



# **MALARIA DRUG POLICY (2007)**



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## **NATIONAL DRUG POLICY ON MALARIA (2007)**

### **Preamble**

Malaria is one of the major public health problem of the country. Around 2 million laboratory confirmed cases of malaria are reported in the country annually. Out of the total malaria cases, 40-50% is *P.falciparum*. The *P.falciparum* species is spreading wider due to migration of population from endemic to non endemic areas and vis-à-vis has increased tremendously. One of the reasons attributed to rise in *P.falciparum* is resistance to drug chloroquine, which is being used as a first line of treatment for malaria cases. During recent years it has been observed that chloroquine resistance is widely spread as per the results of the drug sensitivity studies conducted. This is a serious concern to the programme as this species is responsible for mortality. It is observed that *P.falciparum* infection may lead to complications in 0.5% to 2% of cases. Mortality may result in about 30% of such cases if timely treatment is not given. Use of an appropriate anti malaria drugs is very important not only to save the life in *P.falciparum* cases but also to contain the spread of this species.

At present the main thrust in the programme is on early diagnosis and prompt treatment which are the key components of malaria control. Malaria diagnosis is carried out by microscopic examination of blood films collected by active and passive agencies. The presumptive treatment ( chloroquine at a dose of 10 mg/kg body weight ) is given at the time of blood smear collection and radical treatment (chloroquine at a dose of 25 mg/kg body weight + primaquine as per the species) to confirmed malaria patients on microscopy confirmation. The treatment schedule varies from area to area depending on endemicity and status of resistance to antimalarials. The WHO technical advisory group on malaria in its meeting held in India on 15-17 December, 2004 has recommended that the Member countries should be discouraged from implementing presumptive, single-dose and incomplete treatment with chloroquine. If a patient is suspected of having malaria which cannot be immediately confirmed, full treatment with recommended drugs should be given. Health agencies and volunteers running fever treatment in inaccessible areas should be provided with rapid diagnostic kits for diagnosis and to ensure full radical treatment to confirmed malaria cases. Priority for treatment should be given to clinically

suspected cases rather than on the basis of only fever. Further, the WHO malaria treatment guidelines also recommend that anti malarial treatment policy should be changed when treatment failure rates are considerably lower i.e the initiation of alternative treatment regimen at the treatment failure proportion exceeds 10%. The reasons attributed for implications of using drugs with low efficacy is that once the drug resistance has emerged in a locality, the continued use of the failing drug will result in the rapid spread of drug resistance in the area.

***According to WHO: An antimalarial treatment policy is a set of recommendations and regulations concerning the availability and rational use of antimalarial drugs in a country It should be the part of the national essential drug policy and the national malaria control policy and in line with the overall national health policy.***

The main purpose of the national anti-malaria drug policy is to provide a framework for the safe and effective treatment of uncomplicated and severe malaria as well as prevention of malaria in travellers and vulnerable groups, such as pregnant women and young children. All health care providers in both the public and private sectors must be aware of, understand the rationale for, and implement the national anti-malaria drug policy.

An effective treatment policy should aim to:

- Reduce morbidity
- Prevent the progression of uncomplicated disease into severe and potentially fatal disease and thereby reduce malaria mortality
- Reduce the impact of placental malaria infection and maternal malaria-associated anaemia through chemoprophylaxis or preventive intermittent therapy
- Prevent or delay the development of antimalarial drug resistance by correct diagnosis and rational treatment of all malaria positive cases.

National anti-malaria drug policy was first drafted in 1982. Thereafter the policy is being reviewed periodically by the expert committee on chemotherapy of malaria constituted by Director General of Health Services. The recommendations of this committee are being ratified by the Technical Advisory Committee constituted by the MOH&FW under the Chairmanship of Director General of Health Services. The present national drug policy for Malaria has been framed keeping in view of proper deployment of effective anti malarial

drugs and its judicious use for the treatment of clinically suspected and confirmed malaria cases.

