1.3.2.1 Patient Information Leaflet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PLASMOQUINE (200 mg, capsules)

Sugar free

Read all of this leaflet carefully before you start taking PLASMOQUINE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- PLASMOQUINE 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 PLASMOQUINE is and what it is used for.

2. What you need to know before you take PLASMOQUINE.

3. How to take PLASMOQUINE.

4. Possible side effects.

5. How to store PLASMOQUINE.

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6. Contents of the pack and other information.

1. What PLASMOQUINE is and what it is used for

What PLASMOQUINE is:

PLASMOQUINE contains the active ingredient chloroquine.

What it is used for:

PLASMOQUINE is mainly used to protect against malaria when people travel to areas where this can be a problem. It is also used to treat people who have a form of malaria called non-falciparum malaria.

2. What you need to know before you take PLASMOQUINE

Do not take PLASMOQUINE:

- if you are hypersensitive (allergic) to chloroquine or any of the other ingredients of PLASMOQUINE (listed in section 6);
- if you have a pre-existing eye disorder called maculopathy;
- if you have known hypersensitivity to 4-aminoquinoline compounds.

PLASMOQUINE should not be used in children under 6 years.

PLASMOQUINE should not be used in children over 6 years for long periods.

Warnings and precautions

Take special care with PLASMOQUINE:

- if you have or have ever had liver disease;

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- if you have a heart disease;
- if you suffer from prolonged QT interval (a rare heart problem that may cause irregular heartbeat, fainting or sudden death);
- if you have an irregular heartbeat;
- if you are taking antacids containing magnesium, kaolin or cimetidine, used to neutralise stomach acid;
- if you have a glucose-6-phosphate dehydrogenase (G-6-PD) deficiency (an inherited blood disease);
- if you have hearing problems;
- if you suffer from porphyria or other blood disorders;
- if you have a skin disorder called psoriasis;
- if you suffer from seizures;
- if you suffer from diabetes;
- if you suffer from weakness in your knees and ankles;
- if you have ever had vision changes while taking chloroquine;
- if you are pregnant or plan to become pregnant. If you become pregnant while using chloroquine phosphate, call your doctor;
- if you are breastfeeding or plan to breastfeed, tell your doctor. PLASMOQUINE can harm a nursing infant.

No malaria prevention is fully effective and therefore the prevention of mosquito bites remains the most important malaria preventative measure.

Preventative measures which should be taken are:

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- Visit areas, where malaria is prevalent, during the dry season or when rainfall is low.
- Sleep under a mosquito net which is tucked in under the mattress.
- Install screening in doors and windows.
- Regularly apply mosquito repellent to exposed skin.
- Spray living quarters with insecticide in the late afternoon.
- Use mosquito coils or pads.
- Limit outdoor activities after sunset when mosquitoes are more active.
- Wear long-sleeved shirt and trousers when outdoors between dusk and dawn.

High risk persons should avoid malaria areas altogether.

High risk persons include:

- Babies and children under the age of ~~5~~ 6 years.
- Pregnant women.
- The elderly (older than 65 years).
- Cancer patients on chemotherapy, individuals on long term steroid therapy, acquired immunodeficiency syndrome (AIDS) patients and persons who have had spleens removed.

Upon returning from a malaria area, be particularly aware of symptoms such as fever, which may alternate with chills and shivers, joint and muscular pains, severe headache, nausea, diarrhoea and fatigue (flu-like symptoms). If these symptoms are experienced, inform your doctor that you have been to a malaria area.

Children and adolescents

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Do not give PLASMOQUINE to children under 6 years of age.

Other medicines and PLASMOQUINE

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

Tell your doctor if you are taking any of the following medicines:

- Any medicine to treat depression, including the herbal product St John's wort.
- Digoxin, Flecainide, Propafenone - medicine used to treat heart disease.
- Medicines to treat diabetes.
- Medicines used to suppress the immune system such as ciclosporin.
- Antidysrhythmic medicines such as amiodarone.
- Other antimalarial medicines e.g halofantrine.
- Medicines to treat epilepsy, such as carbamazepine and phenobarbital.
- Tamoxifen (a medicine used to treat breast cancer).
- Anti-infective medicines.
- Some antibiotics used for bacterial infections (such as moxifloxacin, azithromycin, clarithromycin, erythromycin and roxithromycin). Taking these antibiotics at the same time as chloroquine may increase the chance of you getting side effects that affect your heart which could be life-threatening.
- Medicines that may affect your blood.
- Medicines that may affect your eyes.

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- Antacids containing magnesium, kaolin or cimetidine, used to neutralise stomach acid. PLASMOQUINE should be taken at least two hours apart from antacids or kaolin. Adsorbents and antacid medicines may reduce the amount of PLASMOQUINE absorbed from your gut. This may mean that the full dose of PLASMOQUINE is not absorbed into your body and it will not work properly. Therefore, you should take these medicines at least two hours before or after taking your PLASMOQUINE dose.
- Itraconazole, an antifungal medication.
- Rifampicin (antibiotics).
- Anticoagulant medicines such as dabigatran and clopidogrel.
- Medicines to treat high cholesterol, such as gemfibrozil and statins.
- Ritonavir (a medicine used to treat HIV).
- Praziquantel (used to treat infections of the bowel and bladder caused by parasites).
- Mefloquine (taken to prevent malaria) may increase the risk of convulsions or fits when taken at the same time as PLASMOQUINE.
- Agalsidase (used to treat Fabry Disease), as PLASMOQUINE may reduce its activity.

