## 上市许可持有人药品不良反应报告表（试行）

**严重报告□ 境外报告□ 首次报告□ 跟踪报告□ 病例编号\***

**报告来源\* 医疗机构□ 经营企业□ 个人□ 文献□ 研究□ 项目□ 其他□ 监管机构□**

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| **患者信息** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **姓名\*** | | | **性别\*** | | | | | | **出生日期\*** | | | | | | **年龄** | | | | **国籍** | | | | | **民族/种族** | | | | | **身高（cm）** | | | | | | | | **体重（kg）** | | | | | **联系电话** | | | |
|  | | |  | | | | | |  | | | | | |  | | | |  | | | | |  | | | | |  | | | | | | | |  | | | | |  | | | |
| **医疗机构/经营企业名称：** | | | | | | | | | | | | | | | | | | | **既往药品不良反应及药物过敏史 有□ 无□** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **病历号/门诊号：** | | | | | | | | | | | | | | | | | | |
| **相关重要信息：**  **吸烟 有□ 无 □ 不详□**  **饮酒 有□ 无 □ 不详□**  **其他过敏史 有□ 无 □ 不详□**  **其他（如肝病史，肾病史, 家族史） 有□ 无 □ 不详□** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **相关疾病信息 （可重复）** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **序号** | | **疾病名称** | | | | | | | | | **开始日期** | | | | | **结束日期** | | | | | | | | | | | | | | **报告当时疾病是否仍存在** | | | | | | | | | | | | | | | |
| **1** | |  | | | | | | | | |  | | | | |  | | | | | | | | | | | | | | **是□ 否□ 不详□** | | | | | | | | | | | | | | | |
| **怀疑用药（可重复）** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **序号** | **批准文号\*** | | | **商品名** | | | | **通用名称\*** | | **剂型\*** | | **规格** | | **上市许可持有人/生产企业\*** | | | **产品批号** | | | **失效日期/有效期至** | | | **用法用量** | | | | | | | | | **用药起止日期\*** | | | | | | **用药时间** | | | **治疗疾病\*** | | **是否存在以下情况(可多选)注1** | **对药品采取的措施注2** | |
| **给药途径** | | | **单次剂量** | **给药频次** | | | | | **起** | | **止** | | | |
| **1** |  | | |  | | | |  | |  | |  | |  | | |  | | |  | | |  | | |  |  | | | | |  | |  | | | |  | | |  | |  |  | |
| **2** |  | | |  | | | |  | |  | |  | |  | | |  | | |  | | |  | | |  |  | | | | |  | |  | | | |  | | |  | |  |  | |
| **注1:1-假药 2-用药过量 3-父源暴露 4-使用了超出有效期的药品 5-检测并合格的批号 6-检测并不合格的批号 7-用药错误 8-误用 9-滥用 10-职业暴露 11-超说明书使用** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **注2:1-停止用药 2-减少剂量 3-增加剂量 4-剂量不变 0-不详 9-不适用** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **合并用药（可重复）** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **序号** | **批准文号** | | | **商品名** | | | | **通用名称\*** | | **剂型\*** | | **规格** | | **上市许可持有人/生产企业** | | | **产品批号** | | | **失效日期/有效期至** | | | **用法用量** | | | | | | | | | **用药起止日期** | | | | | | | **用药时间** | **治疗疾病\*** | | | **是否存在以下情况(可多选)注1** | | **对药品采取的措施注2** |
| **给药途径** | | | **单次剂量** | **给药频次** | | | | | **起** | | | **止** | | | |
| **1** |  | | |  | | | |  | |  | |  | |  | | |  | | |  | | |  | | |  |  | | | | |  | | |  | | | |  |  | | |  | |  |
| **2** |  | | |  | | | |  | |  | |  | |  | | |  | | |  | | |  | | |  |  | | | | |  | | |  | | | |  |  | | |  | |  |
