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TGA Therapeutic Goods Administration

REQUEST FOR SPECIAL ACCESS SCHEME (SAS) APPROVAL
CATEGORY B and C PATIENTS ONLY

Commonwealth Department of Health and Family Services

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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

2/3/01

Prescribing doctor details

Name (Initial / Surname)	S KITCHENER
Postal address	c/- AMI
	Weary Dunlop Drive.
	Gallipoli Barracks
	ENOGGERA Postcode 4052
Hospital	—
Department	Clinical Field.
Phone number	07 3332 4801
Fax number	07 3332 4800.

Drug details

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

Patient details

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

Diagnosis: Recurrent vivax malaria

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

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

Prescribing doctor: S. J. KITCHENER

Signature:

Date: 29/11/94

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

Send by Mail to: The SAS Officer, TGA, PO Box 100, Woden ACT 2606

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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. Scott Kitchener, Army Malaria Institute, Enoggerra, Brisbane

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 SmithKline Beecham, 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 (IAW 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 IAW 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
LTCOL
DEPUTY DIRECTOR, AMI

Tel: 07 3332 4930; Fax: 07 3332 4800

29 Jan. 01