



00099534

Completed forms must be sent to
ANRS within 48 hrs.
Email: pharmacovigilance@anrs.fr
Fax: +33 153 946 002

SAE No.

SAE Visit Date

2013 09 03

Initial Notification Date

2013 09 04

Notification time

13 30

1. Patient details

TasP ID

14344

Name

B-G

Sex

☒ Male

☐ Female

Date of birth

19700503

Enrolment date

20120726

2. Measurements

Height

179 Cms

Last known: Weight

59

Kgs

Weight Date

2013 09 03

CD4 count

355

CD4 Date

2013 08 06

Viral Load

< 50

Viral Load Date

2013 08 14

3. By which criteria is this adverse event considered to be "Serious"?

Tick all that apply

☐

Resulted in death → Date of death

Probable cause

☒

Life threatening (i.e. at risk of death at time of event)

☒

Caused or prolonged hospitalisation (not elective hospitalisation for a pre-existing condition)

☐

Persistent or significant disability / incapacity

☐

Congenital abnormality / birth defect

☐

Grade 4 clinical and biological events

☐

Other serious, medically-important condition → Specify

DCP - J
2013-09-20
DATA CAPTURED

4. Details of SAE

Enter each adverse event (e.g. symptom, sign, syndrome or diagnosis) on a separate line

Event Name
Date investigator
Date of onset of SAE
became aware

1.

STABBED

ABDOMEN

2013 09 04

2013 08 17

2.

3.

4.

5.

5. Description of SAE

Include details of body site, relevant laboratory tests, treatments received and relevant medical history.

Attach copies of any relevant hospital records, laboratory test results etc.

STABBED ABDOMEN ON 17-8-13. ADMITTED AT HOSPITAL. EXPLORATORY LAPAROTOMY PERFORMED AND PATIENT CONDITION STABILIZED. PATIENT WAS DISCHARGED ON 26-08-13. HE CAME TO OUR CLINIC ON 03-09-13 FOR COLLECTION OF HIS MEDICATION AND WAS COMPLAINING OF BODY PAIN. CLINICALLY HE WAS STABLE.

6. Medications

List all drugs taken (or prescribed) before occurrence of SAE

Generic Name	Daily dose	Route of administration	Indication	Date started	Date stopped	Causality assessment	Expected reaction? (BNF/SPC)	Action taken
1. ATROPINE	245 mg 200 mg 600 mg	oral	nausea	20130207		Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
2. VITAMIN B-complex	7 tabs	oral		20130207		Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
3.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
4.						Unrelated	Yes	None
						Poss. related	No	Reduce
						Cannot be assessed		Interrupt
								Stop
5.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	Interrupt
								Stop
6.						Unrelated		None
						Poss. related	Yes	Reduce
						Cannot be assessed	No	Interrupt
								Stop

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7. Other causes of SAE, if unrelated to drugs mentioned in Section 6 above

7a. According to the physician, is this SAE likely to be related to participation in the research?

Yes No

7b. According to the physician, is this SAE related to any causes other than the research?

This includes the patient's medical history

Yes No

Describe

STARBED ABDOMEN

8. SAE Outcome

Died

Unknown to date

Ongoing

Improved

Recovered

A complementary SAE notification must be submitted within 8 days

Date of recovery

Recovered without sequelae

or

Recovered with sequelae

Describe

Physician reporting SAE

Name DR NGUNDM OSEE BETH HUMA

Signature

Date form completed 20130905