

Serious Adverse Event Reporting


00317298

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

20150420

i.e. Date of original Initial Notification Form

Complementary Notification Date

20150514

1. Patient details

TasP ID

40923

Name

H.N.

Sex

Male

☒ Female

Date of birth

19790612

Enrolment date

20140922

2. Description of the reported SAE

Developed diarrhoea & vomiting of 4 days duration associated with confusion & weakness. Presented to hospital on 9/4/2015 and was admitted. Had raised urea & creatinine; was started on IV fluid & Rappin. She self discharged from hospital on 15/4/2015.

Date of SAE onset

20150405

3. Complementary information

We contacted participant to arrange follow up. Relative passed away that after self-discharge from hospital, she went to traditional healer. She came home and later died at home on 23/4/2015.

DATA CAPTURED

2015-05-14

PS QS DATA CAPTURED

4. New diagnosis?

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. | | | Unrelated 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?
This includes the patient's medical history

Yes No
Describe

Acute gastroenteritis resulting in renal failure exacerbated by Zencain. Patient not fully treated; resulting in death.

8. SAE Outcome

● Death

→ Date of death

20150423

Probable Diagnosis

Renal failure

Unknown to date

Ongoing

Improved

Worsened

Recovered

→ Another complementary SAE notification form must be submitted.

→ Date of recovery

Recovered without sequelae
or

Recovered with sequelae

→ Describe

Physician reporting SAE Complementary Notification

Name DR GUGLIUME MARULIS

Signature

Date form completed 20150514