

→ EDG

# INITIAL INFORMATION

NOTED  
WJL  
2/11/00

163217

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Protocol	Centre Number	Subject Number	Subject Initials	SB Receipt Date	Serious Adverse Experiences
252263/046	- - /			Day Month Year	

## SERIOUS ADVERSE EXPERIENCE (SAE)

Person Reporting SAE <u>J. KITCHENER</u> (Please print clearly)		AEGIS Number
Serious Adverse Experience (Please print clearly)	Relapse vivax malaria	
For SmithKline Beecham		
Onset Date and Time	02 DEC 00 11.00 Day Month Yr 24hr:min	
End Date and Time (If ongoing please leave blank)	Day Month Yr 24hr:min	
Outcome If subject died, please complete Form D	<input type="checkbox"/> Resolved <input checked="" type="checkbox"/> Ongoing <input type="checkbox"/> Died	
Experience Course	<input checked="" type="checkbox"/> Intermittent → No. of episodes <u>1/1</u> <input type="checkbox"/> Constant	
Intensity (maximum)	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input checked="" type="checkbox"/> Severe	
Action Taken with Respect to Investigational Drug	<input checked="" type="checkbox"/> None <input type="checkbox"/> Dose reduced <input type="checkbox"/> Dose increased <input type="checkbox"/> Drug interrupted/restarted <input type="checkbox"/> Drug stopped	
Relationship to Investigational Drug	<input checked="" type="checkbox"/> Not related <input type="checkbox"/> Unlikely <input type="checkbox"/> Suspected (reasonable possibility) <input type="checkbox"/> Probable	
Corrective Therapy If 'Yes', record details in the Concomitant Medication section	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Was subject withdrawn due to this specific SAE?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Specify reason(s) for considering this a serious AE. Mark all that apply. [1] <input type="checkbox"/> fatal [2] <input type="checkbox"/> life threatening [3] <input type="checkbox"/> disabling/incapacitating [4] <input checked="" type="checkbox"/> results in hospitalisation (excluding elective surgery or routine clinical procedures) [5] <input type="checkbox"/> hospitalisation prolonged [6] <input type="checkbox"/> congenital abnormality [7] <input type="checkbox"/> cancer [8] <input type="checkbox"/> overdose [9] <input type="checkbox"/> Investigator considers serious or a significant hazard, contraindication, side effect or precaution		
Did the SAE abate? <input type="checkbox"/> Yes <input type="checkbox"/> No If study medication was interrupted, stopped or dose reduced: Was study medication reintroduced (or dose increased)? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, did SAE recur? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>Assessment</b> The SAE is probably associated with: <input type="checkbox"/> Protocol design or procedures (but not to study drug) Please specify _____ <input checked="" type="checkbox"/> Another condition (eg, condition under study, intercurrent illness) Please specify _____ <input type="checkbox"/> Another drug Please specify _____		



# INITIAL INFORMATION

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Protocol	Centre Number	Subject Number	Subject Initials	SB Receipt Date	Serious Adverse Experiences
252263/046	- - /			Day Month Year	

## SERIOUS ADVERSE EXPERIENCE (SAE) (cont)

### Relevant Laboratory Data

Please provide relevant abnormal laboratory data below

Test	Date	Value	Units	Normal Range
Blood Film	03 05 2000 Day Month Yr			Nil.
	Day Month Yr			
	Day Month Yr			
	Day Month Yr			

Remarks (Please provide a brief narrative description of the SAE, attaching extra pages eg. hospital discharge summary if necessary)

Presented with symptoms of malaria. Diagnosed as vivax malaria. 1st third recurrence. Conventional CQ treatment for acute phase. Case presents 10 weeks after last dose (1654m).

If applicable, was randomisation code broken at investigational site?

☐ No

☐ Yes

Randomisation / Study Medication Number:

Investigator's Signature:

(confirming that the above data are accurate and complete)

Date

11 25 2000  
Day Month Year

Please PRINT Name

SCOTT KITCHENER

SB Medical Monitor's Signature:

Date

Day Month Year

Please PRINT Name

## INITIAL INFORMATION

Protocol		Subject Initials		Concomitant Medication
252263/046		<div></div>		

### CONCOMITANT MEDICATION

*Record any changes in concomitant medication taken.*

[illegible]





Thursday, 21 December, 2000

The Secretary  
ADRAC  
Australian Drug Evaluation Committee  
PO Box 100  
Woden ACT 2606

Dear Sir/Madam

**Re: Clinical Trial Serious Adverse Event (Local ID# 2461)**

Please find attached details regarding a serious adverse event for the following trial:

Please note that this case was **NOT** unblinded as the drug is being provided under compassionate use.