| **注1:1-假药 2-用药过量 3-父源暴露 4-使用了超出有效期的药品 5-检测并合格的批号 6-检测并不合格的批号 7-用药错误 8-误用 9-滥用 10-职业暴露 11-超说明书使用** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **注2:1-停止用药 2-减少剂量 3-增加剂量 4-剂量不变 0-不详 9-不适用** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **相关器械：** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **不良反应（可重复）** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **怀疑药品—不良反应术语\*：**  **发生时间\*： 年 月 日 结束时间： 年 月 日 持续时间： （分/小时/天）**  **严重性\* 非严重□**  **导致死亡□ 危及生命□ 导致住院或住院时间延长□ 导致永久或显著的残疾/功能丧失□ 先天性异常/出生缺陷□ 导致其他重要医学事件，如不进行治疗可能出现上述所列情况□**  **非预期\* 是□ 否□**  **停药或减量后，反应是否消失或减轻\* 是□ 否□ 不详□ 不适用□**  **再次使用可疑药品后是否再次出现同样反应\* 是□ 否□ 不详□ 不适用□**  **结 果\* 治愈□ 好转 □未好转□ 有后遗症□ 死亡 □ 不详 □**  **初始报告人评价\* 肯定 □ 很可能□ 可能□ 可能无关 □ 待评价 □ 无法评价 □**  **上市许可持有人评价\* 肯定 □ 很可能□ 可能□ 可能无关 □ 待评价 □ 无法评价 □** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **不良反应过程描述\*（包括发生场所、症状、体征、临床检验等）及处理情况（可附页）：** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **死亡时间： 年 月 日 直接死因：**  **是否尸检：是□ 否□ 不详□ 尸检结果：** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **相关实验室检查信息 (可重复）** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **序号** | | | | | | | **检查项目** | | | | | | **检查日期** | | | | | | | | **结果 （单位）** | | | | | | | | | | | | **正常值范围 (低值- 高值）** | | | | | | | | | | | | |
| **1** | | | | | | |  | | | | | |  | | | | | | | |  | | | | | | | | | | | |  | | | | | | | | | | | | |
| **妊娠报告有关信息** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **父/母姓名** | | | | | | **性别** | | | | | | | **出生日期** | | | | | **年龄** | | | | | | | **身高（cm）** | | | **体重（kg）** | | | | | | | | **末次月经时间** | | | | | | | | | |
|  | | | | | |  | | | | | | |  | | | | |  | | | | | | |  | | |  | | | | | | | |  | | | | | | | | | |
| **妊娠相关描述项（既往妊娠史，本次妊娠单胎、多胎，妊娠结局，生产方式，胎儿结局等）（可附页）：** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **相关疾病信息 （可重复）** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **序号** | | | | | | | **疾病名称** | | | | | | **开始日期** | | | | | | | | | **结束日期** | | | | | | | | | **报告当时疾病是否仍存在** | | | | | | | | | | | | | | |
| **1** | | | | | | |  | | | | | |  | | | | | | | | |  | | | | | | | | | **是□ 否□ 不详□** | | | | | | | | | | | | | | |
| **既往用药史（可重复）** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **序号** | | | | | | | **药物名称** | | | | | | **开始日期** | | | | | | | | | **结束日期** | | | | | | | | | **治疗疾病** | | | | | | | | | | | | | | |
| **1** | | | | | | |  | | | | | |  | | | | | | | | |  | | | | | | | | |  | | | | | | | | | | | | | | |
| **初始报告人姓名\* 职业\* 医生□ 药师□ 护士□ 其他医务人员□ 消费者□ 其他人员□**  **所在单位： 联系电话： 电子邮箱：** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **事件发生国家/地区\*： 首次获知时间\*： 企业病例编码\*：**  **最近一次获知时间\*（仅适用于跟踪报告）：**  **上市许可持有人名称\*： 联系人\*： 电话\*： 地址\*：** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **备 注** | | | | | **其他需说明的情况：** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |