



00317354

ANRS 12249 Complementary SAE Notification

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

SAE No.

Initial Notification Date

20150624

i.e. Date of original Initial Notification Form

Complementary Notification Date

20150626

1. Patient details

TasP ID

14328

Name

S.Z.

Sex

☒ Male

☐ Female

Date of birth

19890923

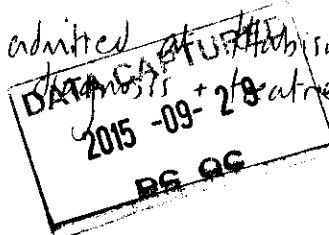
Enrolment date

20120724

2. Description of the reported SAE

Patient had a psychiatric problem + was admitted at Hlabisa hospital.
Inpatient notes have been misplaced, so diagnosis + treatment are unknown.

Date of SAE onset 20150606


3. Complementary information

The patient attended TasP clinic. Unfortunately he doesn't have a discharge letter and doesn't know his diagnosis or treatment. He reports that he had auditory hallucinations + uncontrollable 'tic' - head nodding soon after starting ART. In Hlabisa he did not receive any ART + he improved. On discharge he re-started ART. He reports his head-nodding has worsened since re-starting.

4. New diagnosis?
☒ Yes → Describe
☐ No

Possible EFV induced psychosis

We have ① Stopped atipravir
② Started TDF/FTC/Aluvia
③ Written to Hlabisa psychologist to request diagnosis + treatment.

Date of new diagnosis 20150626

5. Patient treatment

a) Did the event resolve after discontinuation of treatment?

☒ Yes

☐ No

☐ N/A

Which treatment?

TDF/FTC/EFV; Atripla.

Date discontinued

~~20150625~~ 2015/06/06
(ERROR NOTED)

b) Did the event reappear after reintroduction of treatment?

☒ Yes

☐ No

☐ N/A

Which treatment?

TDF/FTC/EFV

Date reintroduced

20150617

(Stopped again 2015/06/25)

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. Atorlipa	T	OD	Unrelated
			<input checked="" type="radio"/> Poss. related
			Cannot be assessed
2.			Unrelated
			Poss. related
			Cannot be assessed
3.			Unrelated
			Poss. related
			Cannot be assessed
4.			Unrelated
			Poss. related
			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? ☐ Yes ☒ No

This includes the patient's medical history

Describe

It is likely that this is EFV induced or related psychosis. We await a report from the psychologist at Hlabisa hospital.

8. SAE Outcome

Death → Date of death

Probable

Diagnosis

Unknown to date

Ongoing

Improved

Worsened

Another complementary SAE notification form must be submitted.

☒ Recovered

→ Date of recovery

2015 06 25

☒ Recovered without sequelae

or

Recovered with sequelae

Describe

Physician reporting SAE Complementary Notification

Name MELANIE HILL

Signature

[Signature]

Date form completed 2015 06 26