**StudyTitle:** Study 046

**Study #** 252263/046

**CTX/CTN #:** N/A

**Study Drug:** Tafenoquine

**Comparator Drug(s):**

**Relationship to Study Drug (causality):** Not Related

Please note the investigator has classified this Adverse Experience as not related to the drug under investigation. This form has been sent to you because of an apparent failure in the treatment with this drug.

Should you have any enquiries regarding this case, please do not hesitate to contact me on [REDACTED] or directly on [REDACTED]

Yours Sincerely

28 DEC 2000

Medical Affairs Department

*Pharmaceuticals*

300 Frankston Road, Dandenong, Victoria 3175, Australia.  
Postal Address: Private Mail Bag 34, Dandenong, Victoria 3175, Australia  
Telephone: 61 - 3 - 9213 4444; Facsimile: 61 - 3 - 9706 5883; [www.sbaustralia.com](http://www.sbaustralia.com)  
Division of SmithKline Beecham (Australia) Pty. Ltd. ABN 73 008 399 411



TO: HEAD, CES 1 (2) 3 4 5 (circle)

FROM: Rhonda Whybrow

Experimental Drugs Section.

DATE: 11/5/01

Please find attached an Adverse Drug Reaction report from GlaxoSmith Kline

1. Please indicate whether further information should be requested regarding this report.

Request further information: ☐ Yes ☒ No

*pkd*

2. If further information is required, please indicate below any text to be included in footnote 2 of the standard request letter.

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3. In accordance with instructions listed on the inside cover of this temporary file, please indicate below if you want a copy of this ADR forwarded to ADRAC for coding into the ADRAC database.

To ADRAC for coding: ☐ Yes (please sign) ☒ No

*[Signature]*  
11/5/01





Friday, 23 March 2001

The Secretary  
ADRAC  
Australian Drug Evaluation Committee  
PO Box 100  
Woden ACT 2606

300 Frankston Road  
Dandenong Victoria 3175  
Australia  
Postal Address  
Private Mail Bag 34  
Dandenong Victoria 3175  
Australia  
Tel. 61 3 9213 4444  
Fax. 61 3 9706 5883  
www.gsk.com.au

Dear Sir/Madam

**Re: Clinical Trial Serious Adverse Event (Local ID# 2461 )**

Please find attached **additional** details regarding a Serious Adverse Event for the following trial which was **initially reported on 21 December, 2000**

**Study Title:** Study 046

**Study #** 252263/046

**CTX/CTN #:** N/A

**Study Drug:** Tafenoquine

**Comparator Drug(s):**

**Relationship to Study Drug (causality):** Not Related

Should you have any enquiries regarding this case, please do not hesitate to contact me on [REDACTED] or directly on [REDACTED]

Yours sincerely

[REDACTED]  
[REDACTED]  
Medical Affairs Department

29 MAR 2001



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ADDITIONAL INFORMATION



GlaxoSmithKline

**FAX**

To Clinical Trials Group - Attn Andrea Corbin

Company UK Clinical Safety

Fax

From

Tel

E-mail

Date 22-Mar-2001

Pages including cover 12

CC Safety Officer; Singapore TT

Subject Follow up SAE Reoprt

Please respond to our fax no: 61 3 9213 4539

Study Number: 252263/046

Centre Number: 001

Patient Number:

AEGIS: 2000036277-1

SAE: Relapsed vivax malaria

Date of event: 2/12/00

Outcome: ongoing

Investigator Causality Assessment: Not related

SAE follow up from site attached.

