

**ADVERSE DRUG REACTION REPORT FORM****(1) PATIENT DETAILS**

Patient name: _____

Medical record no. / Identity card no. : _____

Sex: Male Female Date of birth: _____ Weight, if known (kg): _____ Height, if known (m): _____Nationality: _____ Ethnic group: Malay Chinese Other (please specify) : _____**(2) SUSPECTED MEDICINE(S) (Additional pages may be attached if there are more than 2 suspected medicines)**

| Medicine (brand/ generic name & strength) | Form | Dosage regimen (dosage, frequency & route) | Manufacturer Name/ Registration No. / Batch No. (if known) | Date begun | Date stopped | Reason(s) for use |
|---|------|--|--|------------|--------------|-------------------|
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(3) OTHER MEDICINE(S) (INCLUDE SELF-MEDICATION, HERBAL & TRADITIONAL MEDICINES) TAKEN AT THE TIME OF REACTION AND/ OR 3 MONTHS BEFORE (Additional pages may be attached if more medicines taken)

| Medicine (brand/ generic name & strength) | Form | Dosage regimen (dosage, frequency & route) | Manufacturer Name/ Registration No. / Batch No. (if known) | Date begun | Date stopped | Reason(s) for use |
|---|------|--|--|------------|--------------|-------------------|
| | | | | | | |
| | | | | | | |

(4) ADVERSE REACTION

• Description of Adverse Reaction(s): _____

• Time/ Date of onset of reaction (in relation to initial dose): _____

• Do you consider the reaction to be serious? No YesIf **yes**, please indicate why the reaction is considered to be serious (please tick all that apply): Patient died due to reaction Involved or prolonged inpatient hospitalisation Life threatening Involved persistent or significant disability or incapacity Congenital abnormality Medically significant; please give details: _____

• Description of treatment of reaction : _____

• Outcome: Recovered (Date): _____ Not yet recovered Fatal (Date of Death): _____ Unknown

• Sequelae (any permanent complications or injuries as a result of the adverse reaction):

 No Yes (please specify): _____ Unknown**(5) REPORTER DETAILS**

Name:

Address :

Profession:

Signature:

Date:

Tel No:

Email:

(6) COMMENTS

Other relevant information: e.g. medical history, allergies, pregnancy, smoking, action taken (drug stop, dose reduced, dose increased), suspected drug interactions, rechallenge (if performed). Please provide as much detail as possible and include any results of relevant supportive laboratory data, as well as, other investigations. Additional pages may be attached if required.

Thank you for taking the time to complete this form.

FOLD HERE FIRST

CONFIDENTIALITY

Identities of reporter and patient will be kept confidential.

WHAT TO REPORT?

An adverse drug reaction is a response to a drug that is noxious (harmful) and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.

Please report if you suspect that the drug may be related to an adverse reaction. Please do not be deterred from reporting even if some details are not known.

The Ministry of Health encourages the reporting of all suspected adverse reactions to drugs and medicinal substances (including herbal, traditional or alternative medicines). Please report:

- All suspected reactions to established products and new medicines.
- All suspected drug interactions.
- Adverse reactions which are suspected of significantly affecting a patient's management, including reactions suspected of causing death, danger to life, admission to hospital, prolongation of hospitalization, absence from productive activity, increased investigational or treatment costs, birth defects.

HOW TO REPORT?

The Adverse Drug Reaction Report form can be obtained from the section below. This form should be filled as completely as possible and can be return to the address below or return to the nearest government pharmacy facility (hospital/ health center).

FOLD HERE SECOND

To:

Adverse Drug Reaction Unit, Drug and Poison Information Section,
 Department of Pharmaceutical Services, Ministry of Health,
 Simpang 433, Madaras
 Brunei Darussalam BB3910
 Tel: 2393298 ext 201, 206, 207
 Email: nadrmc.dps@moh.gov.bn