

 Global Pharmacovigilance

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| Bayercoloured bar**Adverse Event/Injury - Spontaneous Report Form**   |
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| **Local Bayer PV case ID:** | **Date of receipt of information:**  |
| **Initial report** **[ ]  Follow-up report [ ]**  | **Follow-up information requested:** Yes [ ]  No [ ]  |

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| ⮊ **Give information on the subject who has experienced the Adverse Event/Injury**  |
| **Initials**  | **Gender\*** **male [ ]** **female [ ]**  | **Age\***[years] | **Is this subject the**: (select one) **\*** **Patient /Consumer [ ]  Treating Physician [ ]**  **Other person handling the product [ ]  specify:**       |

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| ⮊ **What Adverse Event(s)/Injury occurred? \*** |
| **1. \***           | **2.**            | **3.**            | **4.**            |
| **Date: \***       | **Date:**       | **Date:**       | **Date:**       |
| Was the patient hospitalized?**\*** Yes [ ] No [ ]  Did the patient die?**\***Yes [ ] No [ ]  Medical/Surgical Intervention performed?**\***Yes [ ]  No [ ]  |
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| ⮊ **Describe details of the Adverse Event(s)/Injury and Performed Intervention(s). \*** |
|                          For contrast agents, please describe the procedure. (e.g. MRI, CT) |
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| ⮊ **Which Bayer drug(s) / device(s) were involved? \***  |
| **Trade Name/** **Generic Name\*** | **Formu-****lation** | **Total****daily dose** | **Dose****regimen** | **Route of applica-tion** | **Lot number\*\*** | **Date****from-to or****duration\*** | **Indication for use** |
| Ciprobay/Ciprofloxacin(E X A M P L E) | **Tablet** | **500 mg** | **2x250 mg** | **oral** | **678 9045** | **12 May 12****17 May 12**  | **urinary tract infection** |
|            |  |  |  |  |  |  |  |
|            |  |  |  |  |  |  |  |
|            |  |  |  |  |  |  |  |
| **Device Availability for Return? Yes [ ]  No [ ]  Device Serial Number       Model Number** **Device Software Version Number** |
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| ⮊ **Who has reported the Adverse Event(s)/Injury \*** |
| **Name** |       |
| **Address**  |             |
| **Phone/Fax/****E-Mail** |            |
| Physician**\*** | [ ]  | Consumer | [ ]  | Other [ ]  Specify:       |
| **Associate with Product Technical Complaint (PTC) Yes [ ]  No [ ]**  |

**🛈 CONTRACT PARTNER STAFF MUST SEND THIS FORM BY E-MAIL OR FAX WITHIN ONE (1) BUSINESS DAY OF INFORMATION RECEIPT TO LOCAL BAYER PHARMACOVIGILANCE DEPARTMENT, UNLESS DIFFERENTIALLY DEFINED IN A PVA (Pharmacovigilance Agreement)**

**🛈 INTERNAL BAYER STAFF MUST SEND THIS FORM BY E-MAIL OR FAX WITHIN 24 HOURS OF INFORMATION RECEIPT TO LOCAL BAYER PHARMACOVIGILANCE (PV) DEPARTMENT**

**🛈 IF A TECHNICAL COMPLAINT INFORMATION IS REPORTED FOR A BAYER PRODUCT, BAYER LOCAL PV OR INTERNAL PERSONNEL SHOULD FORWARD THIS INFORMATION WITHIN ONE BUSINESS DAY OF INFORMATION RECEIPT TO BAYER LOCAL QUALITY REPRESENTATIVE**

**🛈 \*Fields to be filled mandatory; \*\*Lot number mandatory for biological products, for devices and if report is associated with a PTC**