Patient Information Leaflet
ARINATE® 120
Artesunate 120mg Powder, solvent and diluent for solution for injection

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. If you have questions or you notice side effects not mentioned in this leaflet, contact your doctor or your healthcare professional. Do not pass this medicine on to others.

1. What Arinate® 120 is and what it is used for

Arinate®120 is an antimalarial containing artesunate for intravenous (IV) or intramuscular (IM) injection. Arinate ® 120 is used for the treatment of severe malaria caused by Plasmodium falciparum.

2. What you need to know before you use Arinate® 120

Do not use Arinate® 120 if you are allergic to artesunate.

Warnings and precautions

- After the IV or IM treatment of the critical phase of malaria, you will need to take a complete 3 day oral Artemisinin Combination Therapy (ACT).
- A reduction of the red blood cells within the first month after therapy has been reported, particularly in small children and travellers. Therefore, the doctor may monitor your blood count in the first weeks of malaria treatment.

Other medicines and Arinate® 120

Tell the doctor, pharmacist or the hospital's health care provider if you are taking any other medicine, including medicines without prescription.

Pregnancy and breastfeeding

- Severe malaria is especially hazardous during pregnancy. In that case IV or IM artesunate treatment should be administered at any stage of pregnancy, without delay.
- Only a small amount of artesunate passes from the maternal blood into the breast milk, but this amount is not expected to cause adverse effects in breastfed infants. Your doctor will advise you on breast-feeding during artesunate treatment.

Driving and using machines

The doctor will assess your clinical status and will advise on your ability to drive or operate machines.

3. How to use Arinate® 120

Instructions for the preparation and administration are explained at the end of this leaflet.

4. Possible side effects

Arinate® 120 can cause reductions of the blood cells

Reductions in the amount of red blood cells (important for oxygen transport), white blood cells (important for defence against infections) and in platelets (important for blood clotting) can occur but are generally uncommon (1 in 100 people).

A low number of red blood cells (anaemia) may occur only after one month of treatment, especially in young children and in travellers. Severe reduction in red blood cells is very rare (1 in 10.000 people). If you feel extremely tired, very weak or short of breath up to 4 weeks after treatment, inform your doctor or other health care provider.

Arinate® 120 can cause symptoms of intolerance or hypersensitivity

The most important side effect of artesunate is a severe allergic reaction which can involve urticarial rash (round, red welts on the skin) as well as other symptoms like hypotension, pruritus and oedema (itchy and swollen skin) and dyspnoea (short of breath). Although this reaction is rarely reported, the estimated risk is approximately 1 in 3.000 patients.

More common minor side effects (1 in 10 people) are dizziness, feeling sick, vomiting, light-headiness, sleeplessness, hearing problems, flu-like symptoms like fever, tiredness, bone and muscle pain, cough, altered taste, abdominal pain, diarrhoea, rash and pain at the injection site.

Inflammation of the liver is rare (1 in 1.000 people) and can result in yellowing of the eyes and skin and inflammation of the pancreas (pancreatitis).

5. How to store Arinate® 120

Keep out of the reach and sight of children.
Store below 30°C, in the original package to protect from moisture and light.
Do not use after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.

6. Contents of the pack and further information

What the pack Arinate® 120 contains

A. Artesunate: vial with a white crystalline powder containing 120 mg artesunate without excipients.
B. Solvent: ampoule with 2 ml of solution to reconstitute the drug containing 50 mg/ml sodium bicarbonate in water for injections (5%).
C. Diluent: ampoule with 10 ml of diluent containing 9 mg/ml sodium chloride in water for injections (0.9%).

Arinate® 120 is a prescription medicine.

Manufacturer: Systacare Remedies Village & P.O Balkalan, Majitha Road, Amritsar -143 601, India.

Marketing Authorisation Holder: Dafra Pharma GmbH, Mühlenberg 7, CH-4052 Basel, Switzerland.

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Arinate® 120 - Preparation and method of administration

Reconstitution of the drug

To activate the powder of artesunate inject the complete content of the ampoule with the bicarbonate solution (B) in the vial with the artesunate powder (A). Shake gently until dissolution. The solution will be cloudy. The reconstituted solution will clear in about 2 minutes. Discard the vial if not clear.

Dilution of the reconstituted solution

Dilute with the supplied ampoule (C).
The reconstituted artesunate solution can only be diluted with sodium chloride 0.9% for injection or with dextrose 5% if saline solution is not available. Important: water for injections is not an appropriate diluent.

Route of administration	IV	IM
Volume of the reconstituted solution	2 ml	2 ml
Volume for dilution	**10 ml**	**4 ml**
Total volume	12 ml	6 ml
Concentration ready for use	**10 mg/ml**	**20 mg/ml**

Procedure for dilution

- Fill a syringe with the required volume of diluent and inject it into the vial with the reconstituted solution
- Shake to mix well, ensuring that the resulting solution is still clear. If the solution appears cloudy or a precipitate is present, it should be discarded.

Calculate the dose

- Patients with a body weight under 20 kg: dose 3 mg/kg
- Patients with a body weight over 20 kg: dose 2.4 mg/kg

Number of vials Arinate® 120 needed (per dose)

Patient's weight	< 25 kg	26-50 kg	51-75 kg	> 75 kg
Number of vials	1	1	2	2

Required volume per parenteral administration of the solution ready for injection

Body weight	Dose	**Volume to inject in ml**	
kg	mg	**IV route Solution of 10 mg/ml**	**IM route Solution of 20 mg/ml**
6-7	20	2	1
7-10	30	3	2
11-13	40	4	2
14-16	50	5	3
17-20	60	6	3
20-25	60	6	3
26-29	70	7	4
30-33	80	8	4
34-37	90	9	5
38-41	100	10	5
42-45	110	11	6
46-50	120	12	6
51-54	130	13	7
55-58	140	14	7
59-62	150	15	8
63-66	160	16	8
67-70	170	17	9
71-75	180	18	9
76-79	190	19	10
80-83	200	20	10
84-87	210	21	11
88-91	220	22	11
92-95	230	23	12
96-100	240	24	12

Administration of the drug

- IV : slow bolus over 1-2 minutes (3-4 ml/min)
- IM : Inject slowly. Spread the doses of more than 2 ml over different sites for babies and children and of more than 5 ml for adults.

The solution of artesunate must be used within one hour of preparation. Prepare a fresh solution for each administration. Discard immediately any unused solution

Dosing schedule

Start-up treatment: give 3 parenteral doses (IV or IM) over the first 24 hours with an interval of 12 hours (ho – h12 – h24).

Follow-up treatment: A course of injectable artesunate should always be followed by a 3-day course of recommended first line oral Artemisinin Combination Therapy

(ACT). When the patient can take oral medication, prescribe the full 3-day course of ACT. The first dose of ACT should be taken between 8 and 12 hours after the last injection of artesunate. When the patient is not able to take oral medication, continue parenteral treatment (one dose a day) for a maximum of 7 days.