

+252328112 DRUG EVALUATION

545 P01

SEP 26 '00 11:04

REQUEST FOR SPECIAL ACCESS SCHEME (SAS) APPROVAL
CATEGORY B and C PATIENTS ONLYCommonwealth Department of
Health and
Family Services

- Category B: Persons suffering from a life-threatening medical condition, even if they are not critically ill.
- Category C: Persons suffering from a serious but not life-threatening illness.

PLEASE USE BLACK PEN, PRINT CLEARLY AND COMPLETE ALL SECTIONS

Prescribing doctor details

Name	I SEIDL	Hospital	ADF.
Postal address	RAWO 5/7 RAR	Department	5/7 RAR (MECH)
	ROBERTSON BARNAKUS	Phone number	(08) 8935 3057
	PRIMMERSTON NT	Fax number	(08) 8935 3050
	Postcode 0830		

Drug details

Active ingredient	TAFENOQUINE	Trade name	
Dose form	200mg tablet	Company/supplier	SKB
Dosage	200mg daily x 3 + 200mg weekly x 8	Route of administration	oral
		Duration of treatment	Eight weeks

Patient details

Patient initials		Patient category		Date of Birth		Sex	
		Patient ID		Previous SAS No.			

Diagnosis Vivax malaria

Justification for use of drug (include previous and current treatment; state whether requesting renewal of SAS approved)

Recurrent vivax malaria as per protocol from the Army Malaria Institute.

Prescribing doctor

Signature

DR ISAAC SEIDL

Date

30/4/01

Fax to: The Experimental Drugs Team
(02) 6232 8112

or

Send by Mail to:

The SAS Officer
TGA
PO Box 100
Woden ACT 2608



ARMY MALARIA INSTITUTE

Weary Dunlop Dve., Gallipoli Barracks, ENOGGERA, 4152

AMI 548-7-41

AMI /01

Mr. Z Hodak
Experimental Drugs Section
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

ENDORSEMENT TO PRESCRIBE TAFENOQUINE

The Army Malaria Institute endorses

Dr. Isaac Seidl, 5/7 RAR, Darwin.

to be an authorised prescriber of Tafenoquine under the prescribing direction provided by the Institute.

Prescribing of Tafenoquine endorsed by the Army Malaria Institute

Tafenoquine is an aminoquinolone analogous to Primaquine. Primaquine is presently recommended by the Army Malaria Institute (AMI) for the eradication and treatment of Vivax Malaria. Tafenoquine has been trialed by AMI in both Bougainville and East Timor for eradication and treatment. It has been found to be effective and safe. This supports trials conducted by Glaxo SmithKline, the manufacturer of Tafenoquine.

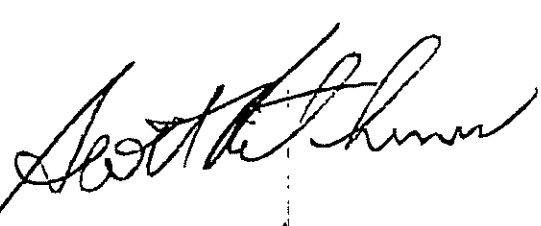
AMI directs prescribing of Tafenoquine for the purposes of treating recurrent Vivax Malaria in Defence Personnel after initial treatment with Chloroquine (LAW HPD215). For endorsement to prescribe Tafenoquine in treatment of recurrent Vivax Malaria, the following requirements must be met by the endorsed and prescribing medical officer:

- Discussion of each case with the AMI Medical Officer on call (T: 0407 150384),
- Diagnosis of recurrent Vivax Malaria and the primary episode of Vivax Malaria must be confirmed to AMI (to the satisfaction of the OC Clinical Field, AMI) prior to use of Tafenoquine,
- The case will be treated with Chloroquine initially (LAW HPD215),
- The patient will be informed of the nature and potential side effects of Tafenoquine and this is to be recorded in the Patient Medical Documents,
- Tafenoquine treatment is to begin prior to any further evidence of Vivax Malaria (usually within one week of concluding Chloroquine treatment),

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- The protocol for Tafenoquine shall be:
 - 200mg base daily for three days
 - followed by 200mg base weekly for eight weeks.
- Provision of blood samples are required:
 - Prior to onset of treatment with Chloroquine (IAW HPD215), Smear, FBC, LFT
 - Following treatment with Chloroquine, immediately prior to onset of treatment with Tafenoquine, Smear, FBC, LFT
 - Following treatment with Tafenoquine, 12 hours after the final dose (including separation of plasma for drug levels), Smear, FBC, LFT, plasma for TQ levels
 - At week 2 and week 6 after commencement of the loading dose samples should be collected within 2 hrs of receiving the next weekly dose (ie., trough steady-state levels of Tafenoquine), Smear, FBC, LFT, plasma for TQ levels
 - At week 4 and week 8 after commencement of the loading dose samples should also be collected at about 12 hours post-dose (ie., peak steady-state Tafenoquine levels), Smear, FBC, LFT, plasma for TQ levels and
 - On the occurrence of any intercurrent illness requiring medical attention during the course of the treatment program, Smear, FBC, LFT, plasma for TQ levels or
 - In the event of any recurrence of Vivax Malaria in the following 12 months Smear, FBC, LFT, plasma for TQ levels.


M D EDSTEIN ASD
LTCOL
DEPUTY DIRECTOR, AMI

Tel: 07 3332 4930; Fax: 07 3332 4800

02 Feb. 01

for.