



Antiretroviral Treatment as Prevention - ANRS 12249  
(Ukaphila kwami, ukuphila kwethu / new health for our people)

*Machweni*  
**Ukaphila kwami, ukuphila kwethu**  
Africa Centre TasP Trial

SAE-AI

**Serious Adverse Event Reporting**

**ANRS 12249 Initial SAE Notification**

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



00057405

SAE No.

SAE Visit Date

20130722

Initial Notification Date

20130724

Notification time

**1. Patient details**

TasP ID

16966

Name

GT

Sex

Male

☒ Female

Date of birth

19790621

Enrolment date

20130114

**2. Measurements**

Height

159 cms

Last known: Weight

95.7

Kgs

Weight Date

20130724

CD4 count

518

CD4 Date

20130530

Viral Load

<50

Viral Load Date

20130530

**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

**4. Details of SAE**

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

Event Name

Date investigator  
became aware

Date of onset of SAE

1. SEVERE 20130722 20130717  
HEPATITIS

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.

Started Atripla on 07/03/2013. ALT normal prior to initiation of ART. In May 2013, ALT 135 with normal bilirubin. Presented to clinic on 22/7/2013 with jaundice and dark urine. No abdominal pain. No nausea and vomiting. Clinically well. All drugs discontinued. Started on Kaletra monotherapy to cover efavirenz tail.

## 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. ATRIPLA TDF/FTC/EFV	300/200/600	PO	HW	2013 03 07	2013 07 22	Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
2. ISONIAZID	300mg	PO	TB PROPHYLAXIS	2013 06 27	2013 07 22	Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
3. PYRIDOXINE	25mg	PO	NEUROPATHY PROPHYLAXIS	2013 06 27	2013 07 22	Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
4. VIT B12	T	PO	SUPPLEMENT	2013 03 07		Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
5.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop
6.						Unrelated Poss. related Cannot be assessed	Yes No	None Reduce Interrupt Stop

## 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? ☐ Yes ☒ No  
This includes the patient's medical history ☐ Describe

## 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

Signature

Date form completed

COLLINS jmwjl  
Xmp  
2013 07 24