Ministry of Health and Family Welfare
Government of India

World Health Organization
COUNTRY OFFICE FOR India

# ADVERSE DRUG REACTION REPORTING FORM FOR KALA-AZAR TREATMENT

## I. PATIENT DETAILS

| Patient Initials: | Patient Code No: | Patient Contact No: | AMC report number: |
|---|---|---|---|
| Patient Age: (Yr) | | Weight: (Kg) | |
| Gender: M ☐ F ☐ Others ☐ | | Breastfeeding an infant: Yes☐ No☐ | Worldwide unique number: |
| Pregnant: Yes ☐ No ☐ Uncertain ☐ | | If Pregnant, estimated current gestation (weeks): | |

## II. TREATMENT

| **A) CONDITION TREATED** | | | |
|---|---|---|---|
| Kala Azar (VL) ☐ | Post Kala Azar Dermal Leishmaniasis (PKDL) ☐ | HIV-VL Co-infection ☐ | Others ☐ (Specify) |

**B) TREATMENT RECEIVED**

Mono Therapy ☐ Combination Therapy ☐

| **Drug Received** | **Batch No./ Expiry Date** | **Drug Dose & Unit** | **Frequency** | **Route** | **Start Date** (dd/mm/yyyy) | **Start Time** (Hr:Min) | **Stop Date** (dd/mm/yyyy) | **Stop Time** (Hr:min) |
|---|---|---|---|---|---|---|---|---|
| Liposomal Amphotericin B | | | | | | | | |
| Miltefosine | | | | | | | | |
| Paromomycin | | | | | | | | |
| Amphotericin B deoxycholate | | | | | | | | |
| SSG/ SAG | | | | | | | | |
| ………………………. | | | | | | | | |

## III. CONCOMITANT DRUGS

| **S. No.** | **Name** | **Indication** | **Batch Number/ Expiry Date** | **Drug Dose Unit (if I.V) Infusion rate in ml/hour** | **Dose & Unit** | **Frequency** | **Route** | **Start Date** | **Stop date** |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |

## IV. ADVERSE EVENTS INFORMATION

Reporter's Narrative (Describe the course of events, timing and suspected causes):

| **Adverse Event/ Reaction Term** | Event I | Event II | Event III |
|---|---|---|---|
| **Date of Onset** | DD/MM/YY | DD/MM/YY | DD/MM/YY |
| **Date Resolved** | DD/MM/YY | DD/MM/YY | DD/MM/YY |
| **Severity** | ☐ Mild<br>☐ Moderate<br>☐ Severe | ☐ Mild<br>☐ Moderate<br>☐ Severe | ☐ Mild<br>☐ Moderate<br>☐ Severe |
| **Seriousness** | ☐ **Non-Serious ADR**<br>☐ **Serious AE/ADR**<br>please specify category ;<br>☐ Death<br>☐ Hospitalization/ Prolonged<br>☐ Life threatening<br>☐ Permanent disability/disabling<br>☐ Congenital anomaly/ birth defect<br>☐ Other medically important condition | ☐ **Non-Serious ADR**<br>☐ **Serious AE/ADR**<br>please specify category ;<br>☐ Death<br>☐ Hospitalization/ Prolonged<br>☐ Life threatening<br>☐ Permanent disability<br>☐ Congenital anomaly<br>☐ Other medically important condition | ☐ **Non-Serious ADR**<br>☐ **Serious AE/ADR**<br>please specify category ;<br>☐ Death<br>☐ Hospitalization/ Prolonged<br>☐ Life threatening<br>☐ Permanent disability<br>☐ Congenital anomaly<br>☐ Other medically important condition |

