e

| **1. Reporter Details** | | ☐Initial ☐Follow-up |
|---|---|---|
| Reporter Name: | | E-mail: |
| **Contact address:** | | Telephone number: |
| | | Fax number: |
| Type: | ☐ Physician (Specialty): _____ | ☐ Consumer or other non healthcare professional |
| | ☐ Pharmacist | ☐ Other (Specify) _____ |
| If reporter is a consumer, have they informed their physician of the exposure? | | ☐ Yes ☐ No |
| Has the consumer provided permission to contact their healthcare professional? | | ☐ Yes ☐ No |

| **If yes, please provide healthcare professional contact details:** | | |
|---|---|---|
| Name: | Type: | Telephone: |
| Address: | | Email: |

| **2. Patient Details** | | | |
|---|---|---|---|
| Date of birth (Day/Month/Year) | Age Yrs/mo. | Height cm | Weight kg |
| | | | |

| **3. Company Drug Section** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Name | Strength | Dose | Route | Indication | Treatment start date (day/month/year) | Treatment end date (day/month/year) | Lot | Expiry |
| 1. | | | | | | | | | |
| 2. | | | | | | | | | |
| 3. | | | | | | | | | |

| **4. Details of Adverse Event** | | | | | |
|---|---|---|---|---|---|
| Adverse Event | Start Date (day/month/year) | Stop Date (day/month/year) | Hospitalization | Outcome | Event Causality |
| | | | ☒ Yes<br>☐ No<br>*If yes, provide dates of hospitalization.* | ☐ Recovered / Resolved<br>☐ Recovered / Resolved With Sequelae<br>☐ Recovering /Resolving<br>☐ Not Recovered /Not Resolved<br>☐ Fatal<br>☐ Unknown | ☐ Related<br>☐ Not Related<br>☐ Unknown |

| **5. Complete Blood Count (CBC)** | | | |
|---|---|---|---|
| | **Date** (day/month/year) | **Results** | **Normal Range** |
| Red blood cell count | | | |
| Hemoglobin | | | |
| Hematocrit | | | |
| White blood cell count | | | |
| Platelet count | | | |

**Attach supporting labs for Complete Blood Count (CBC)**

☐ Chronic or recurrent anemia, *Attach supporting hemoglobin records and reticulocyte*

## 6. Treatment

Transfusions:
☐ Yes, *Attach supporting transfusions records*
☐ No

Treatment provided for event:
Action taken with Company Drug in response to event:

## 7. Concomitant Drugs & Therapies

## 8. Medical History

Patient's concomitant conditions, relevant medical history, known risk factors, relevant tests, laboratory data. *(Include information on familial disorders, known risk factors or conditions that may affect the outcome of the pregnancy e.g. alcohol, smoking, other substance consumption, hypertension, eclampsia, diabetes including gestational, infections during pregnancy, environmental or occupational exposure that may pose a risk factor).*

## 9. Completed By

| Name: | Signature: | Date (day/month/year): |
|---|---|---|
| | | |