

Serious Adverse Event Reporting

ANRS 12249 Initial SAE Notification

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



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| | | | |
|---------|---------------------------|------------|-------------------|
| SAE No. | SAE Visit Date | 2013 06 18 | Notification time |
| | Initial Notification Date | 2013 07 03 | |

1. Patient details

TasP ID: 15691
Name: Z.M.
Sex: ☐ Male ☒ Female
Date of birth: 19711116
Enrolment date: 20130128

2. Measurements

Height: 162 Cms
Last known: Weight: 45.8 Kgs Weight Date: 20130620
CD4 count: 815 CD4 Date: 20130620
Viral Load: <50 Viral Load Date: 20130620

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 Anaemia | 2013 07 02 | 2013 01 28 |
| 2. | | |
| 3. | | |
| 4. | | |
| 5. | | |

DATA CAPTURE

2013-07-12

DCP-F

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.

Severe microcytic hypochromic anaemia - probably due to Iron deficiency. She was prescribed Ferrous Sulphate in January 2013 when her Hb was 7.1g/dL.

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. TEACETIVIR | | | | | | Unrelated | Yes | None |
| | | | | | | Poss. related | No | Reduce |
| | | | | | | Cannot be assessed | | Interrupt |
| | | | | | | | | Stop |
| 2. ATRIPLA | 300/200/600 PO | | HW | 20130318 | | Unrelated | Yes | None |
| TDF/FTC/EFV | | | | | | 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 ☒ No ☐

Describe

PROBABLE IRON DEFICIENCY ANAEMIA

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

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