→ EDG

163217

INITIAL INFORMATION

Page 1

Protocol	Centre Number	Subject Number	Subject Initials	SB Receipt Date (Day Month Year)	Serious Adverse Experiences
252263/046	- - 1	[redacted]	[redacted]		

SERIOUS ADVERSE EXPERIENCE (SAE)

Person Reporting SAE J. KITCHENER *(Please print clearly)*

AEGIS Number

Serious Adverse Experience *(Please print clearly)*: Relapse vivax malaria

→ *Specify reason(s) for considering this a serious AE. Mark all that apply.*

- [1] ☐ fatal
- [2] ☐ life threatening
- [3] ☐ disabling/incapacitating
- [4] ☒ results in hospitalisation (excluding elective surgery or routine clinical procedures)
- [5] ☐ hospitalisation prolonged
- [6] ☐ congenital abnormality
- [7] ☐ cancer
- [8] ☐ overdose
- [9] ☐ Investigator considers serious or a significant hazard, contraindication, side effect or precaution

For SmithKline Beecham

Onset Date and Time: 02 DEC 00 (Day Month Yr) NK. (24hr:min)

End Date and Time *(If ongoing please leave blank)*: (Day Month Yr) (24hr:min)

Outcome *If subject died, please complete Form D* →
- ☐ Resolved
- ☒ Ongoing
- ☐ Died

Experience Course
- ☒ Intermittent → No. of episodes N/K
- ☐ Constant

Intensity *(maximum)*
- ☐ Mild
- ☐ Moderate
- ☒ Severe

Action Taken with Respect to Investigational Drug
- ☒ None
- ☐ Dose reduced
- ☐ Dose increased
- ☐ Drug interrupted/ restarted
- ☐ Drug stopped

Did the SAE abate? ☐ Yes ☐ No

If study medication was interrupted, stopped or dose reduced:
Was study medication reintroduced (or dose increased)? ☐ Yes ☐ No

If yes, did SAE recur? ☐ Yes ☐ No

Relationship to Investigational Drug
- ☒ Not related
- ☐ Unlikely
- ☐ Suspected (reasonable possibility)
- ☐ Probable

→ **Assessment**
The SAE is probably associated with:
- ☐ Protocol design or procedures (but not to study drug)
  Please specify _____
- ☒ Another condition (eg, condition under study, intercurrent illness)
  Please specify _____
- ☐ Another drug
  Please specify _____

Corrective Therapy *If 'Yes', record details in the Concomitant Medication section* →
☒ Yes ☐ No

Was subject withdrawn due to this specific SAE ?
☐ Yes ☒ No

28 DEC 2000

INITIAL INFORMATION

Protocol	Centre Number	Subject Number	Subject Initials	SB Receipt Date (Day Month Year)	Serious Adverse Experiences
252263/046	-/-	[redacted]	[redacted]		

SERIOUS ADVERSE EXPERIENCE (SAE) (cont)

Relevant Laboratory Data
Please provide relevant abnormal laboratory data below

Test	Date	Value	Units	Normal Range
Blood f/m	03 DEC 00 (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. Is third recurrence. Confirmed CQ treatment for acute phase.
Case presents 10 weeks after last dose (~65 CQ)

If applicable, was randomisation code broken at investigational site? ☐ No ☐ Yes

Randomisation / Study Medication Number:

Investigator's Signature: [signature] Date 11 DEC 00 (Day Month Year)
(confirming that the above data are accurate and complete)

Please PRINT Name SCOTT KITCHENER.

SB Medical Monitor's Signature: Date (Day Month Year)

Please PRINT Name

Protocol			Subject Initials		Concomitant Medication
252263/046			[redacted]		

CONCOMITANT MEDICATION

Record any changes in concomitant medication taken.

