*Please complete and forward this form to Biotest AG Corporate Drug Safety, Landsteinerstr. 5, 63303 Dreieich – phone: +49 6103 801 756; fax: +49 6103 801 854 or* *drugsafety@biotest.com*

A privacy notice in relation to the personal data collected on this form is available at the Biotest website ([www.biotest.com](http://www.biotest.com)) under ‘*contact’* tab and by clicking on ‘*Reporting of suspected adverse drug reactions’*.

|  |  |
| --- | --- |
| Reporter name:  |        |
| Address: |       |
| E-mail |       |
| Phone number |       |
| **If healthcare professional, state qualification**[ ]  Physician [ ]  Pharmacist [ ]  Care giver [ ]  Others, please state:       |

|  |
| --- |
| **Patient Data** |
| Initials       | [ ]  Male [ ]  Female [ ]  Diverse | Age       | Height (cm)       | Weight (kg)       |
| Pregnancy[ ]  No [ ]  Yes [ ]  Unknown | If yes, estimated date of delivery (DDMMMYYYY):      |
|  |  |
| **Biotest Product** |
| Suspect drug      | Reason for treatment      | Batch number      |
| Date of first administration       | Last administration before the event       | Temperature of infusion (°C)      |
| Duration of drug administration (unit)      | Total volume infused (ml)      | Rate of infusion (ml/60min)      |
|  |  |  |
| **Suspected Reactions** |
| *Brief description of the effects/side effects/interactions, including any information relevant to the circumstances of this reaction, medication error etc.* |
| Reaction      [ ]  There is a causal relationship between the drug and the ADR[ ]  There is no causal relationship between the drug and the ADR | Treatment given / action taken:       |
| Start date reaction (DDMMMYYYY)      | Duration of reaction      | Outcome of reaction [ ]  Recovered, on (DDMMMYYYY)      [ ]  Recovering [ ]  Not yet recovered[ ]  Rec. with sequelae [ ]  Fatal [ ]  Unknown |
| Did similar reactions occur in this patient before? [ ]  No [ ]  YesIf yes, related to similar drugs? [ ]  No [ ]  Yes If yes, please specify       |
|  |
| **Seriousness** |
| Drug discontinued [ ]  No [ ]  YesDose reduced/infusion rate reduces (please specify)      Improvement of patient [ ]  No [ ]  YesDrug re-administered? [ ]  No [ ]  YesIf yes, did the reaction reappear?[ ]  No [ ]  Yes | Do you consider the reactions serious (at least one of the below listed criteria fulfilled?)[ ]  No [ ]  YesIf yes, please indicate which seriousness criteria apply (multiple possible).[ ]  Fatal[ ]  Immediately life threatening[ ]  Patient hospitalized (overnight) / hospitalization prolonged[ ]  Persistent or significant disability / incapacity[ ]  Congenital anomaly or birth defect[ ]  Medically significant – provide details *(e.g. events that do not meet the standard criteria for seriousness, but based on medical judgment are considered serious as they may jeopardize the patient and may require medical or surgical intervention to prevent the event meeting the standard criteria for seriousness)*:      |
| If seriousness is fatal Date of death (DDMMMYYYY):      Cause of death:      Autopsy: [ ]  No[ ]  Planned Date:      [ ]  Yes Date:      If yes, please provide autopsy report. |
|  |  |
| **Any other drugs used over this period?** |
| [ ]  None [ ]  Unknown |
| Drug | Daily Dose | Route | Dates / duration of treatment | Reason for treatment |
|        |       |       |        |        |
|        |       |       |        |        |
|        |       |       |        |        |
|        |       |       |        |        |
|  |  |  |  |  |
| **Relevant medical history** |
| Description | Start date (DDMMMYYYY) | End date(DDMMMYYYY)  | Continuing? |
|        |        |        | [ ]  No [ ]  Yes |
|        |        |        | [ ]  No [ ]  Yes |
|        |        |        | [ ]  No [ ]  Yes |
| **Allergies** | [ ]  No [ ]  Yes | If yes, please specify        |
| **IgA deficiency** | [ ]  No [ ]  Yes | If yes, please specify        |

|  |  |  |
| --- | --- | --- |
| The local health authority was notified? | [ ]  No [ ]  Yes | If yes, state which authority?       |

**SIGNATURE** **DATE**

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS FORM.