



# EPASIN 60<sup>®</sup>

Artesunate injectable 60 mg

# EPASIN 120<sup>®</sup>

Artesunate injectable 120 mg

**Read this entire leaflet carefully before you start taking this medicine.**

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, if you are unsure, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Never give it to someone else, even in case of identical symptoms, it could be harmful.
- If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, talk to your doctor or pharmacist.

#### What is in this leaflet

1. What EPASIN<sup>®</sup> is and what it is used for
2. What you need to know before you are given EPASIN<sup>®</sup>
3. How EPASIN<sup>®</sup> is given
4. What are the possible side effects ?
5. How to store EPASIN<sup>®</sup>
6. Contents of the pack and other information.

#### 1. WHAT EPASIN<sup>®</sup> IS AND WHAT IT IS USED FOR

EPASIN<sup>®</sup> contains the active substance artesunate. EPASIN<sup>®</sup> is used to treat severe malaria caused by Plasmodium Falciparum in adults and children.

After treatment with EPASIN<sup>®</sup> your doctor will complete your treatment for malaria with a course of anti-malarial medication that can be taken by mouth.

#### 2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN EPASIN<sup>®</sup>

**Do not use EPASIN<sup>®</sup>** if you are allergic to artesunate, to any other antimalarial treatment that contains an artemisinin (e.g. artemether or dihydroartemisinin) or any of the other ingredients of this medicine (listed in section 6).

#### Warnings and precautions:

You may develop anaemia, a reduced number of red blood cells, or other blood changes after treatment with this medicine. Some changes to numbers of blood cells can occur while you are being treated and usually recover after stopping treatment for malaria. However, some individuals develop severe anaemia that can occur up to several weeks after completing treatment for malaria. In most cases, the anaemia recovers without any specific treatment. In a small number of cases the anaemia may be severe and require blood transfusion. Your doctor will carry out regular blood tests and monitor your recovery for 4 weeks after you have completed your treatment for malaria. It is important you attend appointments for these check-ups. Talk to your doctor for more information.

#### Other medicines and EPASIN<sup>®</sup>:

Tell your doctor if you are taking, have recently taken or might take any other medicines. This includes medicines not on prescription.

Some medicines should not be taken with artesunate because they could reduce its effect on malaria.

Some examples include:

- rifampicin (to treat bacterial infections);
- ritonavir, nevirapine (anti-HIV medication);
- carbamazepine, phenytoin (to treat epilepsy).

Some medicines may increase blood levels of artesunate and may increase the risk of side effects.

Some examples include:

- diclofenac (to treat pain or inflammation);
- axitinib, vandetanib and imatinib (used in the treatment of certain cancers).

Artesunate may increase or decrease the blood levels of some other medicines. Your doctor will advise you on taking any medicines during artesunate treatment.

#### Pregnancy and breast-feeding:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, you should talk to your doctor before being given this medicine.

Your doctor will discuss with you the potential risk of taking EPASIN<sup>®</sup> during pregnancy.

Use in the first trimester of pregnancy is not recommended unless your doctor decides that the benefit of treatment for you outweighs the risk to your unborn child. In the later stages of pregnancy, you should only take EPASIN<sup>®</sup> if your doctor feels that there are no suitable alternative medicines. If you are or become pregnant during treatment with this medicine, the doctor will report your pregnancy to the manufacturer, who is keeping a record in order to understand any effects that the treatment may have on the pregnancy and the baby.

Traces of this medicine may be present in your breast milk. It is not known if these could have any effect on a breastfed baby. If you are planning to breastfeed, discuss with your doctor whether the benefits of breastfeeding to you and your baby outweigh the potential risk.

#### Driving and using machines:

You should not drive or use machines if you feel tired or dizzy.

#### EPASIN<sup>®</sup> contains sodium.

#### 3. HOW EPASIN<sup>®</sup> IS GIVEN

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

This medicine will be given to you intravenously or intramuscularly. Your doctor or nurse will inject this medicine for you.

The dose of the medicine you are given is based on your weight and your doctor or nurse will work out the right amount to give you. The recommended dose is 2.4 mg for each kg of body weight. The dose per kg is the same for adults and children of all ages.

You will be given at least three doses of EPASIN<sup>®</sup>, each dose given 12 hours apart. After three doses, if you still cannot take medicines by mouth, you will be given one dose of EPASIN<sup>®</sup> every 24 hours (once a day) until you are able to take a different malaria treatment by mouth.

It is very important that you complete a full course of antimalarial treatment taken by mouth after you have had at least three doses of EPASIN<sup>®</sup> by injection.

#### If you are given more EPASIN<sup>®</sup> than you should:

As this medicine will be given to you in a hospital, it is unlikely that you will be given too much. Tell your doctor if you have any concerns. Signs of an overdose include seizures, dark coloured stools, a blood test showing low blood cell counts, weakness, fatigue, fever and nausea. Your doctor will help to treat these symptoms if you are given too much of this medicine.