Drug Name (Trade Name Preferred)	Unit Dose (e.g. 500mg)	Frequency (eg od, bd, prn)	Route*	Medical Illness/ Diagnosis (or symptom in absence of diagnosis)	Start Date (be as precise as possible) Day Mth Yr	End Date (or if Continuing mark box) Day Mth Yr	
CHLOROQUINE	600mg	stat	PO	Relapse vivax mal.	03 DEC 00	03 DEC 00	
CHLOROQUINE	300mg	od	O	Relapse vivax malaria	03 DEC 00	03 DEC 00	

[redacted]
MEDICAL AFFAIRS SAFETY OFFICER
21 DEC 2000
SMITHKLINE BEECHAM INTERNATIONAL
300 FITZGERALD ROAD
DANDENONG VIC 3175

SmithKline Beecham
International

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

[redacted]

28 DEC 2000

[redacted]

Medical Affairs Department

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 GlaxoSmithKline

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

   Request further information: ☐ **Yes** ☑ **No**

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

   .....

   .....

   .....

   .....

   .....

   .....

   .....

   .....

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) _____ 15/5/01

   ☐ **No**

163217
ORG → EDG, DSEB

GlaxoSmithKline

Friday, 23 March 2001

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

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

StudyTitle: 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]

Medical Affairs Department

29 MAR 2001

PRE-REG CT

NON-ADRAC TRIAL

FI

16327

Acknowledged

ADDITIONAL INFORMATION

GlaxoSmithKline

FAX

To Clinical Trials Group - Attn Andrea Corbin

Company UK Clinical Safety

Fax [redacted]

From [redacted]

Tel [redacted]

E-mail [redacted]

Date 22-Mar-2001 **Pages including cover** 12

CC Safety Officer; Singapore TT

Subject **Follow up SAE Reoprt**

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

Please respond to our fax no: 61 3 9213 4539

Study Number: 252263/046
Centre Number: 001
Patient Number: [redacted]
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

[redacted]

29 MAR 2001

163217

AH5

[redacted]

Department of Defence

AEGIS: 2000036277-1

To: [redacted]	From: ~~LT AM Auliff~~ CAPT T. CARTHEW AMI Gallipoli Barracks Enoggera Qld 4052
Fax: [redacted]	Fax: (07) 33324800 4855
Tel:	Tel: (07) 33324816 4857
Email:	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:

[redacted]

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

[redacted]

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 MIGHT HAVE HAPPENED.

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

29 MAR 2001

TRACY.

ADDIT I HAVE OMITED 1 PAGE — SAE Pge 2 TOTAL OF CRF page = 10. TRACY

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ADDITIONAL INFORMATION

Protocol	Centre Number	Patient Initials	Visit Date (Day / Month / Year)	
252263/046	003	[redacted]	01 / AUG / 00	Screening

ELIGIBILITY CHECKLIST

Please complete the following inclusion criteria.

INCLUSION CRITERIA	Yes	No
1. Subject has given Informed consent	☑	☐
2. Subject is a member of the ADF, currently medical class 1 or 2	☑	☐
3. Subject is aged between (and inclusive of) 18 years and 55 years at the onset of treatment for recurrent *P. vivax* malaria	☑	☐
4. Subject has a confirmed diagnosis of recurrent *P. vivax* malaria - confirmation by blood smear to the satisfaction of Study Coordinator (Prof. K Reickmann)	☑	☐
5. Subject has a previously established and confirmed diagnosis of *P. vivax* 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);	☑	☐
6. Subject has a previous treatment of clinical *P. vivax* 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)	☑	☐
7. Subject is intending to stay within ADF for the next 12 months	☑	☐

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	[redacted]	
2. Subject is female and is : • pregnant, • intending pregnancy within next three months, • lactating, • unwilling or unable to comply with recognised contraception (if sexually active) for a minimum of 6 months		
3. Subject has a Glucose-6-Phosphate Dehydrogenase deficiency		
4. Subject has a previous intolerance to any of the trial compounds		
5. Subject has received another investigational drug within 30 days or 5 half lives (whichever is longer), of study start		

