

**Serious Adverse Event Reporting**
Azidothymidine Treatment as Prevention - ANRS 12249  
(Ukuphila kwami, ukuphila kwethu / my health / for our health)


00098977

**ANRS 12249 Complementary SAE Notification**

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

SAE No.

Initial Notification Date

2013 09 27

i.e. Date of original Initial Notification Form

Complementary Notification Date

2013 10 03

**1. Patient details**

TasP ID

15664

Name

N.A.B

Sex

☒ Male

☐ Female

Date of birth

1962 06 20

Enrolment date

2013 07 16

**2. Description of the reported SAE**

BACTERIAL MENINGITIS

Date of SAE onset

2013 09 14

**3. Complementary information**

PATIENT'S WIFE INFORMED TASP NURSE THAT PATIENT WAS DISCHARGED  
ON 30-09-2013. HE IS STILL WEAK, CAN NOT WALK  
AND TALK PROPERLY. HE IS SCHEDULED TO COME TO  
TASP CLINIC FOR TREATMENT SWITCH AS HE DEVELOPPED

**4. New diagnosis?**

Yes → Describe

☒ No

TREATMENT FAILURE ON  
REGIMEN 1

Date of new diagnosis

**5. Patient treatment**

a) Did the event resolve after discontinuation of treatment?

☐ Yes

☐ No

☒ N/A

Which treatment?

Date discontinued

2013 09 27

b) Did the event reappear after reintroduction of treatment?

☐ Yes

☐ No

☒ N/A

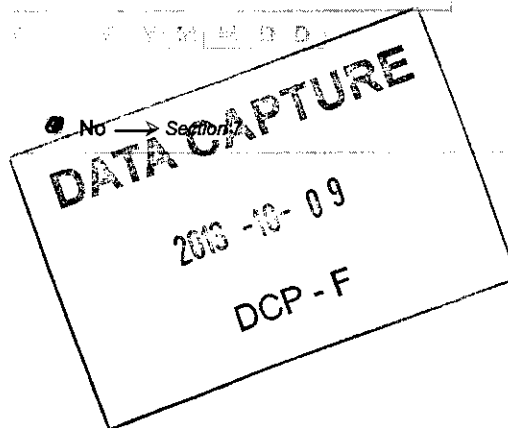
Which treatment?

Date reintroduced

2013 10 03

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

<u>Generic Name</u>	<u>Dose</u>	<u>Frequency</u>	<u>New judgement of causality</u>
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

BACTERIAL MENINGITIS

## 8. SAE Outcome

Unknown to date  
Ongoing  
Improved  
Worsened  
Recovered

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

→ Date of recovery

Recovered without sequelae  
or  
Recovered with sequelae  
→ Describe

## Physician reporting SAE Complementary Notification

Name DR NAMNGU OSEE PRETUMMA

Signature

Date form completed 2013 2003