Kind regards

GLAXOSMITHKLINE

SmithKline Beecham (Australia)

Pty Ltd

ABN 73 008 399 415

300 Frankston Road

Private Mail Bag 34

Dandenong Vic 3175

Australia

Tel: 613 9213 4444

Fax 613 9706 5883

www.gsk.com

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AH



## Department of Defence

Accus: 2000036-277-1

To:	[REDACTED]
Fax:	[REDACTED]
Tel:	
Email:	

From:	LT AM Auliff CAPT T. CARTER AMI Gallipoli Barracks Enoggera Qld 4052
Fax:	(07) 33324800-4855
Tel:	(07) 33324816-4857
Email:	Alyson.Auliff@defence.gov.au

Subject: CRF FOR SAE PATIENT

Reference:

Date: 01 February 2001

Pages (including cover): 18

IMPORTANT: This facsimile remains the property of the Defence Organisation and is subject to the jurisdiction of section 70 of the Crimes Act 1914. If you have received the facsimile in error, you are requested to immediately contact the sender by telephone so that arrangements can be made for the return of the document to the sender.

## Instructions or comments:

The following is the relevant pages from the CRF for the SAE patient, [REDACTED] on the Tafenoquine treatment trial. Please let me know if you also require the source documents. The subject number for this patient has change from [REDACTED]. You can contact me on my mobile 0417744492 or the above phone number if you need to discuss any of the information.

Thanking you

Alyson

AS PROMISED THE CRF PAGE RELATED TO SAE FOR [REDACTED] I HAVE ALSO INCLUDED A COPY OF THE ORIGINAL SAE REPORT WITH THE REQUIRED CORRECTIONS.

AS YOU CAN SEE ALYSON HAD SENT YOU THESE PAGES ON THE 01/02/01. I NOT SURE WHAT MAY HAVE HAPPENED.

PLEASE CALL IF THERE IS ANY FURTHER ASSISTANCE I CAN GIVE.

29 MAR 2001

Tracy.

ADDITION I HAVE OMITTED 1 PAGE - SAE Page 2  
TOTAL OF CRF PAGE = 10. TRACY



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## ADDITIONAL INFORMATION

Protocol 252263/046		Centre Number 003	Patient Initials [REDACTED]	Visit Date Day Month Year 01 AUG 00	Page 1 Screening
------------------------	--	-------------------------	-----------------------------------	---	---------------------

## ELIGIBILITY CHECKLIST

Please complete the following inclusion criteria.

## INCLUSION CRITERIA

- |  | Yes                                 | No                       |
|--|-------------------------------------|--------------------------|
| 1. Subject has given Informed consent  | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 2. Subject is a member of the ADF, currently medical class 1 or 2  | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 3. Subject is aged between (and inclusive of) 18 years and 55 years at the onset of treatment for recurrent <i>P. vivax</i> malaria  | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 4. Subject has a confirmed diagnosis of recurrent <i>P. vivax</i> malaria - confirmation by blood smear to the satisfaction of Study Coordinator (Prof. K Reickmann)   | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 5. Subject has a previously established and confirmed diagnosis of <i>P. vivax</i> malaria as the primary episode of malaria within 6 months of relapse occurring - confirmation by blood smear to the satisfaction of Study Coordinator (Prof. K Reickmann);              | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 6. Subject has a previous treatment of clinical <i>P. vivax</i> malaria (primary episode or relapse) with chloroquine and primaquine (in accordance with Health Policy Directive (HPD) 215 ) OR chloroquine followed by a 3 day tafenoquine regimen (200-400mg once daily) | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 7. Subject is intending to stay within ADF for the next 12 months  | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

Do not admit the Subject to this study if any "No" box has been marked.

Please complete the following exclusion criteria.

## EXCLUSION CRITERIA

- |   | Yes        | No         |
|---|------------|------------|
| 1. Subject has a concomitant significant illness or medical condition<br>Subject is female and is :<br><ul style="list-style-type: none"> <li>• pregnant,</li> <li>• intending pregnancy within next three months,</li> <li>• lactating,</li> <li>• unwilling or unable to comply with recognised contraception (if sexually active) for a minimum of 6 months</li> </ul> | [REDACTED] | [REDACTED] |
| 2.  | [REDACTED] | [REDACTED] |
| 3. Subject has a Glucose-6-Phosphate Dehydrogenase deficiency   | [REDACTED] | [REDACTED] |
| 4. Subject has a previous intolerance to any of the trial compounds   | [REDACTED] | [REDACTED] |
| 5. Subject has received another investigational drug within 30 days or 5 half lives (whichever is longer), of study start   | [REDACTED] | [REDACTED] |

Do not admit the Subject to this study if any "Yes" box has been marked.

