# SUMMARY OF PRODUCTS CHARACTERISTICS

## 1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

**1.1** Brand Name : **QSM-300 Tablet**
**1.2** Generic Name : Quinine Sulphate Tablets 300mg
**1.3** Strength : 300mg/tablet
**1.4** Pharmaceutical Form : Tablet

## 2. QUALITATIVE & QUANTITATIVE COMPOSITION :

Each film-coated tablet contains:
Quinine Sulphate BP 300 mg.
Colour: Titanium Dioxide BP

## 3. PHARMACEUTICAL FORM

Tablet
White coloured, round, biconvex film-coated tablets.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Quinine is used in the treatment of falciparum malaria; nocturnal leg cramps or if the infective species is not known or if the infection is mixed.

### 4.2 Posology and method of administration:

Adult : 600 mg (of quinine salt) every 8 hours for 5–7 days.
Children : 10 mg/kg (of quinine salt) every 8 hours for 7 days.

### 4.3 Contraindications:

**QSM (Quinine Sulphate)** is contraindicated in haemoglobinuria, myasthenia gravis, optic neuritis, tinnitus.

### 4.4 Special warnings and special precautions for use:

Cardiac disease (including atrial fibrillation, conduction defects, heart block), elderly—monitor ECG during parenteral treatment; monitor blood glucose and electrolyte concentration during parenteral treatment; G6PD deficiency.

**Hepatic and Renal impairment:** For treatment of malaria in severe impairment, reduce parentral maintenance dose to 5-7mg/kg of quinine salt.

### 4.5 Interaction with other FPPs and Other forms of Interaction

Increased risk of ventricular arrhythmias when Quinine given with amiodarone, moxifloxacin, artemether/lumefantrine, pimozide, droperidol, haloperidol, riserperidone, saquinavir, citalopram and escitalopram.

Increased risk of convulsions when Quinine given with mefloquine (but should not prevent the use of intravenous quinine in severe cases).

Quinine increases plasma concentration of flecainide, warfarin, digoxin, amandine.

Metabolism of quinine inhibited by cimetidine (increased plasma concentration). Plasma concentration of quinine is reduced by rifampicin.

### 4.6 Pregnancy and lactation

Falciparum malaria is particularly dangerous in pregnancy, especially in the last trimester, High doses of Quinine sulphate are teratogenic in first trimester, but in malaria, benefit of treatment outweighs risk. Quinine sulphate is present in milk but not known to be harmful.

### 4.7 Effects on ability to drive and use machines

None known

### 4.8 Undesirable effects

Side effects of Quinine may include cinchonism, including tinnitus, headache, hot and flushed skin, nausea, abdominal pain, rashes, visual disturbances (including temporary blindness), agitation, confusion; cardiovascular effects; dyspnoea; hypersensitivity reactions including angioedema; hypoglycaemia (especially after parenteral administration); blood disorders (including thrombocytopenia and intravascular coagulation); acute renal failure; muscle weakness; photosensitivity.

### 4.9 Overdose & Treatment

Overdosage of quinine, is extremely hazardous and difficult to treat. Urgent advice from the National Poisons Information Service is essential. Life-threatening features include arrhythmias (which can have a very rapid onset) and convulsions (which can be intractable).

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Quinine, a Cinchona alkaloid is a rapidly acting blood schizonticide with activity against P.falciparum, P.vivax, P. ovale and P.malariae. It is active against the ametocytes of P. malariae and P.vivax but not against the mature gametocytes of P. falciparum. The precise mechanism of action of Quinine is not clear, but it may interfere with the lysosome function of nucleic acid synthesis in the malaria parasite.

### 5.2 Pharmacokinetic properties

The pharmacokinetics of quinine is altered significantly by malaria infection, the major effects being reductions in both its apparent volume of distribution and its clearance.

**Absorption:**

Quinine is rapidly and almost completely absorbed from the GI tract and peak concentrations in the circulation are attained about 1-3 hours after oral administration of the sulfate.

**Distribution:**

Plasma protein binding is about 70% in healthy subjects and rises to 90% or more in patients with malaria. Quinine is widely distributed throughout the body. Concentrations attained in the CSF of patients with cerebral malaria have been reported to be about 2-7% of those in the plasma.

**Biotransformation:**

Quinine is extensively metabolised in the liver and rapidly excreted mainly in the urine. Estimates of the proportion of unchanged quinine excreted in the urine vary from less than 5% to 20%. The pharmacokinetics of quinine are altered significantly by malaria infection, with reductions in both the apparent volume of distribution and clearance.

**Elimination:**

Excretion is increased in acid urine. The elimination half-life is about 11 hours in healthy subjects but may be prolonged in patients with malaria. Small amounts of quinine also appear in the bile and saliva. Quinine crosses the placenta and is excreted in the breast milk.

### 5.3 Preclinical safety data

None Known

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of Excipients

| SN | Ingredients | Spec. |
|---|---|---|
| 01. | Starch (Maize) | BP |
| 02. | Microcrystalline Cellulose | BP |
| 03. | Sod. Methyl Hydroxybenzoate (Sodium Methylparaben) | BP |
| 04. | Sod. Propyl Hydroxybenzoate (Sodium Propylparaben) | BP |
| 05. | Purified Talc (Talcum) | BP |
| 06. | Magnesium Stearate | BP |
| 07. | Colloidal Anhydrous Silica (Colloidal Silicon Dioxide) | BP |
| 08. | Sodium Starch Glycolate | BP |
| 09. | Purified Water | BP |
| **Coating** | | |
| 10. | Hypromellose (HPMC-15 cps) | BP |
| 11. | Colour Titanium Dioxide (77981) | BP |
| 12. | Macrogol-4000(P.E. G.- 4000) | BP |
| 13. | Diethyl Phthalate | BP |
| 14. | Purified Talc (Talcum) | BP |
| 15. | Dichloromethane (Methylene Chloride) | BP |
| 16. | Isopropyl Alcohol | BP |

### 6.2 Incompatibilities

Not Known

### 6.3 Shelf life

36 months

**6.4 Special precautions for storage**

Store at a temperature not exceeding 30°C. Protect from light. Keep out of reach of children. Keep away from moisture.

**6.5 Nature and contents of container**

10 blisters of 10 tablets packed in an inner carton. (10x10)

**6.6 Instructions for use and handling**

Please see the package insert.

**7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS**

**LEBEN LABORATORIES PVT. LTD.,**

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**8. MARKETING AUTHORISATION NUMBER**
**AMD/12/2002 & AMD/6/2002:**

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**
**a) Date of first authorization: 21/01/1989.**
**b) Date of latest renewal: 01/01/2018.**

**10. DATE OF REVISION OF THE TEXT**
**01/01/2023**