#### If a dose of EPASIN<sup>®</sup> is forgotten:

As this medicine will be given to you in a hospital, your doctor or nurse will manage your treatment and it is unlikely a dose will be forgotten. Should a dose be delayed, your doctor or nurse will give the required dose at the earliest opportunity and continue to give future doses 12 or 24 hours apart. If you have any further questions on the use of this medicine, ask your doctor or nurse.

#### 4. WHAT ARE THE POSSIBLE SIDE EFFECTS ?

The most important reported side effect of artesunate is a rare severe allergic reaction (estimated risk approximately 1 in 3000 patients), which has involved urticarial rash as well as other symptoms, including hypotension, pruritus, oedema, and/or dyspnoea.

More common minor side effects associated with IV administration have included dizziness, light-headedness, rash, and taste alteration (metallic/ bitter taste). Nausea, vomiting, anorexia and diarrhea have also been reported, however it is uncertain whether such events have been symptoms of severe malaria.

Adverse events considered at least possibly related to artesunate are listed below by body system, organ class and absolute frequency. Frequencies are defined as very common ( $\geq 1/10$ ), common ( $1/100-1/10$ ), uncommon ( $1/1000-1/100$ ), rare ( $1/10\ 000-1/1000$ ), and very rare ( $< 1/10\ 000$ ).

#### Very common side effects (may affect more than 1 in 10 people):

A lack of healthy red blood cells, which can make you feel tired and weak (anaemia); this can develop at least 7 days or sometimes several weeks after treatment has finished.

#### Common side effects (may affect up to 1 in 10 people):

- Inflammation of a vein;
- Altered sense of taste;
- Raised body temperature or fever;
- Very dark yellow or reddish brown coloured urine;
- Reduced kidney function, including low urine output;
- Bruising easily or slow clotting of any cuts or wounds;
- Abnormal levels of liver enzyme levels detected in blood tests;
- Yellowing of the skin (jaundice);
- Diarrhoea;
- Abdominal pain;
- Vomiting;
- Slow heart rate;
- Low blood pressure;
- Cough;
- Rhinitis (blocked and/or runny nose);
- Feeling dizzy or weak;
- Headache.

#### Uncommon (affecting less than 1 in 100 patients):

- Tiredness;
- Feeling sick;
- Constipation;
- Pain at injection site;
- Painful widespread rash with blisters especially near mouth, nose, eyes and genitals, flu-like symptoms for several days (Stevens-Johnson syndrome or SJS);
- Loss of appetite;
- Rash;
- Itching;
- Swelling and reddening of the face;
- Flushing.

#### 5. HOW TO STORE EPASIN<sup>®</sup>

The reconstituted solution should be used immediately. Store at a temperature below 30°C. Protect from light and moisture.

Do not use this medicine after the expiry date which is stated on the label on the carton after EXP.

#### Keep medicines out of the reach of children.

#### 6. CONTENTS OF THE PACK AND OTHER INFORMATION

#### What EPASIN<sup>®</sup> contains:

- The active substance is artesunate.

#### EPASIN 60<sup>®</sup>

Each Combipack contains:

- 1 vial of Artesunate: 60 mg;
- 1 mL ampoule of Sodium Bicarbonate injectable: 5.0% w/v;
- 5 mL ampoule of Sodium Chloride injectable: 0.9% w/v.

#### EPASIN 120<sup>®</sup>

Each Combipack contains:

- 1 vial of Artesunate: 120 mg;
- 2 mL ampoule of Sodium Bicarbonate injectable: 5.0% w/v;
- 10 mL ampoule of Sodium Chloride injectable: 0.9% w/v.

#### What EPASIN<sup>®</sup> looks like and contents of the pack:

The powder is white or almost white, fine crystalline powder in a glass vial. The solvent is a clear, colourless liquid in a glass vial.

Each pack contains 1 vial of powder and 2 vials of buffer solvent with a patient information leaflet.

#### The following information is intended for healthcare professionals only:

#### Preparation:

Because of the instability of artesunate in aqueous solutions the reconstituted solution must be used within one hour of preparation. Therefore the required dose of artesunate should be calculated (dose in mg = patient's weight in kg x 2.4) and the number of vials of artesunate needed should be determined prior to reconstituting the artesunate powder.

#### Reconstitution of the artesunate solution:

##### EPASIN 60<sup>®</sup>:

Using a syringe, withdraw 1 mL of the supplied sodium bicarbonate injectable 5.0% w/v from the ampoule and inject into the vial containing the artesunate powder. Shake the vial for several minutes to mix well until the powder is completely dissolved and the solution is clear. If the solution appears cloudy or a precipitate is present, it should be discarded. The reconstituted artesunate solution should always be used immediately, and discarded if not used within one hour.

