SAMQUINE TABLET

CHLOROQUINE PHOSPHATE 250mg

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Document type: Summary of Product Characteristics

Document status: Final

Release date: 7th January 2020

Number of pages: 8 pages

1. NAME OF THE MEDICINAL PRODUCT

CHLOROQUINE PHOSPHATE 250mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

Each tablet contains Chloroquine Phosphate 250mg.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORMS

White circular beveled tablet with 'SAMQUINE' marked on one side and breakline on the other side

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication.

Chloroquine is used for the suppression, prevention and treatment of malaria, rheumatoid arthritis, amoebic hepatitis and lupus erythematosus.

4.2 Posology and method of administration.

Posology

The dose should be taken after food.

Adult dosage:

Initial dose equivalent to 600mg base, followed by a dose equivalent to 300mg base after 6 – 8 hours and a further dose of equivalent to 300mg base on each of the 2 following days.

- In partially immune patients, a single dose equivalent to 45mg base is usually sufficient to terminate an attack.
- For the suppression of malaria, the equivalent of 300mg base should be given regularly once a week during exposure to risk and for 3 weeks after leaving a malarial area. In most cases, this dosage will suppress all species of the malaria parasites and will cure malaria due to plasmodium falciparum.

- For the prevention of recrudescences, a single dose equivalent to 600mg base should be given to kill erythrocytric parasites, this dose being followed by a course of treatment with primaquine.
- Malaria/infection resistance to Samquine should be treated with quinine, pyrimathamine together with a sulphonamide or silphone.
- In case of hepatic amoebiasis and amoebic liver abscess, the equivalent of 300mg base should be taken twice a day for 2 days or longer, and then once a day for a further 2-3weeks.
- In case of lupus erythematosus, start treatment with the equivalent of 300-400mg base daily, and later reduce the dosage to the equivalent 150mg base per day.
- In rheumatoid arthritis, the recommended dosage is the equivalent of 75 to 300mg base per day for 2-3 months

Children:

Initial dose of 10mg/kg base then a single dose of 5mg/kg after 6-8 hours then a single dose of 5mg/kg daily for 2 days. For the suppression of malaria in children, the suggested dose as follows

- For those aged under 1 year, weekly dose is 37mg
- For children 1 – 4 years, weekly dose of 75mg is recommended.
- For aged 5 to 8 years, weekly dose of 150mg

Method of Administration

For oral administration

4.3 Contraindications

Caution must be exercise in administering chloroquine to patients with impaired liver or renal function or with prophyria or psoriasis.

4.4 Special warnings and precaution for use.

When used as malaria prophylaxis official guidelines and local information on prevalence of resistance to anti-malarial drugs should be taken into consideration.

Chloroquine has been shown to cause severe hypoglycaemia including loss of consciousness that could be life threatening in patients treated with and without antidiabetic medications. Patients treated with chloroquine should be warned about the risk of hypoglycaemia and the associated clinical signs and symptoms. Patients presenting with clinical symptoms suggestive of hypoglycaemia during treatment with chloroquine should have their blood glucose level checked and treatment reviewed as necessary.

Caution is necessary when giving chloroquine to patients with impaired hepatic function, particularly when associated with cirrhosis.

Caution is also necessary in patients with porphyria. Chloroquine may precipitate severe constitutional symptoms and an increase in the amount of porphyrins excreted in the urine. This reaction is especially apparent in patients with high alcohol intake.

A small number of cases of diffuse parenchymal lung disease have been identified in patients taking chloroquine. A response after therapy with steroids has been observed in some of these cases.

4.5 Interaction with other medicinal product and other forms of interaction.

Chloroquine should be used with caution in patients receiving drugs known to prolong the QT interval e.g. Class IA and III antiarrhythmics, tricyclic antidepressants, antipsychotics, some anti-infectives due to increased risk of ventricular arrhythmia. Halofantrine should not be administered with chloroquine. In particular, amiodarone should not be used and its use is contraindicated. Antacids (aluminium, calcium and magnesium salts) and adsorbents (e.g. kaolin) may reduce the absorption of chloroquine, so should be taken well separated from chloroquine (at least four hours apart).

Chloroquine may lower the convulsive threshold and thus antagonise the actions of antiepileptics.

Thyroid medication: increased Thyroid Stimulating Hormone levels have been observed with the concomitant use of levothyroxine, dosage adjustment of thyroid medication may be necessary.

There is a theoretical risk of inhibition of intra-cellular α-galactosidase activity when chloroquine is co-administered with agalsidase.

4.6 Pregnancy and Lactation.

Pregnancy

Chloroquine should not be used during pregnancy unless, in the judgement of the physician, potential benefit outweighs the risk.

Malaria in pregnant women increases the risk of maternal death, miscarriage, still-birth and low birth weight with the associated risk of neonatal death. Travel to malarious areas should be avoided during pregnancy but, if this is not possible, women should receive effective prophylaxis.

