

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** |
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|  | | | | |  | |  |  | |  |  |  | |  |
| **Device Availability for Return? Yes  No  Device Serial Number       Model Number**  **Device Software Version Number** | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | |
| ⮊ **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**