COMBI PACK

Artesunate for Injection

AMERICAN Artecan 180 Injection

COMPOSITION :

The pack contains:

One Vial of Artesunate (Sterile) for injection	180 mg
3 ml of Sodium Bicarbonate Injection BP	5% w/v
20 ml of Sodium Chloride Injection BP	0.9% w/v

READ THIS LEAFLET CAREFULLY BEFORE USING THIS MEDICINE AS IT CONTAINS IMPORTANT INFORMATION FOR YOU.

- Keep this leaflet. You may need to read it.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed to you personally. Do not give it to other people, even if you have the same signs. It could be harmful to them.
- If you experience any side effects, talk to your doctor or pharmacist. This applies to any side effects that are not mentioned in this leaflet.

WHAT IS IN THIS LEAFLET

1. What is **Artecan-180** injection, and what are they used for
2. What is important information to know before using **Artecan-180** injection
3. How to use **Artecan-180** injection
4. What are the possible side effects
5. How to store **Artecan-180** injection
6. Pack contents and other information

1. What is Artecan-180 injection, and what are they used for

Artecan-180 contains artesunate, an artemisinin derivative belonging to the antimalarial drug class. **Artecan-180** injection is used in the treatment of severe malaria caused by Plasmodium falciparum.

2. What is important information to know before using Artecan-180 injection

Do not use **Artecan-180** injection if you are allergic to artesunate, any artemisinin derivative, or any components of this medication. This medicine should not be used as first-line treatment for malaria.

Other medications and Artecan-180

Artecan-180 may interact with other medications. Inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription and, in particular, if you are taking any of the following medicines: chloroquine or one of its derivatives, omeprazole and free radical scavengers.

Pregnancy and Breastfeeding

This medicine could be used during pregnancy. Your doctor will judge the benefit and potential risks of its use. It is not known whether artesunate passes into breast milk. Therefore, women should not breastfeed during treatment.

3. How to use Artecan-180 injection

Consult your doctor before using this medicine. The dosage will be determined by your doctor.

Method of administration: Intravenous or intramuscular.

DOSAGE

Withdraw the required dose (in ml) according to the route of administration used based on body Calculation:

Less than 20 kg =

$$\frac{\text{3.0 mg x body weight (kg)}}{\text{IV Artesunate solution concentration 10 mg/ml}}$$

$$\frac{\text{3.0 mg x body weight (kg)}}{\text{IM Artesunate solution concentration 20 mg/ml}}$$

More than 20 kg =

$$\frac{\text{2.4 mg x body weight (kg)}}{\text{IV Artesunate solution concentration 10 mg/ml}}$$

$$\frac{\text{2.4 mg x body weight (kg)}}{\text{IM Artesunate solution concentration 20 mg/ml}}$$

Strength	Intravenous Dosage		Intramuscular Dosage	
	Concentration : 10 mg/ml		Concentration : 20 mg/ml	
Artesunate 180 mg	Sodium Bicarbonate 5% w/v	3 ml	Sodium Bicarbonate 5% w/v	3 ml
	Sodium Chloride 0.9% w/v or Glucose Solution 5%	15 ml	Sodium Chloride 0.9% w/v or Glucose Solution 5%	6 ml
	Total Volume	18 ml	Total Volume	9 ml

- Artesunate should not be administered as an intravenous drip.
- Do not use water for injection for reconstitution of artesunate powder or for dilution of the resulting solution before injection.

RECONSTITUTION METHOD:

Artecan-180 injection comes in the form of a vial of artesunate powder, an ampoule of solvent containing 3 ml of a 5% sodium bicarbonate solution and FFS pack of diluent containing 20 ml of 0.9% w/v sodium carbonate solution.

1. Add the sodium bicarbonate solution to the bottle containing the powder;
2. Stir gently for a few minutes until a clear solution is obtained;
3. Let the gas (CO_2) escape from the bottle by inserting a needle into its end;
4. Add 15 ml (intravenous route) or 6 ml (intramuscular route) of 0.9% sodium chloride solution to the bottle;
5. Stir until a homogeneous and clear solution is obtained
6. The concentration of the solution obtained will be 10 mg/ml of artesunate and its volume is 18 ml for IV and 20 mg/ml of artesunate and its volume is 9 ml for IM.

4. What are the Possible side effects

Like all medications, **Artecan-180** injection can cause side effects, some of which may be serious. It is therefore essential that you inform your doctor of any side effects. The most common adverse reactions reported with artesunate and artemisinin derivatives are:

- Rashes, itching
- In the ENT sphere: Cough, nasal congestion and ringing in the ears
- At the level of the Central Nervous System: dizziness, convulsions, headaches and insomnia
- At the level of the Digestive System: bitter taste, nausea, vomiting, diarrhea, abdominal pain and loss of appetite
- At the heart level: slow heart rate (bradycardia), abnormalities in the electrocardiogram (prolongation of the QT interval)
- Joint and muscle pain
- General disorders - fever, hair loss
- Increased urine volume
- Biological abnormalities (less frequently reported)
- Transient elevation of hepatic transamin level
- Reversible decrease in the level of reticulocytes and white blood cells in the blood
- Late-onset hemolytic anemia and persistent hemolytic anemia have been observed

5. How to store Artecan-180 Injection

Store at a temperature below 30°C, Protected from light.
Keep medicines out of reach of children.
Do not use after the expiry date indicated on the package.
The expiration date indicates the last day of the indicated month.
Shelf life before reconstitution is 3 years.

6. Pack contents and other information

Artecan-180 contains:

Artesunate powder for injection
Solvent: sodium bicarbonate 5% w/v
Diluent: sodium chloride 0.9% w/v

Packing:

Combipack contains vial of artesunate injection with one ampoule of sodium bicarbonate 5% w/v & one ampoules of sodium chloride 0.9% w/v of 15ml packed in a tray with insert, in a carton.

Manufactured by:

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Care & Cure with Research

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