Breast-feeding

Although chloroquine is excreted in breast milk, the amount is too small to be harmful when used for malaria prophylaxis but as a consequence is insufficient to confer any benefit on the infant. Separate chemoprophylaxis for the infant is required. However, when long-term high doses are used for rheumatoid disease, breast feeding is not recommended.

4.7 Effect on the ability to drive and use machine.

Defects in visual accommodation may occur on first taking of chloroquine and patients should be warned regarding driving or operating machinery.

4.8 Undesirable effect.

The adverse reactions which may occur at doses used in the prophylaxis or treatment of malaria are generally not of a serious nature. Where prolonged high dosage is required, i.e. in the treatment of rheumatoid arthritis, adverse reactions can be of a more serious nature.

Most of the side effects are transient which include anorexia, nausea, gastro-intestinal disturbances particularly in patients with a sensitive stomach which can be prevented or alleviated by not taking the drug on an empty stomach, but after meals and with suficient amount of liquid.

Ocassionally, Nervous symptoms, daze, insomina, restlessness and headache can occur. Skin reactions such as itching, exanthema, hypersensitivity to light and a transitory decolouration of the hair occur only in rare cases.

Individual reponse to drug can vary significantly in patients with psoriasis. Neuromyopathy in the form of muscular debility in the legs is observed only rarely. Disturbances subside on discontinuation of the drug.

4.9 Overdose.

Chloroquine is highly toxic in overdose and children are particularly susceptible. The chief symptoms of overdosage include circulatory collapse due to a potent cardiotoxic effect, respiratory arrest and coma. Symptoms may progress rapidly and include:

- General features include nausea and vomiting. Hypokalaemia is common in severe poisoning and metabolic acidosis may also develop. Rarely hepatotoxicity, nephritis, gastric haemorrhage, haematological abnormalities and psychiatric features may occur.

- Neurological features include headache, dizziness, drowsiness, blurred vision, diplopia and rarely, blindness, may precede restlessness, increased excitability and convulsions. Coma is less common.

- Cardiac features often appear at an early stage. Cardiac arrest may be a presenting feature. Hypotension is very common and may progress to cardiogenic shock and pulmonary oedema.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties.

The mode of action of chloroquine on plasmodia has not been fully elucidated. Chloroquine binds to and alters the properties of DNA.

In suppressive treatment, chloroquine inhibits the erythrocytic stage of development of plasmodia. In acute attacks of malaria, it interrupts erythrocytic schizogony of the parasite. Its ability to concentrate in parasitised erythrocytes may account for the selective toxicity against the erythrocytic stages of plasmodial infection

5.2 Pharmacokinetic properties.

Studies in volunteers using single doses of chloroquine phosphate equivalent to 300mg base have found peak plasma levels to be achieved within one to six hours. These levels are in the region of 54 - 102microgram/litre, the concentration in whole blood being some 4 to 10 times higher. Following a single dose, chloroquine may be detected in plasma for more than four weeks. Mean bioavailability from tablets of chloroquine phosphate is 89%. Chloroquine is widely distributed in body tissues such as the eyes, kidneys, liver, and lungs where retention is prolonged. The elimination of chloroquine is slow, with a multi exponential decline in plasma concentration. The initial distribution phase has a half-life of 2-6 days while the terminal elimination phase is 10-60 days. Approximately 50-70% of chloroquine in plasma is bound to the plasma proteins.

The principal metabolite is monodesethylchloroquine, which reaches a peak concentration of 10-20 microgram/litre within a few hours. Mean urinary recovery, within 3-13 weeks, is approximately 50% of the administered dose, most being unchanged drug and the remainder as metabolite. Chloroquine may be detected in urine for several months.

5.3 Preclinical safety data.

Product is not a new chemical entity therefore this section is not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Di-calcium phosphate

Maize Starch

Purified Talc.

Magnesium Stearate

Gelatine

Methyl Paraben

Propyl Paraben

Aerosil

6.2 Incompatibilities

Unknown

6.3 Shelf-life

30Months from the date of manufacture

6.4 Special precautions for storage

Protect from heat and light, and store in a cool dry place below 30^0C

6.5 Nature and composition of immediate packaging

1000 tablet is packed into a polythene seal bag and put into a 500cc plastic secured-container.

7. MARKETING AUTHORISATION HOLDER

SAM PHARMACEUTICALS LIMITED.
2, WESTERN RESERVOIR ROAD,
ILORIN,
KWARA STATE, NIGERIA.
08057075266
sampharmaceuticalltd@gmail.com

8. MARKETING AUTHORISATION NUMBER(S)

04 – 4700

9. AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal date: 25th February 2020

10. DATE OF REVISION OF THE TEXT

6th January, 2024