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 [redacted] Day Month Year

Gender [redacted] Male / Female

Race [redacted] Black / White / Oriental / Other → Specify : _____

PREVIOUS TAFENOQUINE STUDY

Previous Study : N/A

- ☐ 033
- ☐ 039
- ☐ 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)
	Test	Value [1]
Haematology	Haemoglobin	132
	WBC	8.6
	Granulocytes	ND
	Lymphocytes	2.34
	Monocytes	1.19
	Platelets	127
Clin. C.	GGT	103
	AGOT/ASAT	30
	SGPT/ALAT	18
Are there any ***clinically significant abnormal*** laboratory values?		☑ No ☐ Yes*

[1] *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

Protocol	Subject Initials	Screening
252263/046	[redacted]	

HISTORY OF MALARIA

Date of initial *P. vivax* attack: 28 FEB 00 (Day Month Yr)

Date of Relapse: 05 JUN 00 (Day Month Yr)

P. vivax count (per ~~500~~ 200 WBC): ND

1-20

PREVIOUS MALARIAL TREATMENTS

	Trade Name	Start Date Day Month Year	Stop Date Day Month Year
0	QUININE	14 JAN 00	18 JAN 00
6	DOXYCYCLINE	14 JAN 00	18 JAN 00
6	CHLOROQUINE	28 FEB 00	01 MAR 00
0	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
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐

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Protocol	Centre Number		Patient Initials	Visit Date Day Month Year	Tafenoquine 8 weeks Treatment 1
252263/046	001		[redacted]	01 AUG 00	

PREGNANCY TEST

Is the subject a female of child bearing potential ?

[redacted] No

Yes → Is the subject pregnant ?

[redacted] 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~~ 200 WBC) 006 1-2-01

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

ADDITIONAL INFORMATION

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Protocol			Subject Initials		Tafenoquine 8 weeks Treatment 1
252263/046			[redacted]		

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~~ 200 WBC)
			Neg	Pos	Yes	No	
24 hrs post last dose CQ	01 JUN 00 (Day Month Yr) 0525 (24hr:min)	08 JUN 00 (Day Month Yr)	☐	☐	☐	☐	000
12 hrs post third TQ	01 AUG 00 (Day Month Yr) 1029 (24hr:min)	01 AUG 00 (Day Month Yr)	☑	☐	☐	☑	000
2 hours prior to Week 2 dose	16 AUG 00 (Day Month Yr) 0750 (24hr:min)	16 AUG 00 (Day Month Yr)	☑	☐	☐	☑	000
12 hours after Week 4 dose	30 AUG 00 (Day Month Yr) 0800 (24hr:min)	30 AUG 00 (Day Month Yr)	☑	☐	☐	☑	000
2 hours prior to Week 6 dose	12 SEP 00 (Day Month Yr) 0840 (24hr:min)	12 SEP 00 (Day Month Yr)	☑	☐	☐	☑	000
12 hours after Week 8 dose	26 SEP 00 (Day Month Yr) 0800 (24hr:min)	26 SEP 00 (Day Month Yr)	☑	☐	☐	☑	000

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Protocol		Subject		Tafenoquine 8 weeks Treatment 7
252263/046		[redacted]		

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	2 hours prior to Week 2 dose
Sample Date		08 JUN 00 Day Month Yr	~~04 AUG 00~~ 03 AUG 00 Day Month Yr	16 AUG 00 Day Month Yr
	Test	Value [1]	Value [1]	Value [1]
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?		☑ No ☐ Yes*	☑ No ☐ Yes*	☑ No ☐ Yes*

[1] *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 [1]	Value [1]	Value [1]
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?		☑ No ☐ Yes*	☑ No ☒ Yes*	☑ No ☐ Yes*

[1] *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

Protocol		Subject Number	Subject Initials		Concomitant Medication
252263/046		[redacted]	[redacted]		

CONCOMITANT MEDICATION

Record any changes in concomitant medication taken since Screening

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

Drug Name (Trade Name Preferred)	Unit Dose (e.g. 500mg)	Frequency (eg od, bd, prn)	Route*	Medical Illness/ Diagnosis (or symptom in absence of diagnosis)	Start Date (be as precise as possible) Day Mth Yr	End Date (or if Continuing mark box) Day Mth Yr	

