



REPORT ON SUSPECTED ADVERSE DRUG REACTIONS

NATIONAL CENTRE FOR ADVERSE DRUG REACTIONS MONITORING

Email: fv@npra.gov.my Website: <http://www.npra.gov.my>

(Please report **all** suspected adverse drug reactions including those for vaccines, cosmetics and traditional products. Do not hesitate to report if some details are not known. **Mandatory fields** are marked with *, but please give as much other information as you can. Identities of Reporter, Patient and Institution will remain **Confidential**.)

REPORT No. (for official use only):

PATIENT INFORMATION

| | | | | | |
|---------------------------|----------------------|--|----------------------|----------------------|--|
| I.C. No. / R/N / Initials | *Age | *Gender (please tick) Male <input type="checkbox"/> Female <input type="checkbox"/> | Wt (kg) | *Ethnic Group | Please tick (if applicable): <input type="checkbox"/> Initial Report <input type="checkbox"/> Follow-up Report |
| <input type="text"/> | <input type="text"/> | | <input type="text"/> | <input type="text"/> | |

*ADVERSE REACTION DESCRIPTION (inc. sequence of adverse events, details of rechallenge, interactions)

| | | | | | |
|-----------------------------|--|--------------------------|-------------------------------------|------------------------|-------------------------------------|
| Time to onset of reaction : | <input type="text"/> mins/ hours/ days/ months/ years (please circle) | Date start of reaction : | <input type="text"/> DD / MM / YYYY | Date end of reaction : | <input type="text"/> DD / MM / YYYY |
|-----------------------------|--|--------------------------|-------------------------------------|------------------------|-------------------------------------|

| | | | | |
|---|------------------------------|-----------------------------|----------------------------------|--|
| Reaction subsided after stopping drug / reducing dose : | Yes <input type="checkbox"/> | No <input type="checkbox"/> | Unknown <input type="checkbox"/> | ♦N/A (drug continued) <input type="checkbox"/> |
|---|------------------------------|-----------------------------|----------------------------------|--|

| | | | | |
|--|------------------------------|-----------------------------|----------------------------------|--|
| Reaction reappeared after reintroducing drug : | Yes <input type="checkbox"/> | No <input type="checkbox"/> | Unknown <input type="checkbox"/> | ♦N/A (not reintroduced) <input type="checkbox"/> |
|--|------------------------------|-----------------------------|----------------------------------|--|

| | | | |
|----------------------|-------------------------------|-----------------------------------|---------------------------------|
| Extent of reaction : | Mild <input type="checkbox"/> | Moderate <input type="checkbox"/> | Severe <input type="checkbox"/> |
|----------------------|-------------------------------|-----------------------------------|---------------------------------|

| | | | | | |
|---------------------------|---|--|--|--|---|
| Seriousness of reaction : | Life threatening <input type="checkbox"/> | Caused or prolonged hospitalisation <input type="checkbox"/> | Caused disability or incapacity <input type="checkbox"/> | Caused birth defect <input type="checkbox"/> | ♦N/A (not serious) <input type="checkbox"/> |
|---------------------------|---|--|--|--|---|

| | |
|--|----------------------|
| Treatment of adverse reaction & action taken : | <input type="text"/> |
|--|----------------------|

| | | | | | | |
|-----------|--|-------------------------------------|--|----------------------------------|--------------------------------|-----------------------------|
| Outcome : | Recovered fully <input type="checkbox"/> | Recovering <input type="checkbox"/> | Not recovered <input type="checkbox"/> | Unknown <input type="checkbox"/> | Fatal <input type="checkbox"/> | Date & Cause of death:..... |
|-----------|--|-------------------------------------|--|----------------------------------|--------------------------------|-----------------------------|

| | | | | | |
|------------------------------|----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|---|
| Drug-Reaction Relationship : | Certain <input type="checkbox"/> | Probable <input type="checkbox"/> | Possible <input type="checkbox"/> | Unlikely <input type="checkbox"/> | Unclassifiable <input type="checkbox"/> |
|------------------------------|----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|---|

*Suspected Drug :

♦N/A: Not applicable

| Product / Generic Name | Dose & Frequency Given | MAL and Batch No. | Therapy Dates | | Indication |
|------------------------|------------------------|-------------------|---------------|------|------------|
| | | | Start | Stop | |
| | | | | | |
| | | | | | |

Concomitant Drug (please state 'NIL' if none) :

| Product / Generic Name | Dose & Frequency Given | MAL and Batch No. | Therapy Dates | | Indication |
|------------------------|------------------------|-------------------|---------------|------|------------|
| | | | Start | Stop | |
| | | | | | |
| | | | | | |

(Please attach additional sheets if necessary)

| Relevant Investigations / Laboratory Data | Relevant Medical History (e.g.: hepatic / renal dysfunction, allergies, pregnancy status, etc) |
|---|---|
| | |

Reporter Details

| | |
|------------------|-------------------------------|
| *Name : | *Institution Name & Address : |
| Designation : | *Tel No : |
| *Email Address : | Date of Report : |
| | Signature : |

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Submission of a report does not constitute an admission that medical personnel or the products caused or contributed to the reaction. *Thank you for reporting.*

ADR Reporting Guide

Before submitting your ADR report, do check if you have inserted the following information.

*Please try to fill every section in the ADR form overleaf, stating 'none / nil' if applicable. A complete report is a useful report.

NO. IMPORTANT POINTS TO NOTE

1 **Definitions:**

- (i) **Time to onset of reaction:** time interval between first dose (initiation) of the drug until first sign of the ADR.
- (ii) **Initial report:** First submission of report to NPRA of a particular patient involving a particular ADR.
- (iii) **Follow-up report:** Submission of further reports related to the same case to inform of additional information not mentioned previously or which occurred after the initial report. Please mention the date of initial report for reference.

2 Please specify any previous history of **allergy** (including drugs, food, etc.).

3 Include information on any **concomitant medications** or **underlying illnesses**? (Please state 'nil' if none)

- Date started and stopped for each medication
- Please state 'cont' for any medication still continued after the ADR

4 Please state the specific **indication** of the suspected drug
(e.g.: 'pneumonia due to *S. Pneumoniae*' - not 'infection' or 'antibiotic').

5 If the ADR reappeared after reintroducing drug (**rechallenge**), please describe the rechallenge fully (dose given, timing, brand used, etc.) under section 'Adverse Reaction Description'.

6 Please specify if any **treatment** was given for the ADR, or if the suspected drug was stopped, what **alternative drug** was started and how the patient responded.

7 Please include the latest / current **outcome** of the patient (e.g. *recovered fully, not recovered*).

- If possible, follow-up the patient periodically until the final outcome is known.
- A follow-up report may be sent in to update on the final outcome of the patient.

8 **Skin reactions:** Please describe the specific type and location of the skin reaction.
(Use the *Cutaneous ADR form and guide* available on <http://www.npra.gov.my>)

9 Do keep your own record of details enabling you to **contact** the patient or trace the case notes later on if necessary
(e.g. *IC number, patient name and phone number*).

Please refer to our website for additional guidance on ADR Reporting, or contact us at fv@npra.gov.my if you have any queries.

Laporan Kesan Advers Ubat

Bahagian Regulatori Farmasi Negara (NPRA)
Kementerian Kesihatan Malaysia

PUSAT PEMONITORAN KESAN ADVERS UBAT KEBANGSAAN

BAHAGIAN REGULATORI FARMASI NEGARA

PETI SURAT 319, JALAN SULTAN

46730 PETALING JAYA

SELANGOR

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