77°F), protected from light.
- Use reconstituted solutions immediately or follow the product's storage guidelines for reconstituted solutions.

Side Effects:

Common side effects of Artesunate Injection include:

- **Headache, dizziness, nausea, and vomiting**
- **Injection site reactions** such as pain, redness, or swelling
- **Transient fever or chills** post-administration

Serious but rare side effects may include:

- **Delayed hemolytic anemia:** This condition can present with fatigue, pallor, or shortness of breath days to weeks after treatment.
- **Severe allergic reactions:** Such as rash, itching, swelling, or difficulty breathing. Seek immediate medical attention if these occur.

In cases of serious side effects, discontinue Artesunate and consult a healthcare provider promptly.

Drug Interactions:

- Artesunate is generally safe with minimal systemic interactions; however, **combination with other antimalarials** should be done under medical supervision to avoid additive toxicities.
- Inform the healthcare provider of any medications currently being taken to check for potential interactions, especially in cases of liver-metabolized drugs.

Patient Counseling Information:

- **Complete follow-up therapy:** Artesunate injection alone is often not sufficient; follow-up oral therapy is necessary to completely eradicate the infection.
- **Report symptoms of anemia:** Such as fatigue, dizziness, or paleness, as delayed hemolytic anemia may occur post-treatment.
- **Hydrate well** and rest to aid recovery during the course of treatment.
- **Pregnancy and breastfeeding:** Inform the healthcare provider if pregnant or breastfeeding, as this may influence treatment choice and monitoring.

This overview provides general information on **Artesunate 60 mg Injection**. Always follow the healthcare provider's instructions and consult them for specific guidance on this medication and follow-up care

Manufactured in India for:

CafoliTM
L I F E C A R E

Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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Storage: