

SCHEDULING STATUS: S4
NS2 (Namibia)

PROPRIETARY NAME (AND DOSAGE FORM):

MIRQUIN SYRUP

COMPOSITION:

Each 5 ml contains:
Chloroquine sulphate 68 mg
equivalent to 50 mg chloroquine base

PRESERVATIVES:

Sodium Benzoate 0,1 % (m/v)
Potassium Sorbate 0,2 % (m/v)

PHARMACOLOGICAL CLASSIFICATION:

A 20.2.6 Medicine against protozoa.

PHARMACOLOGICAL ACTION:

Chloroquine is a blood schizontozide and is effective against asexual erythrocytic forms of *P. vivax* and sensitive strains of *P. falciparum* and gametocytes of *P. vivax*.

INDICATIONS:

Indicated for the prophylaxis of malaria in areas where there is no chloroquine resistance. Indicated for the treatment of malaria, provided that the patient did not contract malaria in a chloroquine-resistant area and was not using chloroquine as prophylaxis for malaria.

CONTRA-INDICATIONS:

Chloroquine should not be given to persons with a known hypersensitivity to chloroquine.

WARNINGS:

As soon as flu-like symptoms appear the patient must inform the doctor that he has been to a malarious area. Care is necessary in administering chloroquine to patients with impaired liver or renal function or to those with porphyria, psoriasis, or a history of epilepsy. Patients with glucose-6-phosphate dehydrogenase deficiency should be observed for haemolytic anaemia during chloroquine treatment. Although there have been reports of foetal abnormalities associated with the use of chloroquine during pregnancy, the risks of malaria are considered to be greater and there appears to be no justification for withholding chloroquine for the treatment or prophylaxis of malaria.

DOSAGE AND DIRECTIONS FOR USE:

DO NOT EXCEED THE RECOMMENDED DOSAGE (Dosages administered to infants or children, orally should not exceed 10 mg of chloroquine base per kilogram of body weight per day: the usual dose is 5 mg of the base per kilogram). The syrup is recommended for children up to the age of ten years.

SUPPRESSION OF MALARIA: A weekly dose should be given, taken on the same day each week. It is advisable to start taking MIRQUIN 2 weeks (or, if not possible, at least 24 hours) before entering an endemic area and to continue for at least 4 – 6 weeks after leaving. A weekly dose of 5 mg/kg is recommended for children.

MASS OF CHILD Kg:	DOSE OF MIRQUIN MEDICINE MEASURES:
5	half x 5 ml (2,5 ml)
10	one x 5 ml
20	two x 5 ml
30	three x 5 ml
40	four x 5 ml
50	five x 5 ml

TREATMENT OF MALARIA: The usual total oral dose for children is the equivalent of about 25 mg of chloroquine base per kg body mass given over 3 days in a variety of ways, e.g. 10 mg per kg followed after 6 to 8 hours by 5 mg per kg, then 5 mg per kg daily for the next 2 days. Alternatively 10 mg per kg may be given daily for the first 2 days and 5 mg per kg on the third day.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side-effects: Side-effects include headache, various skin eruptions, pruritus and gastro-intestinal disturbances such as nausea, vomiting and diarrhoea. Less frequently, mental changes including psychotic episodes, anxiety and personality changes may occur.

Visual disturbances such as blurred vision and difficulties in focusing have occurred but are more common with larger doses, when they may be associated with keratopathy or

retinopathy. Keratopathy usually occurs in the form of corneal opacities and is normally reversible when chloroquine is withdrawn. Retinopathy is the most serious adverse effect of chloroquine on the eyes and it can result in severe visual impairment. Changes may be irreversible and can even progress after chloroquine is discontinued. Those taking large doses of chloroquine over prolonged periods appear to be at greatest risk of developing retinopathy.

Other uncommon adverse effects from prolonged use include loss of hair, bleaching of hair pigment, black pigmentation of the mucous membranes and skin, photosensitivity, tinnitus, reduced hearing, nerve deafness, neuromyopathy and myopathy. Blood disorders have been reported less frequently. They include aplastic anaemia, reversible agranulocytosis, thrombocytopenia and neutropenia.

Special precautions: Because no form of prophylaxis is fully effective, the prevention of mosquito bites should form the mainstay of malaria prophylaxis. The following preventative measures to prevent mosquito bites should be taken:

- endemic areas should preferably be visited during the dry season or in years when rainfall is low.
- high risk patients should avoid malaria areas altogether, namely:
 - babies and young children less than 5 years of age
 - pregnant women
 - immunocompromised individuals such as those on long-term steroids, cancer patients and those on chemotherapy, AIDS patients and those who have had their spleens removed.
- not going outside between dusk and dawn, when mosquitoes are most active
- applying insect repellent to exposed skin and clothing
- using mosquito nets, screens, coils or pads
- wearing long sleeves and trousers at night.

Interactions: Antacids can reduce the absorption of chloroquine and it is recommended that they should be administered at least 4 hours apart. Cimetidine and chloroquine should be used with caution as cimetidine can significantly reduce the metabolism and elimination of chloroquine and increase its volume of distribution. Administration with food may be beneficial as it appears to improve the absorption of chloroquine.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Acute overdose is extremely dangerous and death can occur within a few hours. Initial effects include headache, gastro-intestinal disturbances, drowsiness and dizziness. Visual disturbances may be dramatic with a sudden loss of vision. However, the main effect of overdose with chloroquine is cardiovascular toxicity with hypotension and cardiac arrhythmias progressing to cardiovascular collapse, convulsions, cardiac and respiratory arrest and death. Treatment is symptomatic and supportive.

CONDITIONS OF REGISTRATION:

Advertising to the professions only.

IDENTIFICATION:

A clear red, viscous syrup with a raspberry taste and odour.

PRESENTATION:

Ambor glass bottles of 100 ml.

STORAGE INSTRUCTIONS:

Store below 25 °C, protected from light.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

Z/20.2.6/388
05/20.2.6/0177 (Namibia)

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

Mirren (Pty) Ltd
18 Golden Drive
Morehill
Benoni
South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

1992-05-06

SKEDULERINGSSTATUS: S4

NS2 (Namibië)

EIENDOMSNAAM (EN DOSEERVORM):**MIRQUIN STROOP****SAMESTELLING:**

Elke 5 ml bevat:

Chlorokiensulfaat 68 mg

ekwivalent aan 50 mg chlorokienbasis

PRESERVEERMIDDELS:

Natriumbensoaat 0,1 % (m/v)

Kaliumsorbaat 0,2 % (m/v)

FARMAKOLOGIESE KLASSIFIKASIE:

A 20.2.6 Medisyne teen protosoë.

FARMAKOLOGIESE WERKING:

Chlorokien is 'n bloedsikisontosied en is doeltreffend teen die aseksuele eritosietvorms van *P. vivax* en gevoelige stamme van *P. falciparum* asook gametosiete van *P. vivax*

INDIKASIES:

Aangedui vir die profilakse van malaria in gebiede waar daar geen chlorokienweerstand is nie. Aangedui vir die behandeling van malaria, met die voorsorg dat die malaria nie in 'n chlorokien-weerstandbiedende area opgedoen is nie en dat chlorokien nie as profilakse gebruik was nie.

KONTRA-INDIKASIES:

Chlorokien moenie gegee word aan persone met 'n bekende hipersensitiwiteit teen chlorokien nie.

WAARSKUWINGS:

Sodra griepsimptome voorkom moet die pasiënt die dokter inlig dat hy 'n malariagebied besoek het. Chlorokien moet met oorleg gegee word aan pasiënte met ingekorte lewer of nierfunksie, of pasiënte met porfirie, psoriasis, of 'n geskiedenis van epilepsie. Pasiënte met 'n tekort aan glukose-6-fosfaat-dehidrogenase moet dopgehou word vir hemolitiese anemie tydens chlorokienbehandeling. Alhoewel daar gevalle was van fetale abnormaliteite wat verband hou met die gebruik van chlorokien tydens swangerskap, word beskou dat die risiko van malaria groter is. Daar is dus onwaarskynlik regverdiging om chlorokien vir die behandeling of profilakse van malaria te weerhou.

DOSES EN GEBRUIKSAANWYSINGS:

MOENIE DIE VOORGESKREWE DOSES OORSKRY NIE ('n Dosis wat oraal toegedien word aan babas of kinders moet nie 10 mg chlorokien basis per kilogram liggaamsmassa per dag oorskry nie; die gewone dosering is 5 mg van die basis per kilogram). Die stroop is aangedui vir kinders tot op die ouderdom van 10 jaar.

ONDERDRUKKING VAN MALARIA: 'n Weeklikse dosering moet op dieselfde dag van die week toegedien word. Daar word aanbeveel om MIRQUIN vir 2 weke (of, indien nie moontlik nie, ten minste 24 uur voor 'n endemiese malariagebied binnegegaan word) te gebruik en vir ten minste 4 tot 6 weke nadat die gebied verlaat is. 'n Weeklikse dosering van 5 mg/kg word aanbeveel by kinders.

MASSA VAN KIND Kg:	DOSES VAN MIRQUIN MEDISYNEAAT:
5	half x 5 ml (2,5 ml)
10	een x 5 ml
20	twee x 5 ml
30	drie x 5 ml
40	vier x 5 ml
50	vyf x 5 ml

BEHANDELING VAN MALARIA:

Die gewone totale mondelike dosis vir kinders is die ekwivalent van ongeveer 25 mg chlorokienbasis per kilogram liggaamsmassa oor 'n tydperk van 3 dae op een van die volgende maniere toegedien, bv. 10 mg per kg gevolg deur 5 mg per kg na 6 tot 8 uur, dan 5 mg per kg daagliks vir die volgende 2 dae. Alternatiewelik 10 mg per kg daagliks vir die eerste 2 dae en 5 mg per kg op die derde dag.

NEWE-EFFEKTE EN SPESIALE VOORSORGMATREËLS:

Neuwe-effekte: Neuwe-effekte sluit in hoofpyn, verskeie soorte veluitslag, pruritus en gastro-intestinale verstourings soos naarheid braking en diarree. Minder algemeen is die geestesveranderinge insluitend psigiotiese episodes, angstigheid en persoonlikheidsveranderinge. Visuele verstourings soos dowwe visie en probleme met fokus

van die oë het voorgekom maar is meer algemeen by hoër doserings, wanneer dit in verband gebring kan word met keratopatie of retinopatie. Keratopatie kom gewoonlik voor in die vorm van korneale opasiteite (ondeurskynendheid) en is gewoonlik omkeerbaar wanneer chlorokien onttrek word. Retinopatie is die ernstigste nuwe-effek van chlorokien op die oë en kan ernstige visie-inkorting tot gevolg hê. Veranderinge kan onomkeerbaar wees en kan selfs vererger nadat chlorokien gestaak word. Mense wat hoë doserings chlorokien oor verlengde periodes gebruik, het die grootste risiko om retinopatie te ontwikkel.

Ander seldsame nuwe-effekte van verlengde gebruik, is haarverlies, verbleiking van die haarpigment, swart pigmentasie van die slymvlies en vel, fotosensitiwiteit, tinnitus, ingekorte gehoor, senuweedoofheid, neuromiopatie en miopatie. Bloedafwykings is minder algemeen gevind. Dit sluit in spastiese anemie, omkeerbare agranulose, trombositopenie en neutropenie.

Spesiale voorsorgmaatreëls: Aangesien geen tipe profilakse ten volle doeltreffend is nie, is die voorkoming van muskietbyte die basis van malaria-profilakse. Die volgende voorkomende maatreëls om die muskietbyte te voorkom moet geneem word:

- endemiese gebiede moet verkieslik tydens die droë periode of wanneer die reënval laag is besoek word.
- hoë-risiko pasiënte moet malariagebiede totaal en al vermy, naamlik:
 - babas en jong kinders onder die ouderdom van 5 jaar
 - swanger vroue
 - immuun-gekorte individue soos pasiënte op langtermyn steroïde, kankerpasiënte en pasiënte wat chemoterapie ontvang, VIGS-pasiënte en pasiënte wie se milt verwyder is.
- moenie tydens sonondergang en -opkoms buite loop nie, aangesien muskiete dan baie aktief is
- dra langmoue en 'n langbroek saans
- wend insekweermiddel op die blote vel en klere aan
- gebruik muskietnette, skerms en ander afskrikmiddels.

Interaksies: Teensuurmiddels kan die absorpsie van chlorokien verlaag en dit word aanbeveel om dit ten minste 4 uur uitmekaar in te neem. Simedien en chlorokien moet versigtig saam gebruik word aangesien simedien die metabolisme en uitskeiding van chlorokien erg kan inkort en sodoende die volume beskikbaar vir verspreiding kan vermeerder. Dit kan van voordeel wees om dit met kos te neem aangesien dit waarskynlik die absorpsie van chlorokien bevorder.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Akute oordosering is gevaarlik en kan binne 'n paar uur tot die dood lei. Visieverstourings kan dramaties wees met skielike blindheid. Die belangrikste effek van chlorokien-oordosering is egter kardiovaskulêre toksisiteit met hipotensie en hartaritmieë wat kan vererger tot kardiovaskulêre ineenstorting, konvulsies, hart en respiratoriese arres en die dood. Behandeling is simptomaties en ondersteunend.

VOORWAARDES VIR REGISTRASIE:

S4- mag slegs aan beroepe geadvarteer word.

IDENTIFIKASIE:

'n Helder rooi, viskeuse stroop met 'n framboos smaak en geur.

AANBIEDING:

100 ml Amber glasbottels.

BERGINGSAAANWYSINGS:

Bewaar benede 25 °C en beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

Z/20.2.6/388

05/20.2.6/0177 (Namibië)

NAAM EN BESIGHEIDSDRES VAN DIE APPLIKANT:

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