If you need a vaccination against rabies, make sure you have it before you start your anti-malarial medicine. If you have your rabies injection at the same time as taking your anti-malarial medicine, your rabies vaccine might not work so well.

PLASMOQUINE with food and drink and alcohol

Do not take grapefruit juice with PLASMOQUINE.

Tell your doctor if you drink alcohol.

Pregnancy and breastfeeding and fertility

You should not take PLASMOQUINE if you are pregnant.

The safety of PLASMOQUINE whilst breastfeeding has not been established. The active ingredient (chloroquine) is excreted in breast milk and it is known that infants are extremely sensitive to the toxic effects.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking PLASMOQUINE.

Driving and using machinery

It is not always possible to predict to what extent PLASMOQUINE 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 PLASMOQUINE affects them.

3. How to take PLASMOQUINE

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

Always take PLASMOQUINE exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Malaria prevention:

Adults and children over 12 years:

- 2 capsules per week.

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- It is advisable to start taking PLASMOQUINE one or two weeks before entering a malaria area. Thereafter repeat dosage at strictly adhered to weekly intervals during exposure to risk and for four to six weeks after exposure. The medicine should be taken on the same day of each week.

Malaria treatment:

Adults and children over 12 years:

- 4 capsules taken as a single dose followed by 2 capsules six hours later and then 2 capsules daily for the following two days.

Paediatric population

- Dosages for children are calculated according to the child's body weight.
- Your doctor will work out the correct dose for your child.
- PLASMOQUINE should not be used in children for long periods.

PLASMOQUINE should be taken at least two hours apart from antacids or kaolin.

Your doctor will tell you how long your treatment with PLASMOQUINE will last.
If you have the impression that the effect of PLASMOQUINE is too strong or too weak, tell your doctor or pharmacist.

If you take more PLASMOQUINE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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If you forget to take a dose of PLASMOQUINE

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

PLASMOQUINE can have side effects.

Not all side effects reported for PLASMOQUINE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PLASMOQUINE, please consult your healthcare provider for advice.

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing; rash or itching; fainting.
- Rash with a fever and flulike symptoms and enlarged lymph nodes. This could be a condition called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).
- Blistering, widespread scaly skin, pus-filled spots together with fever. This could be a condition called Acute Generalized Exanthematous Pustulosis (AGEP).
- Blistering or peeling of the skin around the lips, eyes, mouth, nose, genitals, hands or feet, flu-like symptoms and fever. This could be a condition called Stevens-Johnson syndrome (SJS).
- Multiple skin lesions, itching of the skin, joint aches, fever and a general ill feeling. This could be a condition called Toxic Epidermal Necrolysis (TEN).

- Skin reaction including reddish purple color, raised, painful sores, particularly on your arms, hands, fingers, face and neck, which may also be accompanied by fever. This could be a condition called Sweet's syndrome.

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

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

- Visual disturbances.
- Any hearing loss.
- Suicidal behaviour. Having thoughts of self-harm or suicide.
- Feeling depressed, feeling nervous or anxious, feeling confused, agitated, difficulty sleeping, delusions, hallucinations, changes in mood, feeling elated or overexcited.
- Frequent fevers, severe chills, bruising, sore throat or mouth ulcers (these may be signs of blood reactions).
- Changes in the way your heart beats.
- Liver problems. Symptoms may include a general feeling of being unwell, with or without jaundice (yellowing of the skin and eyes), dark urine, nausea, vomiting and/or abdominal pain.
- Symptoms of hypoglycaemia (low blood sugar), including:
  - dizziness,
  - headache,

- feeling sleepy,
- feeling weak,
- shaking,
- a fast heartbeat,
- confusion,
- hunger or sweating.

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

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- abdominal pain,
- nausea,
- diarrhoea,
- vomiting,
- hair loss,
- blurring of vision,
- headache,
- loss of appetite.

The following side effects have been reported less frequently:

- change in colour of skin,
- change in colour of hair,
- restlessness,

- seizures,
- mood changes, change in how you act,
- trouble sleeping,
- feeling confused,
- hallucinations (seeing or hearing things that are not there).

The following side effects have been reported but the frequency is unknown:

- trouble controlling body movements;
- muscle pain or weakness;
- a burning, numbness, or tingling feeling that is not normal.

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 or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of PLASMOQUINE.

5. How to store PLASMOQUINE

Store all medicines out of reach of children.

Store at or below 25 °C.

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Protect from light.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What PLASMOQUINE contains:

The active substance is chloroquine sulphate monohydrate.

The other ingredients are:

Calcium sulphate dihydrate (Edible grade E 516), Microcrystalline cellulose (Avicel PH101)

Colloidal silicon dioxide (Syloid 244), Magnesium stearate (vegetable

grade)

Composition of capsule shell, Blue:

Brilliant blue FCF FD&C Blue 1, Erythrosine FD&C Red 3, Titanium dioxide, Gelatin

Composition of the Body, White:

Titanium dioxide, Gelatin

What PLASMOQUINE looks like and contents of the pack:

What PLASMOQUINE looks like:

A hard gelatine capsule with a white body and a light blue cap.

Contents of the pack:

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The capsules are packed in 20's, 100's and 500's in white polypropylene securitainers with white LDPE lids and a foam insert.

Not all pack sizes may be marketed.

Holder of Certificate of Registration and Manufacturer

Medchem Pharmaceuticals (Pty) Ltd

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website.