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Page 1

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

SERIOUS ADVERSE EXPERIENCE (SAE)

Person Reporting SAE _J. KITCHENER_ *(Please print clearly)*

AEGIS Number

Serious Adverse Experience *(Please print clearly)*: Relapse vivax malaria

For SmithKline Beecham

Onset Date and Time: 02 DEC 00 (Day Month Yr) NR (24hr:min)

End Date and Time *(If ongoing please leave blank)*: (Day Month Yr) (24hr:min)

Outcome *If subject died, please complete Form D*
- ☐ Resolved
- ☒ Ongoing
- ☐ Died

Experience Course
- ☒ Intermittent → No. of episodes N/K
- ☐ Constant

Intensity *(maximum)*
- ☐ Mild
- ☐ Moderate
- ☒ Severe

Action Taken with Respect to Investigational Drug
- ☒ None
- ☐ Dose reduced
- ☐ Dose increased
- ☐ Drug interrupted/ restarted
- ☐ Drug stopped

Relationship to Investigational Drug
- ☒ Not related
- ☐ Unlikely
- ☐ Suspected (reasonable possibility)
- ☐ Probable

Corrective Therapy *If 'Yes', record details in the Concomitant Medication section*: ☒ Yes ☐ No

Was subject withdrawn due to this specific SAE ?: ☐ Yes ☒ No

Specify reason(s) for considering this a serious AE. Mark all that apply.
- [1] ☐ fatal
- [2] ☐ life threatening
- [3] ☐ disabling/incapacitating
- [4] ☒ results in hospitalisation (excluding elective surgery or routine clinical procedures)
- [5] ☐ hospitalisation prolonged
- [6] ☐ congenital abnormality
- [7] ☐ cancer
- [8] ☐ overdose
- [9] ☐ Investigator considers serious or a significant hazard, contraindication, side effect or precaution

Did the SAE abate? ☐ Yes ☐ No

If study medication was interrupted, stopped or dose reduced:
Was study medication reintroduced (or dose increased)? ☐ Yes ☐ No

If yes, did SAE recur? ☐ Yes ☐ No

Assessment
The SAE is probably associated with:
- ☐ Protocol design or procedures (but not to study drug)

Please specify _____

- ☒ Another condition (eg. condition under study, intercurrent illness)

Please specify _____

- ☐ Another drug

Please specify _____

29 MAR 2001

ADDITIONAL INFORMATION

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Page 2.

Protocol	Centre Number	Subject	Subject	SB Receipt Date Day Month Year	Serious Adverse Experiences
252263/046.	[redacted]	[redacted]			

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 00 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. [Is third recurrence] Confirmed CQ treatment for acute phase. info

[Case presents 10 weeks after last dose (Nov 00)] 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] Date 1 Dec 00 Day Month Year

(confirming that the above data are accurate and complete)

Please PRINT Name SCOTT KITCHENER

SB Medical Monitor's Signature: Date Day Month Year

Please PRINT Name

29 MAR 2001

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Page 3.

Protocol 252263/046			Subject Initials [redacted]			Concomitant Medication

CONCOMITANT MEDICATION

Record any changes in concomitant medication taken.

Drug Name (Trade Name Preferred)	Unit Dose (e.g. 500mg)	Frequency (eg od, bd, prn)	Route*	Medical Illness/ Diagnosis (or symptom in absence of diagnosis)	Start Date (be as precise as possible) Day Mth Yr	End Date (or if Continuing mark box) Day Mth Yr	
CHLOROQUINE	600mg	stat	PO	Relapse vivax malaria	03 DEC 00	03 DEC 00	
CHLOROQUINE	300mg	od	O	Relapse vivax malaria	03 DEC 00	05 DEC 00	

MEDICAL AFFAIRS SAFETY OFFICER
26 MAR 2001
GLAXOSMITHKLINE

TOTAL P. 03

29 MAR 2001