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Protocol	Subject Initials	Screening
252263/046	[REDACTED]	

## DEMOGRAPHY

Date of Birth	Day Month Year	Race	Black
			White
Gender	Male		Oriental
	Female		Other → Specify : _____

## PREVIOUS TAFENOQUINE STUDY

Previous Study :	N/A
<input type="checkbox"/> 033	
<input type="checkbox"/> 039	
<input type="checkbox"/> Other, Specify : _____	

## SUBJECT IDENTIFICATION

Corps :	[REDACTED]
Unit :	[REDACTED]
Service :	[REDACTED]

## LABORATORY TESTS

Please take a blood sample for Haematology and Biochemistry and record the results in the appropriate column.		
Visit	Diagnosis	
Sample Date	05 JUN 00 Day Month Yr	
Haematology	Test	Value <sup>1</sup>
	Haemoglobin	132
	WBC	8.6
	Granulocytes	ND
	Lymphocytes	2.34
	Monocytes	1.19
Clin. C.	Platelets	127
	GGT	103
	AGOT/ASAT	30
	SGPT/ALAT	18
Are there any <b>clinically significant abnormal</b> laboratory values?		<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes*
<sup>1</sup> Enter laboratory result or one of the following codes: ND = not done, LE = documented laboratory error * Circle any significant laboratory value and record details in the Adverse Experiences section.		

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## ADDITIONAL INFORMATION

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Protocol	Subject Initials	Screening
252263/046		

## HISTORY OF MALARIA

Date of initial <i>P. vivax</i> attack	28 FEB 00 Day Month Yr
Date of Relapse	05 JUN 00 Day Month Yr
<i>P. vivax</i> count (per 500 WBC)	200 ND

## PREVIOUS MALARIAL TREATMENTS

Trade Name	Start Date Day Month Year	Stop Date Day Month Year
QUININE	14 JAN 00	18 JAN 00
DOXYCYCLINE	14 JAN 00	18 JAN 00
CHLOROQUINE	28 FEB 00	01 MAR 00
PRIMAQUINE	01 MAR 00	15 MAR 00

## SIGNIFICANT MEDICAL/SURGICAL HISTORY AND PHYSICAL EXAMINATION

Is the subject suffering from or has he/she ever suffered from any clinically significant medical or surgical condition?

☒ No

☐ Yes → If 'Yes', please list below one diagnosis per line. (Please print clearly)

Only in the absence of a diagnosis, record the signs and symptoms on separate lines.

Diagnosis	Year of first diagnosis	Past	Ongoing
		<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>

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Protocol 252463/046	Centre Number 001	Patient Initials [REDACTED]	Visit Date Day Month Year 01 AUG 00	Tafenoquine 8 weeks Treatment 1
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**PREGNANCY TEST**

Is the subject a female of child bearing potential ?

No

Yes → Is the subject pregnant ?

No

Yes → Withdraw subject from the study

**STUDY MEDICATION**

Visit	Treatment	Date Day Month Year
CQ Day 1	S Chloroquine 600mg	05 JUN 00
CQ Day 1 + 6 hours	Chloroquine 300mg	05 JUN 00
CQ Day 2	Chloroquine 300mg	06 JUN 00
CQ Day 3	Chloroquine 300mg	07 JUN 00

Has the patient demonstrated a reduction in parasitaemia ?

☐ No☒ Yes → Continue into the tafenoquine dosing phase

P. vivax count (per 500 WBC)

200

500

1.2.01

000

Loading Day 1	S tafenoquine 200mg	01 AUG 00
Loading Day 2	tafenoquine 200mg	02 AUG 00
Loading Day 3	tafenoquine 200mg	03 AUG 00
Week 1	tafenoquine 200mg	09 AUG 00
Week 2	tafenoquine 200mg	16 AUG 00
Week 3	tafenoquine 200mg	23 AUG 00
Week 4	tafenoquine 200mg	30 AUG 00
Week 5	tafenoquine 200mg	05 SEP 00
Week 6	tafenoquine 200mg	12 SEP 00
Week 7	tafenoquine 200mg	19 SEP 00
Week 8	tafenoquine 200mg	26 SEP 00

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## ADDITIONAL INFORMATION

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Protocol 252263/046		Subject Initials [REDACTED]	Tafenoquine 8 weeks Treatment 1
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## ADVERSE EXPERIENCES - All Visits

If there have been any adverse experiences observed or elicited by the following direct question to subject: "Do you feel different in any way since the previous visit?", record details on an Adverse Experience page.