### **Management of malaria case:**

- Clinically diagnosis of malaria on the basis of sign and symptoms
- Confirmation of malaria by Laboratory diagnosis/RDT;
- Referral to secondary/tertiary level of care, if necessary;
- Education of patient or family on :
  - (i) administration of the drugs
  - (ii) when to report to health facility
  - (iii) danger symptoms
  - (iv) prevention of malaria
- Dispensing the correct drugs of assured quality,( first dose be given preferably by dispenser);
- Patient compliance as per instructions;

### **Signs and symptoms**

**Typical:** Sudden onset of high fever with rigors and sensation of extreme cold followed by feeling of burning, leading to profuse sweating and remission of fever by crisis thereafter. The febrile paroxysms occur every alternate day. Headache, body ache, nausea, etc. may be associated features.

**Atypical:** In atypical cases, classical presentation as mentioned above may not manifest. Hence, any fever case in the endemic areas during transmission season may be considered as malaria.

### **Anti malaria drugs**

- 1) Schizonticidal drugs for clinical and parasitological cure
  - Chloroquine, Amodiaquine, Quinine, Quinidine, Pyrimethamine, Trimethoprim, Proguanil, sulfonamides in combination with Pyrimethamine, Mefloquine,

Halofantrine, Artemisinin and its derivatives like Artesunate, Artemether, Arteether.

2) Gametocytocidal and anti-relapse drugs.

- Primaquine, 8-Aminoquinolines groups, only compound having action on gametocytes and Hypnozoites.

The treatment schedule followed under the programme is given in Annexure I.

Categories for the treatment of malaria include drugs for first line of treatment (treatment given to clinical or confirmed malaria), second line of treatment: treatment (given to Treatment failure), severe and complicated malaria, pregnant women, travelers and mass treatment (recommended in epidemics).

## NATIONAL DRUG POLICY ON MALARIA

1. All fever cases should preferably be investigated for malaria by Microscopy or Rapid Diagnostic Kit (RDK).
2. The first line of treatment is chloroquine and the second line is ACT (Artesunate+Sulpha Pyrimethamine) combination. In case resistant to these formulations and to treat severe and complicated malaria quinine will be the drug of choice.
3. Microscopically positive Pf cases should be treated with chloroquine in therapeutic dose of 25 mg/kg body weight over three days and single dose of Primaquine 0.75 mg/kg bw on the first day. This practice is to be followed at all levels including VHWs like DDCs/FTDs/ASHA as well.
4. Microscopically positive Pv cases should be treated with chloroquine in full therapeutic dose of 25 mg/kg body weight over three days. This practice is to be followed at all levels including VHWs like DDCs/FTDs/ASHA etc. Primaquine can be given in dose of 0.25mg/kg bw daily for 14 days under medical supervision only to prevent relapse.
5. Fever cases positive by RDK should be treated according to the diagnosed species as described above. However, if RDK for only Pf is used, negative cases showing sign and symptom of malaria without any other obvious causes should be considered as 'clinical malaria' and treated with chloroquine in full therapeutic dose of 25 mg/kg body weight over three days.
6. In situations where diagnosis by microscopy or RDK is not possible, cases showing sign and symptom of malaria without any other obvious causes should be considered as 'clinical malaria' and treated with chloroquine in full therapeutic dose of 25 mg/kg body weight over three days in low risk area while in high risk area single dose of Primaquine 0.75 mg/kg bw should also be given on the first day. This practice is to be followed at all levels including VHWs like DDCs/FTDs/ASHA as well.
7. ACT is the first line of antimalarial drug for treatment of *P.falciparum* in chloroquine resistant areas. The dose is 4mg/kg bw of artesunate daily for 3 days + 25mg/ kg bw of sulphadoxine/sulphalene + 1.25 mg per kg bw of pyrimethamine on the first day. ACT should be given only to confirmed *P. falciparum* cases found positive by

microscopy or Rapid Diagnostic kits. Compliance and full intake is to be ensured. **Primaquine may not be given with ACT combination as artesunate reduces gametocyte carriage.**

