*Please complete and forward this form within 24 hours of becoming aware of the pregnancy/event to: Biotest AG, Corporate Drug Safety Department, Landsteinerstr. 5, D-63303 Dreieich, GERMANY*

*Tel: +49 6103 801 756 Fax: +49 6103 801 854 oder Email:* [drugsafety@biotest.com](mailto:drugsafety@biotest.com)

Data protection: Privacy notices related to personal data collected on this form can be found on the Biotest website ([www.biotest.com](http://www.biotest.com)) under ‘*Contact’* and ‘*Reporting suspected adverse reactions’*.

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| --- | --- |
| Reporter name |  |
| Address |  |
| E-Mail |  |
| Phone number |  |
| **If you are a healthcare professional, please enter your qualification:**  Midwife / Midwives  Gynecologist  Pediatrician  Mother / Father  Other, please specify: | |

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| **Part 1: Pregnancy** | | | | | |
| **Biotest Product Information** | | | | | |
| Product name | | Reason for treatment | | Batch number | |
| Date of first administration (DDMMMYYYY): | | Date of last administration (DDMMMYYYY): | | Therapy with Biotest products was applied to:  Mother  Father | |
|  | |  | |  | |
| **Information on mother** | | | | | |
| Initials: | Age: | | Height (cm) | | Weight (kg) |
| Last menstruation (DDMMMYYYY) | | | Estimated date of delivery (DDMMMYYYY) | | |
| Is the pregnancy ongoing?  No (*If no, please fill out part 2.)*   Yes | | | | | |

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| **Part 2: Outcome of pregnancy** | | | | |
| Follow-up report. To be filled out at the end of the pregnancy.  If the child experienced an adverse event (AE), please fill out Part 3.  In situations when the mother experienced an AE, miscarriage/stillbirth, spontaneous abortion, delivery complications or abnormal placenta, please fill out the regular Biotest "***Report of Suspected Drug Reaction (ADR)***" form, which can be downloaded on the Biotest website under *Contact’* and ‘*Reporting suspected adverse reactions'*. | | | | |
| Singleton  Multiples (Please complete a report for each child) | | | | |
| **Delivery** | | | | |
| Date of delivery (DDMMMYYYY): | | Mode of delivery:  Vaginal delivery  Caesarean section | | |
| Delivery complications  No  Yes (if yes, please fill out ADR form) | | Abnormal placenta (including ectopic pregnancy)  No  Yes (if yes, please fill out ADR form) | | |
| Elective termination, please specify the reason: | | | | |
| Premature birth in       gestation week | | | | |
| Miscarriage in       gestation week, please continue with part 3. | | | | |
|  | | | | |
| **Infant status** | | | | |
| male   female   diverse | Birth weight (kg) | Birth height (cm) | | APGAR score: |
| Healthy baby | Malformation / Abnormities  *(please specify in Part 3)* | | Other adverse event *(please specify in Part 3)* | |

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| **Part 3: Adverse event(s) of baby** | | | | | | | | | | | | | |
| **Adverse event (AE)** | | | | | | | | | | | | | |
| *Short description of event, including relevant information, symptoms, possible misuse / interaction, etc.* | | | | | | | | | | | | | |
| AE 1: | | | | | | | Treated with: | | | | | | |
| Start date of event (DDMMMYYYY): | | Duration of event: | | | | | Outcome:  recovered / resolved, on (DDMMMYYYY):  recovering / resolving  not recovered / not resolved  resolved with sequelae  fatal  Unknown | | | | | | |
| Causal relationship with drug?  No  Yes | | | | | | | | | | | | | |
| AE 2: | | | | | | | Treated with: | | | | | | |
| Start date of event (DDMMMYYYY): | | Duration of event: | | | | | Outcome:  recovered / resolved, on (DDMMMYYYY):  recovering / resolving  not recovered / not resolved  resolved with sequelae  fatal  Unknown | | | | | | |
| Causal relationship with drug?  No  Yes | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | |
| **Relevant Medical and Drug History of Mother** | | | | | | | | | | | | | |
| Allergies | No  Yes | | | | If yes, please specify: | | | | | | | | |
| IgA-Deficiency | No  Yes | | | | If yes, please specify: | | | | | | | | |
| Risk factors:  Smoking  Alcohol abuse  Drug abuse | | | | | | | | | | | | | |
| Other relevant medical history | | | | | Start date  (DDMMMYYYY) | | | | | End date  (DDMMMYYYY) | | | Continuing? |
|  | | | | |  | | | | |  | | | No  Yes |
|  | | | | |  | | | | |  | | | No  Yes |
|  | | | | |  | | | | |  | | |  |
| **Any other medication used (during pregnancy)?** | | | | | | | | | | | | | |
| No  Unknown | | | | | | | | | | | | | |
| Product | | | | Daily dose | | Route | | | Date / duration of treatment | | | Reason for treatment (Disease) | |
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| **Previous Pregnancies** | | | | | | | | | | | | | |
| No  Yes (*please specify*) | | | | | | | | | | | | | |
| Date of delivery (DDMMMYYYY) | | | Gestational week at delivery | | | | | Outcome | | | Other complications | | |
|  | | |  | | | | | Healthy baby  Miscarriage  Fetal/neonatal abnormities | | |  | | |
|  | | |  | | | | | Healthy baby  Miscarriage  Fetal/neonatal abnormities | | |  | | |
|  | | |  | | | | |  | | |  | | |
| **Relevant medical history of father** | | | | | | | | | | | | | |
| Relevant medical history | | | | | Start Date  (DDMMMYYYY) | | | | | End Date  (DDMMMYYYY) | | | Continuing? |
|  | | | | |  | | | | |  | | | No  Yes |
|  | | | | |  | | | | |  | | | No  Yes |
|  | | | | |  | | | | |  | | |  |
| **Other concomitant medication at time of conception** | | | | | | | | | | | | | |
| No  Unknown | | | | | | | | | | | | | |
| Product | | | | Daily dose | | Route | | | Date / duration of treatment | | | Reason for treatment (Disease) | |
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| 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.