*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

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’*.

|  |  |
| --- | --- |
| 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) |
|        |       |       |        |        |
|        |       |       |        |        |
|        |       |       |        |        |
|        |       |       |        |        |
|  |  |  |  |  |
| **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.