8. The area/PHC showing a treatment failure more than 10% (both Early and Late Treatment Failures ) to the tested drug chloroquine in the minimum sample of 30 cases, should be switched over to the alternate antimalarial drug i.e. Artesunate-Sulpha-Pyrimethamine (ACT) combination.
9. Change of drug to second line of treatment may also be implemented in a cluster of PHCs around the resistant foci after taking into consideration the epidemiological trend of *P.falciparum* ( Pf>30%) and clinical response in these areas and approval of Directorate of NVBDCP.
10. Resistance should also be suspected if in spite of full treatment with no history of vomiting, diarrhea, patient does not respond within 72 hours parasitologically. Such patients should be given alternative drug i.e. ACT combination and report to concerned District Malaria /State Malaria Officer/ROHFW Pf monitoring teams for monitoring of drug sensitivity status.
11. In areas with high disease burden, high proportion of Pf, inadequate facilities for laboratory diagnosis and the inaccessibility and relatively poor communication facilities and the Pf chloroquine resistant pockets, ACT may also be given on clinical diagnosis of malaria by a trained medical officers or trained paramedical personnel after excluding other common causes of fever.
12. The cases resistant to CQ and SP-ACT, oral quinine with tetracycline or doxycycline can be prescribed.
13. Mefloquine should only be given to chloroquine/multi resistant uncomplicated *P.falciparum* cases only in standard doses as prescribed by WHO. This drug is to be made available through the depot system and only to be provided to patients against the prescription of medical practitioners supported by laboratory report showing asexual stage of *P.falciparum* parasite and not gametocyte alone and other species.
14. Primaquine is contra indicated in pregnant woman and infants.
15. Chemoprophylaxis is recommended in selective cases. It is recommended for
  - a) Pregnant women in high-risk areas and

b) Travelers including service personnel who temporarily go on duty to high malarious areas.

In chloroquine sensitive areas, weekly dose of chloroquine will be given but in chloroquine resistant areas it should be supplemented by daily dose of proguanil. However chemoprophylaxis should not exceed 3 years due to the cumulative toxic effect of chloroquine.

16. In severe and complicated *P.falciparum* malaria cases intra-venous Quinine/parenteral Artemisinin derivatives (**for adults and non-pregnant women only**) are to be given irrespective of chloroquine resistance status. In case of non-availability of the above drugs, Chloroquine 10 mg/kg bw in isotonic saline should be infused over 8 hours followed by 15 mg/kg bw in the next 24 hours. This treatment may continue till such time Quinine/Artemisinin derivatives become available.
17. Migratory labour/project population: Since these groups belong to high risk category they need to be screened on weekly basis and treated accordingly.
- 18 All the medical, paramedical and village level health volunteers should be adequately trained before their involvement in the programme.
19. Artesunate tablets should not be administered as monotherapy. It should invariably be combined with sulphapyrimethamine tablets in prescribed dosages.

**DRUG SCHEDULE FOR TREATMENT OF MALARIA UNDER NVBDCP.****1. Chloroquine**

Chloroquine base	Day 1	10mg/kg	(600 mg adult)
Chloroquine base	Day 2	10mg/kg	(600 mg adult)
Chloroquine base	Day 3	5mg/kg	(300 mg adult)

**Dosage as per age groups**

Age in years	Day 1	Day 2	Day -3
	Tab. chloroquine	Tab. Chloroquine	Tab. Chloroquine
<1	½	½	¼
1-4	1	1	½
5-8	2	2	1
9-14	3	3	1½
15 & above	4	4	2

**2. Primaquine**

**PRIMAQUINE IS CONTRAINDICATED IN INFANTS AND PREGNANT WOMEN**

**Dosage as per age groups****(a) *P. falciparum***

Age in years	Primaquine On Day 1		
	mg base	No. of Tablets (2.5 mg base)	No. of Tablets (7.5 mg base)
<1	Nil		0
1-4	7.5	3	1
5-8	15	6	2
9-14	30	12	4
15 & above	45	18	6

