

Serious Adverse Event Reporting


00059975

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

20130724

i.e. Date of original Initial Notification Form

Complementary Notification Date

20130919

1. Patient details

TasP ID

16966

Name

G.T.

Sex

Male

☒ Female

Date of birth

19790621

Enrolment date

20130114

2. Description of the reported SAE

CHRONIC HEPATITIS Probable drug induced.

Date of SAE onset

20130725

3. Complementary information

Patient with hepatitis B on 22/7/2013, previously admitted to hospital on 5/8/2013 and has been visiting hospital for follow-up, presented to the clinic on 18/9/13 with abdominal pain, no vomiting, no fever. latest LFT not completed Total bilirubin - 228 ↑ INR - 1.76. No report from hospital with regards USS scan.

4. New diagnosis? Referent back to hospital.

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. ATRIPLA ^{TDF} ^{FDC} ^{EFV}	300/200/600	daily	Unrelated
			<input checked="" type="radio"/> Poss. related
			Cannot be assessed
2. ISONIAZID	300mg	daily	Unrelated
			<input checked="" type="radio"/> Poss. related
			Cannot be assessed
3. Pyridoxine	25mg	daily	<input checked="" type="radio"/> Unrelated
			Poss. related
			Cannot be assessed
4. Vit B ₁₂ CO	1	daily	<input checked="" type="radio"/> 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

8. SAE Outcome

Unknown to date

☒ Ongoing

Improved

Worsened

Recovered → Date of recovery

Recovered without sequelae

or

Recovered with sequelae

→ Describe

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

Physician reporting SAE Complementary Notification

Name DR. CLUMUNYA A. CHONGE

Signature [Signature]

Date form completed 20130919.