## CONCOMITANT MEDICATION - All Visits

Please record all changes in concomitant medication on a Concomitant Medication page.

## PARASITAEMIA ASSESSMENT

Visit	Date and Time of PK sample	Smear Date	Result		Symptoms of malaria ?		P. vivax count (per 500 WBC) 200 1500 1-2
			Neg	Pos	Yes	No	
24 hrs post last dose CQ	08 JUN 00 0500 Day Month Yr 24hr:min	08 JUN 00 Day Month Yr	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	000
12 hrs post third TQ	01 AUG 00 1029 Day Month Yr 24hr:min	01 AUG 00 Day Month Yr	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	000
2 hours prior to Week 2 dose	16 AUG 00 0750 Day Month Yr 24hr:min	16 AUG 00 Day Month Yr	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	000
12 hours after Week 4 dose	30 AUG 00 0800 Day Month Yr 24hr:min	30 AUG 00 Day Month Yr	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	000
2 hours prior to Week 6 dose	12 SEP 00 0840 Day Month Yr 24hr:min	12 SEP 00 Day Month Yr	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	000
12 hours after Week 8 dose	26 SEP 00 0800 Day Month Yr 24hr:min	26 SEP 00 Day Month Yr	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	000

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Protocol		Subject		Tafenoquine 8 week Treatment 1
252263/046				

## LABORATORY TESTS

Please take a blood sample for Haematology and Biochemistry and record the results in the appropriate column.

Visit	CQ Day 3 +24hrs	Loading Day 3 +12hrs 12.5	2 hours prior to Week 2 dose
Sample Date	08 JUN 00 Day Month Yr	08 JUN 00 Day Month Yr	16 AUG 00 Day Month Yr
Test	Value <sup>1</sup>	Value <sup>1</sup>	Value <sup>1</sup>
Haematology			
Haemoglobin	128	128 141	140
WBC	12.6	12.6 8.4	13.6
Granulocytes	ND	ND ND	ND
Lymphocytes	3.55	3.55 2.8	3.7
Monocytes	1.16	1.16 0.3	0.7
Platelets	137	137 190	233
Clin. C.			
GGT	83	83 60	77
AGOT/ASAT	13	29 13 17	35
SGPT/ALAT	17	25 17 28	27
Are there any clinically significant abnormal laboratory values?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes

<sup>1</sup>Enter laboratory result or one of the following codes: ND = not done, LE = documented laboratory error

\* Circle any significant laboratory value and record details in the Adverse Experiences section.

## LABORATORY TESTS - Continued

Please take a blood sample for Haematology and Biochemistry and record the results in the appropriate column.

Visit	12 hours after Week 4 dose	2 hours prior to Week 6 dose	12 hours after Week 8 dose
Sample Date	30 AUG 00 Day Month Yr	12 SEP 00 Day Month Yr	28 SEP 00 Day Month Yr
Test	Value <sup>1</sup>	Value <sup>1</sup>	Value <sup>1</sup>
Haematology			
Haemoglobin	167	150	149
WBC	4.2	10	8.7
Granulocytes	ND	ND	ND
Lymphocytes	17	3.8	3.6
Monocytes	0.1	0.2	0.4
Platelets	71	228	235
Clin. C.			
GGT	25	100	143
AGOT/ASAT	51	27	40
SGPT/ALAT	9	44	67
Are there any clinically significant abnormal laboratory values?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Yes	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes

<sup>1</sup>Enter laboratory result or one of the following codes: ND = not done, LE = documented laboratory error

\* Circle any significant laboratory value and record details in the Adverse Experiences section.

