# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

| 1. PATIENT INITIALS (first, last) | 1a. COUNTRY | 2. DATE OF BIRTH Day | Month | Year | 2a. AGE | 3. SEX | 3a. WEIGHT | 4-6 REACTION ONSET Day | Month | Year |
|---|---|---|---|---|---|---|---|---|---|---|
| PRIVACY | UNITED STATES | | PRIVACY | | 50 Years | Male | Unk | 03 | JUL | 2023 |

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)

nausea [Nausea]
dizziness/Gets lightheaded when standing [Dizziness] [Dizziness]
body pain [General body pain] [General body pain]
emotional changes/distraught [Emotional disorder] [Emotional disorder]
nausea/vomiting [Vomiting] [Vomiting]
feeling exhausted/tired [Exhaustion] [Exhaustion]

Case Description: This case, manufacturer control number 2023-0635631 is a report from a solicited Patient Assistance Program referring to a(n) Adult (Age: 50 years, Gender: Male) patient .

**(Continued on Additional Information Page)**

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☒ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☐ OTHER

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1 ) LEDIPASVIR/SOFOSBUVIR (LEDIPASVIR, SOFOSBUVIR) Tablet {Lot # 020071}

15. DAILY DOSE(S)
#1 ) 90/400mg, 1 dosage form, QD

16. ROUTE(S) OF ADMINISTRATION
#1 ) Oral use

17. INDICATION(S) FOR USE
#1 ) Hep C (Hepatitis C)

18. THERAPY DATES(from/to)
#1 ) 03-JUL-2023 / Ongoing

19. THERAPY DURATION
#1 ) Unknown

20. DID REACTION ABATE AFTER STOPPING DRUG?
☐ YES ☐ NO ☒ NA

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
☐ YES ☐ NO ☒ NA

## III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

| From/To Dates | Type of History / Notes | Description |
|---|---|---|
| Unknown to Ongoing | Current Condition | Hepatitis C (Hepatitis C) |

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
GILEAD
Leo Plouffe
333 Lakeside Drive
Foster City, CA 94404 UNITED STATES
Phone: +1 1-800-445-3235

26. REMARKS
Study ID: Patient Assistance Program

24b. MFR CONTROL NO.
**2023-0635631**

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
11-AUG-2023

24d. REPORT SOURCE
☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ OTHER:

DATE OF THIS REPORT
16-AUG-2023

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

## ADDITIONAL INFORMATION

**7+13. DESCRIBE REACTION(S) continued**

The Consumer or other Non HCP reported the following event(s) for this case: nausea,dizziness/Gets lightheaded when standing [Dizziness],body pain [General body pain],emotional changes/distraught [Emotional disorder].

Medical history included:

Current condition(s): Hep C (Hepatitis C) Start Date: Date not provided

Historical condition(s): None Reported

Historical drug(s): None Reported

Concomitant medications were not reported by the Consumer or other Non HCP.

On 03-JUL-2023, the patient received LEDIPASVIR/SOFOSBUVIR 90/400mg, 1 dosage form, QD, Oral use route of administration for treatment of Hep C.

On 04-JUL-2023, the patient experienced nausea
,On an unspecified date , the patient experienced dizziness/Gets lightheaded when standing [Dizziness]
,On an unspecified date , the patient experienced body pain [General body pain]
,On an unspecified date , the patient experienced emotional changes/distraught [Emotional disorder]

No laboratory/diagnostic tests were reported.

The action taken with LEDIPASVIR/SOFOSBUVIR was No Change
Dechallenge: N/A
Rechallenge: N/A

The Consumer or other Non HCP assessed the event of nausea as Serious (, Disability), causality of Not Reported for LEDIPASVIR/SOFOSBUVIR. The outcome of this event was Not Resolved

,The Consumer or other Non HCP assessed the event of dizziness/Gets lightheaded when standing [Dizziness] as Non-Serious (), causality of Not Reported for LEDIPASVIR/SOFOSBUVIR. The outcome of this event was Not Resolved

,The Consumer or other Non HCP assessed the event of body pain [General body pain] as Non-Serious (), causality of Not Reported for LEDIPASVIR/SOFOSBUVIR. The outcome of this event was Unknown

,The Consumer or other Non HCP assessed the event of emotional changes/distraught [Emotional disorder] as Non-Serious (), causality of Not Reported for LEDIPASVIR/SOFOSBUVIR. The outcome of this event was Not Resolved

The initial report was received on 07-JUL-2023 and received by Gilead Safety on 07-JUL-2023.

Follow-up information was received on 11-AUG-2023 and received by Gilead on 11-AUG-2023. Start date of event dizziness was updated, new event vomiting and feeling exhausted/tired was added. This is a significant follow-up.

The Consumer or other Non HCP reported the following event(s) for this case: nausea/vomiting [Vomiting],feeling exhausted/tired [Exhaustion].

,On 03-JUL-2023, the patient experienced dizziness/Gets lightheaded when standing [Dizziness]
,On 03-JUL-2023, the patient experienced nausea/vomiting [Vomiting]
,On 03-JUL-2023, the patient experienced feeling exhausted/tired [Exhaustion]

,The Consumer or other Non HCP assessed the event of nausea/vomiting [Vomiting] as Non-Serious (), causality of Not Reported for LEDIPASVIR/SOFOSBUVIR. The outcome of this event was Not Resolved

,The Consumer or other Non HCP assessed the event of feeling exhausted/tired [Exhaustion] as Non-Serious (), causality of Not Reported for LEDIPASVIR/SOFOSBUVIR. The outcome of this event was Not Resolved

Case Comment: Lack of clinical information including full medical history, details of clinical course, full historical medication list, onset date of the events and dates of therapy, concomitant medication and lab/diagnostic tests, limits causality assessment for the reported events of Nausea, Dizziness, Pain, Vomiting, Fatigue and Emotional disorder.