PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

Artesunate 60 mg Cospharm

Powder for solution for injection

Artesunate

Sugar free

Read all of this leaflet carefully before you are given Artesunate 60 mg Cospharm

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What Artesunate 60 mg Cospharm is and what it is used for
2. What you need to know before you are given Artesunate 60 mg Cospharm
3. How Artesunate 60 mg Cospharm should be administered.
4. Possible side effects
5. How to store Artesunate 60 mg Cospharm
6. Contents of the pack and other information

1. What Artesunate 60 mg Cospharm is and what it is used for

Artesunate 60 mg Cospharm contains artesunate, which is used to treat patients with malaria.

Artesunate 60 mg Cospharm is used for the treatment of severe malaria infections caused by a parasite called *Plasmodium falciparum* in adults and children.

2. What you need to know before you are given Artesunate 60 mg Cospharm

Artesunate 60 mg Cospharm should not be administered to you:

- if you are hypersensitive (allergic) to artesunate, artemisinins or any of the other ingredients of Artesunate 60 mg Cospharm (listed in section 6).

Warnings and precautions

After intravenous or intramuscular treatment of the critical phase of the falciparum malaria infection, the patient will need to take oral medication to complete the treatment and avoid relapse.

A reduction of red blood cells within the first month after therapy with artesunate has been reported, particularly in small children and travelers.

The health care provider may therefore monitor the patient's blood count in the first weeks after malaria therapy.

Other medicines and Artesunate 60 mg Cospharm

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before being given this medicine.

Pregnancy

Severe malaria is especially hazardous during pregnancy, therefore full dose parenteral artesunate treatment should be administered at any stage of pregnancy without delay.

Breastfeeding

A small amount of the medicine enters human breast milk, but it will not protect the child from malaria.

The health care provider will advise the patient on breastfeeding.

Driving and using machines

It is not always possible to predict to what extent Artesunate 60 mg Cospharm may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Artesunate 60 mg Cospharm affects them.

3. How to take Artesunate 60 mg Cospharm

Artesunate 60 mg Cospharm will be given to you by a person who is qualified to do so.
Your doctor will prescribe the dose that you should take.

If you receive more Artesunate 60 mg Cospharm than you should

Since a health care provider will administer Artesunate 60 mg Cospharm, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of Artesunate 60 mg Cospharm

Since a health care provider will administer Artesunate 60 mg Cospharm, it is unlikely that the dose will be missed.

4. Possible side effects

Artesunate 60 mg Cospharm can have side effects.
Not all side effects reported for Artesunate 60 mg Cospharm are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Artesunate 60 mg Cospharm, please consult your health care provider for advice.
If any of the following happens, stop using Artesunate 60 mg Cospharm and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- Rash or itching,
- Fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to Artesunate 60 mg Cospharm.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain,
- angina,
- changes in the way your heart beats, for example, if you notice it beating faster,
- difficulty breathing,
- signs of recurrent infections such as fever or sore throat,
- less urine than is normal for you,
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

These are all serious side effects. You may need urgent medical attention.

Frequent side effects

- Dizziness
- Headache
- Ringing in the ears
- Nasal symptoms
- Taste alteration (metallic/bitter taste)
- Abdominal pain or cramps
- Anorexia
- Muscle pain

- Feeling weak or tired
- Light-headedness
- Trouble with sleeping
- Cough
- Rash
- Nausea and vomiting
- Diarrhoea
- Hair loss
- Pain at the injection site
- fever

Less frequent side effects

- Hypersensitivity
- Loss of balance or coordination
- Pins and needles feeling in your hands and feet
- Anaemia (low red blood cell count)
- Neutropenia (low white blood cell count)
- Rise in liver enzymes (may indicate liver damage)
- Reduction in platelets (which are important for blood clotting)
- Allergic reactions
- Inflammation of the liver (hepatitis, with yellowing of eyes and skin)
- inflammation of the pancreas (pancreatitis)
- Severe reduction in red blood cells
- tingling sensation and nerve pain
- Anaemia (low red blood cells) may occur within one month after treatment.

It has been reported especially in young children and in travellers. If you feel excessively tired, weak or short of breath up to 4 weeks after treatment, inform your doctor or healthcare provider.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of Artesunate 60 mg Cospharm.

5. How to store Artesunate 60 mg Cospharm

Store all medicines out of reach of children.

Store at or below 30 °C until it is ready to be used to create a solution.

The reconstituted and diluted solutions should be stored at or below 30 °C and the total in-use period should not exceed one hour.

Protect against direct sunlight. Do not store in a refrigerator or freezer.

The product must be destroyed if crystals or cloudiness are visible in the solution.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Artesunate 60 mg Cospharm contains:

The active ingredient is artesunate, each vial contains 60 mg Artesunate.

Artesunate powder for injection: No excipients.

Solvent: Sodium bicarbonate and water for injection.

Diluent: Sodium chloride and water for injection.

What Artesunate 60 mg Cospharm looks like and contents of the pack

Artesunate for injection is a sterile white crystalline powder, 60 mg.

Diluent: Sodium Chloride 0.9 % w/v for Artesunate 60 mg is packed in 5 mL clear ampoules.

Holder of Certificate of Registration

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This leaflet was last revised in

12 December 2023

Registration number

55/20.2.6/0742