(b) *P. vivax*

Age in year	Primaquine Daily dose for 14 days*		
	mg base	No. of Tablets (2.5 mg base)	No. of Tablets (7.5 mg base)
< 1	Nil	Nil	Nil
1-4	2.5	1	1/3
5-8	5.0	2	2/3
9-14	10.0	4	1 1/3
15 & Above	15.0	6	2

- *\*Primaquine for 14 days should be given under medical supervision only*

3. Artesunate + Sulpha-pyrimethamine (ACT) combination

Age wise Dose Schedule for AS+SP

Age		1 <sup>st</sup> Day (number of tabs)*	2 <sup>nd</sup> Day (number of tabs)	3 <sup>rd</sup> Day (numbers of tabs)
<1 Year	AS	1/2	1/2	1/2
	SP	1/4	Nil	Nil
1-4 Yeas	AS	1	1	1
	SP	1	Nil	Nil
5-8 Year	AS	2	2	2
	SP	1 1/2	Nil	Nil
9-14 Year	AS	3	3	3
	SP	2	Nil	Nil
15 and above	AS	4	4	4
	SP	3	Nil	Nil

Strength of each Artesunate tablet: contains 50 mg & each Sulpha Pyrimethamine (SP) tablet contain 500mg sulphadoxine/sulphalene and 25mg pyrimethamine

*\*Artemisinin group of drugs is not recommended in pregnancy*

***\*\*Primaquine may not be given with ACT combination as artesunate reduces gametocyte carriage.***

#### 4. Severe and complicated malaria cases

- (1) In severe and complicated malaria of *P.falciparum* (clinically/microscopically confirmed) parenteral artemisinin or quinine is the drug of choice, irrespective of chloroquine resistance status of the area.
- (2) Quinine salt .10mg /kg bw 8 hourly in 5% dextrose saline is preferred. Patients should be switched over to oral quinine as early as possible and oral dose is 10 mg/kg bw eight hourly not exceeding 2gm in a day in any case. Minimum total duration for quinine therapy should be for 7 days including both parental and oral doses.
- (3) Injectable form of artemisinin derivatives may be used for the management of severe and complicated malaria (**For adults and non-pregnant only**) in the dosage given below:
  - **Artesunate:** 2.4 mg/kg bw IM/IV followed by 1.2 mg/kg bw after 12 hours then 1.2 mg/kg bw once daily for total duration of 5 days.
  - **Artemether:** 1.6 mg/kg bw IM followed by 1.6 mg/kg bw daily for total of 6 injections or 1.6 mg./kg bw IM injection twice daily for 3 days, a total of 6 injections.
  - **Arteether:** 150 mg daily IM for 3 days in adults only.
  - **Artemisinin** 10 mg/kg bw at 0 and 4 hours followed by 7 mg/kg bw at 24, 36, 48 and 60 hours.

#### 5. Chemoprophylaxis

- *In chloroquine sensitive areas-chloroquine*
- *In chloroquine resistant areas-chloroquine+ proguanil*
- Chemoprophylaxis is to be started a week before arriving to malarious area for visitors and for pregnant women prophylaxis should be initiated from second trimester.

- Start with loading dose of 10 mg/kg bw and followed by a weekly dose of 5 mg/kg bw. This is to continue till 1 month after delivery in case of pregnancy and in travelers till one month after return from endemic area. The terminating dose should be radical treatment for *P.vivax* i.e 25 mg/kg bw over 3 days along with 0.25 mg/kg bw of primaquine for 14 days under medical supervision.
- Chemoprophylaxis with chloroquine is not recommended beyond 3 years because of its cumulative toxicity.
- In chloroquine resistant areas chemoprophylaxis is recommended with chloroquine 5 mg/kg bw weekly supplemented with proguanil 200mg daily.

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