#### Following reconstitution the solution must be diluted according to the method of injection, as described below.

##### For intravenous (IV) injection:

Using a syringe, add 5 mL of sodium chloride injectable 0.9% w/v to the vial containing the reconstituted artesunate solution. This will yield 6 mL of a solution containing artesunate 10 mg/mL. 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. The volume required will be equal to:  $\frac{\text{desired dose in mg}}{10}$  mL.

Withdraw the required volume of artesunate solution from the vial with a syringe and then inject slowly intravenously, the speed of IV consistent with slow bolus: 3-4 mL/min.

EPASIN<sup>®</sup> should NOT be administered as an intravenous drip.

##### For intramuscular (IM) injection:

Using a syringe, add 2 mL of sodium chloride injectable 0.9% w/v to the vial containing the reconstituted artesunate solution. This will yield 3 mL of a solution containing artesunate 20 mg/mL. 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. The volume required will be equal to:  $\frac{\text{desired dose in mg}}{20}$  mL.

Withdraw the required volume of artesunate solution from the vial with a syringe and then inject intramuscularly; the anterior thigh is usually the preferred site for injection. If the total volume of solution to be injected intramuscularly is large, it may be preferable to divide the volume and inject it at several sites, e.g. both thighs.

Do not use water for injection for reconstitution of the artesunate powder or for dilution of the resulting solution prior to injection.

#### Reconstitution instructions:

##### Step 1:

Add B to A and mix well until you get a clear solution.



##### Step 2:

Add C to B + A and mix well.



#### Single use:

**Step 1:** Add 1 mL of Sodium Bicarbonate injectable 5.0% w/v to the artesunate vial and mix well until a clear solution is obtained.

**Step 2:** For use in IV: add 5 mL of Sodium Chloride injectable 0.9% w/v to the solution obtained in step 1, mix well and use intravenously slowly for 3 to 4 minutes (do not put the solution in the IV drip). For IM use: add 2 mL of sodium chloride injectable 0.9% w/v to the solution obtained in step 1, mix again and use IM.

#### EPASIN 120<sup>®</sup>:

Using a syringe, withdraw 2 mL of the supplied sodium bicarbonate injectable 5.0% w/v from the ampoule and inject into the vial containing the artesunate powder. Shake the vial for several minutes to mix well until the powder is completely dissolved and the solution is clear. If the solution appears cloudy or a precipitate is present, it should be discarded. The reconstituted artesunate solution should always be used immediately, and discarded if not used within one hour.

#### Following reconstitution the solution must be diluted according to the method of injection, as described below.

##### For intravenous (IV) injection:

Using a syringe, add 10 mL of sodium chloride injectable 0.9% w/v to the vial containing the reconstituted artesunate solution. This will yield 12 mL of a solution containing artesunate 10 mg/mL. 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. The volume required will be equal to:  $\frac{\text{desired dose in mg}}{10}$  mL.

Withdraw the required volume of artesunate solution from the vial with a syringe and then inject slowly intravenously, the speed of IV consistent with slow bolus: 3-4 mL/min.

EPASIN<sup>®</sup> should NOT be administered as an intravenous drip.

##### For intramuscular (IM) injection:

Using a syringe, add 4 mL of sodium chloride injectable 0.9% w/v to the vial containing the reconstituted artesunate solution. This will yield 6 mL of a solution containing artesunate 20 mg/mL. 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. The volume required will be equal to:  $\frac{\text{desired dose in mg}}{20}$  mL.

Withdraw the required volume of artesunate solution from the vial with a syringe and then inject intramuscularly; the anterior thigh is usually the preferred site for injection. If the total volume of solution to be injected intramuscularly is large, it may be preferable to divide the volume and inject it at several sites, e.g. both thighs.

Do not use water for injection for reconstitution of the artesunate powder or for dilution of the resulting solution prior to injection

#### Reconstitution instructions:

##### Step 1:

Add B to A and mix well until you get a clear solution.



##### Step 2:

Add C to B + A and mix well.

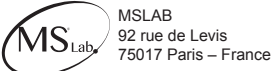


#### Single use:

**Step 1:** Add 2 mL of Sodium Bicarbonate injectable 5.0% w/v to the artesunate vial and mix well until a clear solution is obtained.

**Step 2:** For use in IV: add 10 mL of Sodium Chloride injectable 0.9% w/v to the solution obtained in step 1, mix well and use intravenously slowly for 3 to 4 minutes (do not put the solution in the IV drip). For IM use: add 4 mL of Sodium Chloride injectable 0.9% w/v to the solution obtained in step 1, mix again and use IM.

#### Marketing Authorization Holder:



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