# ADR Reporting Form

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

**NDoH Pharmacovigilance Centre for Public Health Programmes (NPC)**
**Adverse Drug Reaction (ADR) / Product Quality Problem Report Form**
**This report will be shared with the**
**South African Health Products Authority (SAHPRA)**
**adr@sahpra.org.za or call 012501031**

| **Reporting Health Care Facility/Practice** | | | | |
|---|---|---|---|---|
| **Tel:** 012 395 9506 (NPC)<br>**Fax:** 086 241 2473<br>**Email:** npc@health.gov.za | Facility/Practice | | | |
| | District | | Tel | |
| | Province | | Fax | |

| **Patient Details** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Patient Initials | | File/Reference Number | | | Date of Birth/Age | | | | |
| Sex | □M □F □Unk | Race | | Weight (kg) | | Height (cm) | | Pregnant? | □N □Y |
| Allergies | | | | Estimated Gestational Age at time of reaction | | | | | |

**Suspect Medicine(s)** **[Medicines suspected to have caused the ADR]**

| Trade Name [Generic Name if Trade Name is unknown] | Name of Manufacturer | Route | Dose (mg) and Interval | Date Started | Date Stopped | Reason for use | Batch Number / Expiry Date |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |

**All other Medicines Patient was taking at time of reaction** **[Including over-the-counter and herbal products]**

| Trade Name [Generic Name if Trade Name is unknown] | Name of Manufacturer | Route | Dose (mg) and Interval | Date Started | Date Stopped | Reason for use | Batch Number / Expiry Date |
|---|---|---|---|---|---|---|---|
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**Adverse Drug Reaction/Product Quality Problem**

| Date and time of onset of reaction | | Date reaction resolved/duration | |
|---|---|---|---|

Please describe Adverse Reaction/Product Quality Problem: (kindly add as much clinical information as possible)

| **Intervention** **[tick all that apply]** | **Patient Outcomes** **[tick all that apply]** |
|---|---|
| □ No intervention | □ Patient recovered □ Patient recovering |
| □ Intervention unknown | □ Patient not recovering □ Outcome unknown |
| □ Patient counselled/non-medical treatment | □ Patient died; Date of death:_____ |
| □ Discontinued Suspect Drug; **Replaced with**:_____ | □ Impairment/Disability □ Congenital Anomaly |
| □ Decreased Suspect Drug Dosage; **New Dose**:_____ | □ Patient hospitalised or hospitalisation prolonged |
| □ Treated ADR with:_____ | □ Life threatening □ Other:_____ |
| □ Referred to hospital; **Hospital Name**_____ | □ ADR reappeared after restarting suspect drug/similar drug (rechallenge)?: □ N □ Y □ Not done □ Unknown |
| □ Other Intervention (e.g. dialysis): _____ | |

**Laboratory Results**

| Lab Test | Test Result | Test Date | Lab Test | Test Result | Test Date |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

**Co-morbidities/Other Medical Condition(s)** **[tick all that apply]**

□ Hypertension □ Diabetes □ Asthma □ Tuberculosis □ HIV/AIDS □ Other:

**Reported by**

| Name | | E-mail | |
|---|---|---|---|
| Designation | □ Nurse □ Pharmacist □ Doctor □ Other: | Date Reported | |
| Telephone | | Signature | **VERSION 35.0 May 2021** |

**THIS ADR REPORT IS NOT A CONFIRMATION THAT THE REPORTER OR THE SUSPECT MEDICINE(S) CAUSED THE ADR**