PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

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

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 or pharmacist.
- **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.

1. WHAT GARSUN CONTAINS

The active ingredient 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)

2. WHAT GARSUN IS USED FOR

GARSUN is used for the treatment of severe malaria infections caused by a parasite called "*Plasmodium falciparum*" in adults and children.

GARSUN is used to treat adults and children.

3. BEFORE YOU ARE GIVEN GARSUN

You should not be given GARSUN:

If you are allergic (hypersensitive) to artesunate or any of the other ingredients of **GARSUN**.

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.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please inform your doctor, pharmacist or other healthcare professional for advice before being given **GARSUN**. Your doctor will discuss with you the potential risk of being given **GARSUN** during pregnancy as safety has not been established.

If you want to breastfeed talk to your doctor first. **GARSUN** is present in your breast milk. You should not breastfeed your baby whilst on treatment with **GARSUN**.

Driving and using machines:

No studies on the effects on the ability to drive and use machines have been performed.

Taking other medicines with GARSUN:

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

4. HOW TO RECEIVE 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. 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.

5. 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 while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Allergic reactions may occur with **GARSUN**. Call your doctor or get emergency treatment right away if you have any of the following symptoms:

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

Frequent side effects:

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

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

Less frequent side effects:

- hypersensitivity
- loss of balance or coordination
- pins and needles feeling in hands and feet

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

6. STORING AND DISPOSING OF GARSUN

*Storage conditions for **GARSUN** prior to reconstitution:*

Keep this medicine out of sight and 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.

7. PRESENTATION OF GARSUN

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 and paper carton.

8. IDENTIFICATION OF GARSUN

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.

9. REGISTRATION NUMBER

48/20.2.6/0866

NAME AND THE BUSINESS ADDRESS OF REGISTRATION HOLDER

Equity Pharmaceuticals (Pty) Ltd

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