



Ausereitho Treatment as Prevention - ANRS 12249  
Ukuphila kwami, ukuphila kwethu (my health, for our health)

Ukuphila kwami, ukuphila kwethu

Africa Centre TasP Trial

SAE-AC

Serious Adverse Event Reporting



00059979

ANRS 12249 Complementary SAE Notification

Completed forms must be sent to  
ANRS within 8 days.  
Email: [pharmacovigilance@anrs.fr](mailto:pharmacovigilance@anrs.fr)  
Fax: +33 153 946 002

SAE No.

Initial Notification Date

2013 09 03

i.e. Date of original Initial Notification Form

Complementary Notification Date

2013 09 04

1. Patient details

TasP ID

1 43 44

Name

B-G

Sex

☒ Male

☐ Female

Date of birth

1970 05 03

Enrolment date

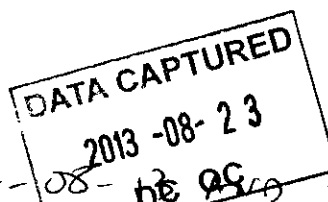
2012 07 26

2. Description of the reported SAE

PHYSICAL ASSAULT - STABBED ABDOMEN

Date of SAE onset

2013 08 17



3. Complementary information

STABBED ABDOMEN ON 17-08-2013. ADMITTED TO HOSPITAL.  
EXPLORATORY LAPAROTOMY WAS PERFORMED AND DAMAGE  
CONTROLLED. PATIENT CONDITION IMPROVED AND  
DISCHARGED ON 26/08/2013

4. New diagnosis?

Yes → Describe

☒ No

Date of new diagnosis

5. Patient treatment

a) Did the event resolve after discontinuation of treatment?

Yes

No

☒ N/A

Which treatment?

Date discontinued

b) Did the event reappear after reintroduction of treatment?

Yes

No

☒ N/A

Which treatment?

Date reintroduced

c) Has the complementary information mentioned above modified your judgement of causality regarding one or more treatments compared to your initial notification?

Yes → Section 6

☒ No → Section 7

## 6. Medications

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

Generic Name	Dose	Frequency	New judgement of causality
1. ATRAPLA	245mg 200mg 600mg	once a day	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
2. Vitamin B Complex	1 kg	daily	<input checked="" type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
3.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed
4.			<input type="radio"/> Unrelated <input type="radio"/> Poss. related <input type="radio"/> Cannot be assessed

## 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

STABBED ABDOMEN

## 8. SAE Outcome

Unknown to date  
Ongoing  
Improved  
Worsened  
☒ Recovered

→ Another complementary SAE notification form must be submitted within 8 days from now.

→ Date of recovery 2013 08 26

☒ Recovered without sequelae  
or  
Recovered with sequelae  
→ Describe

## Physician reporting SAE Complementary Notification

Name DR NGUNDU OSEE BETHTUMA

Signature

Date form completed 2013 09 05