



00547573

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

SAE No.

SAE Visit Date

20150407

Initial Notification Date

20151020

Notification time

**1. Patient details**

TasP ID

42967

Name

HZ

Sex

Male

☒ Female

Date of birth

19630403

Enrolment date

20140922

**2. Measurements**

Height

161 cms

Last known: Weight

60.3

Kgs

Weight Date

20151007

CD4 count

484

CD4 Date

20151007

Viral Load

&lt;40

Viral Load Date

20151007

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

Tick all that apply

- ☐ Resulted in death → Date of death
- ☐ 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

2015-10-21  
DC QC  
Probable cause

**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

Grade IV increase

became aware

1. IN GGT 20150415 20150407

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.

LFTs were abnormal at the baseline clinic visit, ALT 36, ALP 78  
GGT 212 on 22/09/2014. Started Atripla 13/10/2014. LFTs gradually  
got worse with time. Most recent LFTs from 7/10/2015 showed  
ALT 43, ALP 161, GGT 583. Patient abusing alcohol and herbal  
remedies

## 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.	TISF/FTC/EFV	300/700/600	PO	HN	20141013		Unrelated	<input checked="" type="radio"/> Yes	<input checked="" type="radio"/> None
							<input checked="" type="radio"/> Poss. related	No	Reduce
							Cannot be assessed		Interrupt Stop
2.							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

## 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  
Describe

No

LFTs abnormal at baseline. Synergistic toxicity from Atupla + Alcohol + herbal remedies

## 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 Imaji  
Xmp

20151020