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### ADDITIONAL INFORMATION

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Protocol	Subject Number	Subject Initials	Concomitant Medication
252263/046			

### CONCOMITANT MEDICATION

*Record any changes in concomitant medication taken since Screening*

If there have been no concomitant medication changes since Screening, mark this box ☒

[illegible]

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Protocol 252263/046	Centre Number	Subject Number	Subject Initials	SB Receipt Date Day Month Year	Serious Adverse Experiences
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## SERIOUS ADVERSE EXPERIENCE (SAE)

Person Reporting SAE <u>J. KITCHENER</u> (Please print clearly)		AEGIS Number
Serious Adverse Experience (Please print clearly)	Relapse of malaria	
For SmithKline Beecham		
Onset Date and Time	02 DEC 00 NR Day Month Yr 24hr:min	
End Date and Time (If ongoing please leave blank)		
Outcome If subject died, please complete Form D	<input type="checkbox"/> Resolved <input checked="" type="checkbox"/> Ongoing <input type="checkbox"/> Died	
Experience Course	<input checked="" type="checkbox"/> Intermittent → No. of episodes <u>4/6</u> <input type="checkbox"/> Constant	
Intensity (maximum)	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input checked="" type="checkbox"/> Severe	
Action Taken with Respect to Investigational Drug	<input checked="" type="checkbox"/> None <input type="checkbox"/> Dose reduced <input type="checkbox"/> Dose increased <input type="checkbox"/> Drug interrupted/restarted <input type="checkbox"/> Drug stopped	
Relationship to Investigational Drug	<input checked="" type="checkbox"/> Not related <input type="checkbox"/> Unlikely <input type="checkbox"/> Suspected (reasonable possibility) <input type="checkbox"/> Probable	
Corrective Therapy If 'Yes', record details in the Concomitant Medication section	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Was subject withdrawn due to this specific SAE?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
→ Specify reason(s) for considering this a serious AE. Mark all that apply. (1) <input type="checkbox"/> fatal (2) <input type="checkbox"/> life threatening (3) <input type="checkbox"/> disabling/incapacitating (4) <input checked="" type="checkbox"/> results in hospitalisation (excluding elective surgery or routine clinical procedures) (5) <input type="checkbox"/> hospitalisation prolonged (6) <input type="checkbox"/> congenital abnormality (7) <input type="checkbox"/> cancer (8) <input type="checkbox"/> overdose (9) <input type="checkbox"/> Investigator considers serious or a significant hazard, contraindication, side effect or precaution		
Did the SAE abate? <input type="checkbox"/> Yes <input type="checkbox"/> No If study medication was interrupted, stopped or dose reduced: Was study medication reintroduced (or dose increased)? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, did SAE recur? <input type="checkbox"/> Yes <input type="checkbox"/> No		
Assessment The SAE is probably associated with: <input type="checkbox"/> Protocol design or procedures (but not to study drug) Please specify _____ <input checked="" type="checkbox"/> Another condition (eg. condition under study, intercurrent illness) Please specify _____ <input type="checkbox"/> Another drug Please specify _____		

29 MAR 2001



ADDITIONAL INFORMATION

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Protocol 252263/046	Centre [REDACTED]	Subject [REDACTED]	Subject [REDACTED]	SB Receipt Date Day Month Year [REDACTED] [REDACTED] [REDACTED]	Page 2	Serious Adverse Experiences
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SERIOUS ADVERSE EXPERIENCE (SAE) (cont)

Relevant Laboratory Data  
Please provide relevant abnormal laboratory data below

Test	Date	Value	Units	Normal Range
Blood Film	03 Dec 2000 Day Month Yr			Nil
	Day Month Yr			
	Day Month Yr			
	Day Month Yr			

Remarks (Please provide a brief narrative description of the SAE, attaching extra pages eg. hospital discharge summary if necessary)

Presented with symptoms of malaria. Diagnosed as vivax malaria. [15 third recurrence] Conventional AQ treatment for acute phase.  
[Case presents 10 weeks after last dose (16500)] info.

Possible

If applicable, was randomisation code broken at investigational site?

☒ No ☐ Yes

BATCH NUMBER N99354

Randomisation / Study Medication Number: [REDACTED]

Investigator's Signature: [Signature]

(confirming that the above data are accurate and complete)

Date

11 Dec 2000  
Day Month Year

Please PRINT Name

SCOTT KITCHENER

SB Medical Monitor's Signature: [REDACTED]

Date

Day Month Year

Please PRINT Name

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### CONCOMITANT MEDICATION

*Record any changes in concomitant medication taken.*

~~MEDICAL AFFAIRS SAFETY OFFICER~~

~~26 MAR 2001~~

GLAXOSMITHKLINE

29 MAR 2001