PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

GARSUN (60 mg powder and solvent for solution for injection)

Artesunate

Sugar free

Read all of this leaflet carefully before you are given GARSUN

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other healthcare provider.
- GARSUN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What GARSUN is and what it is used for

The active ingredient is artesunate.

GARSUN 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 the use of GARSUN

You should not be given GARSUN:

If you are allergic (hypersensitive) to artesunate or any of the other ingredients of GARSUN (listed in section 6).

Your doctor or healthcare professional will check and confirm whether:

- you are infected with "*Plasmodium falciparum*" before giving the injection. GARSUN has not been tested in the treatment of malaria caused by other malarial parasites.

Warnings and precautions

Special care should be taken with GARSUN:

- after intravenous or intramuscular treatment of the critical phase of the falciparum malaria infection, you will need to take oral medication to complete the treatment and avoid relapse
- your doctor should choose the correct antimalarial regimen in order to prevent resistance
- a reduction of red blood cells within the first month after therapy with GARSUN has been reported, particularly in small children and travellers. The healthcare provider may therefore monitor your blood count in the first weeks after malaria therapy.

Other medicines and GARSUN

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Pregnancy and 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 healthcare provider for advice before receiving GARSUN.

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

If you want to breastfeed talk to your doctor first. GARSUN is present in your breast milk.

The medicine levels are not expected to cause any adverse effects in breastfed infants. The amount of medicine present in breast milk does not protect the infant from malaria.

Driving and using machines

There have been no studies to investigate the effect of GARSUN on driving performance or the ability to operate machinery. However, GARSUN may cause dizziness which may influence the ability to drive and use machines (see section 4 below).

3. How to use GARSUN

Do not share medicines prescribed for you with any other person.

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

GARSUN is injected in a vein or intramuscularly (into a muscle). You will receive three injections within 24 hours, then once daily if necessary. As soon as you are able to swallow medication, your doctor will stop the GARSUN injection and prescribe another antimalarial treatment course.

If you have the impression that the effect of GARSUN is too strong or too weak, talk to your doctor.

If you receive more GARSUN than you should

Since a healthcare professional will administer GARSUN, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of GARSUN

Since a healthcare professional will administer GARSUN, he/she will control the frequency with which you receive the injections. If you missed a dose of GARSUN, tell your doctor immediately.

4. Possible side effects

GARSUN can have side effects.

Not all side effects reported for GARSUN are included in this leaflet. Should your general health worsen or if you

experience any untoward effects while taking GARSUN, please consult your healthcare provider for advice.

If any of the following happens, stop using GARSUN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- rash or hives,
- difficulty breathing,
- chest tightness,
- swelling of the face, lips, tongue or throat.

These are all very serious side effects. If you have them, you may have had a serious reaction to GARSUN. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- 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
- dizziness
- light-headedness
- headache
- trouble with sleeping
- ringing in ears
- convulsions
- cough
- nasal symptoms
- rash
- taste alteration (metallic/bitter taste)
- nausea and vomiting
- abdominal pain or cramps
- diarrhoea

- anorexia
- hair loss
- muscle pain, joint pain
- pain at the injection site
- feeling weak or tired
- fever

Less frequent side effects:

- neutropenia (low white blood cell count), reduction in platelets (which are important for blood clotting)
- an abnormal decrease of new, immature red blood cells, decrease of red blood cells in a complete blood count
- hypersensitivity
- pins and needles feeling in hands and feet
- heart rhythm problems (slow or irregular heartbeat)
- blockage in arteries
- retinal vascular damage caused by hypertension
- inflammation of the pancreas (pancreatitis)
- increased liver enzymes
- inflammation of the liver (hepatitis, with yellowing of eyes and skin)
- blockage by a gallstone or by a substance known as biliary sludge of the main opening to the gallbladder, called the cystic duct
- loss of balance or coordination

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. This includes any possible side effects not listed in this leaflet. 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 GARSUN.

5. How to store GARSUN

Storage conditions for GARSUN prior to reconstitution:

Store all medicines out of reach of children.

Store GARSUN at or below 30 °C.

Keep the vial and the ampoules in the outer carton until required for use.

Do not use GARSUN after the expiry date printed on the vial or outer carton.

Storage conditions for GARSUN after reconstitution:

After reconstitution, the injection should preferably be used immediately.

However, the doctor may store the reconstituted solution at room temperature up to 30 °C for 1 hour. If the doctor has not used GARSUN within 1 hour after reconstitution, the solution must be thrown away.

Disposal

GARSUN should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of GARSUN no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What GARSUN contains

The active substance is artesunate. Each vial contains 60 mg artesunate.

No other inactive ingredients are included in the vial (powder formulation).

Solvent: 5 % Sodium Bicarbonate Solution for Injection (50 mg/ml)

Diluent: 0,9 % Sodium Chloride Solution for Injection (9 mg/ml)

What GARSUN looks like and contents of the pack

GARSUN is a white crystalline powder. After reconstitution, the resulting solution is clear to colourless and essentially free of visible particles.

The solvent and diluent are clear to colourless solutions essentially free of visible particles.

GARSUN is supplied in kits containing:

- A single-use vial with white powder (7 ml Type I clear, colourless glass vial closed with grey bromobutyl rubber stopper and aluminium lid with a blue flip-off plastic cover).
- One ampoule with 1 ml of 5 % sodium bicarbonate solution for injection (Type I clear colourless glass ampoule).
- One ampoule with 5 ml of 0,9 % sodium chloride solution for injection (Type I clear colourless glass ampoule).

The Artesunate powder + solvent + diluent are co-packaged into a plastic tray, paper box, and paper carton.

Holder of Certificate of Registration

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This leaflet was last revised in

03 April 2024

Registration Number

48/20.2.6/0866