| | | | |
|---|---|---|---|
| **Outcome** | ☐ Recovered/ resolved<br>☐ Recovering/resolving<br>☐ Fatal<br>☐ Not Recovered/not resolved<br>☐ Recovered with Sequalae<br>☐ Unknown | ☐ Recovered/ resolved<br>☐ Recovering/resolving<br>☐ Fatal<br>☐ Not Recovered/not resolved<br>☐ Recovered with Sequalae<br>☐ Unknown | ☐ Recovered/ resolved<br>☐ Recovering/resolving<br>☐ Fatal<br>☐ Not Recovered/not resolved<br>☐ Recovered with Sequalae<br>☐ Unknown |
| **Dechallenge/ Action Taken** | ☐ Drug Withdrawn<br>☐ Dose Reduced<br>Dose……………<br>☐ Dose not changed<br>☐ Unknown<br>☐ Not Applicable | ☐ Drug Withdrawn<br>☐ Dose Reduced<br>Dose……………<br>☐ Dose not changed<br>☐ Unknown<br>☐ Not Applicable | ☐ Drug Withdrawn<br>☐ Dose Reduced<br>Dose……………<br>☐ Dose not changed<br>☐ Unknown<br>☐ Not Applicable |
| **Rechallenge** | ☐ No<br>☐ Yes<br>Dose (if reintroduced)……...<br>☐ Unknown | ☐ No<br>☐ Yes<br>Dose (if reintroduced)……...<br>☐ Unknown | ☐ No<br>☐ Yes<br>Dose (if reintroduced)……...<br>☐ Unknown |
| **Expectedness** | ☐ Expected (yes)<br>☐ Unexpected (no) | ☐ Expected (yes)<br>☐ Unexpected (no) | ☐ Expected (yes)<br>☐ Unexpected (no) |
| **For Death** | Date of Death………………<br>Primary cause of death (if known):<br>…………<br>Was autopsy performed?<br>☐ No<br>☐ Yes<br>Hospital Admission Date ……<br>Hospital Discharge Date…….. | Date of Death………………<br>Primary cause of death (if known):<br>……………<br>Was autopsy performed?<br>☐ No<br>☐ Yes<br>Hospital Admission Date ………<br>Hospital Discharge Date……….. | Date of Death………………<br>Primary cause of death (if known):<br>……………<br>Was autopsy performed?<br>☐ No<br>☐ Yes<br>Hospital Admission Date……<br>Hospital Discharge Date…… |
| **Causality**<br>[-Certain<br>-Probable<br>- Possible<br>- Unlikely<br>- Conditional<br>- Unassessable] | ☐ Ambisome……………..<br>☐ Miltefosine ....................<br>☐ Paromomycin.................<br>☐ Amphotericin deoxycholate........<br>☐ SSG/ SAG.....................<br>☐ Others (....................)…… | ☐ Ambisome……………..<br>☐ Miltefosine ..............<br>☐ Paromomycin...................<br>☐ Amphotericin deoxycholate....<br>☐ SSG/ SAG.....................<br>☐ Others (...................)………….. | ☐ Ambisome……………..<br>☐ Miltefosine ..............<br>☐ Paromomycin...................<br>☐ Amphotericin deoxycholate........<br>☐ SSG/ SAG.....................<br>☐ Others (....................)………….. |

## V. MEDICAL HISTORY

***Briefly describe diseases and concurrent illness:***

## VI. RELEVANT LABORATORY TESTS

| **LABORATORY TESTS** | | | | | |
|---|---|---|---|---|---|
| **Test** | **Date** | **Result (units)** | **Test** | **Date** | **Result (units)** |
| Haemoglobin | | | Creatinine | | |
| ALT (SGPT) | | | $Na^+$ | | |
| AST (SGOT) | | | $K^+$ | | |
| | | | | | |

## VII. OTHER CLINICALLY RELEVANT INFORMATION

**Treatment For Managing ADR:**

**Counseling with Toll Free Number (18001803024):** ☐ **Yes** ☐ **No**

## VIII. REPORTERS INFORMATION

| | | |
|---|---|---|
| **Name:** | **Designation:** | **Signature:** |
| **Email:** | **Contact No.:** | |
| **Professional Address:** | **PIN Code:** | **Date:** |
| **Name of Paramedical:** | **Designation:** | **Signature:** |