附表1： **归档编码：**

上市许可持有人药品不良反应/事件报告表（试行）

快速报告□ 严重报告□ 境外报告□ 首次报告□ 跟踪报告□ \*病例编号：

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| 患者信息 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| \*姓名 | | \*性别 | | | | | | \*出生日期：  年 龄： | | | | | | | | | 国籍： | | | | | | 种族： | | | | | 民族： | | | | | 身高（cm） | | | | | | | 体重（kg） | | | | | 联系电话： | | | |
| 医疗机构名称： | | | | | | | | | | | | | | | | | | | | 既往药品不良反应：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□  过敏史 有□ 无 □ 不详□  其他（如肝病史，肾病史, 家族史）□ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 | | | 批号 | | | | | 失效日期 | 用法用量 | | | | | | | | | | | \*用药起止日期 | | | | | | \*给药维持时间 | | \*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 |  | | |  | | | | | |  |  | | | |  | | |  | | |  | | | | |  |  | | | | |  | |  | | | |  | |  | | | |  | |  |  |  |
| 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 | | | 批号 | | | | 失效日期 | 用法用量 | | | | | | | | | | 用药起止日期 | | | | | | \*给药维持时间 | | | \*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 |  | | | |  | | | |  | | |  | | | |  | | |  | | |  | | | |  |  | | | |  | |  | | | |  | | | |  | |  | | |  |  |  |
| 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 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1 | \*怀疑药品—不良反应术语： （可重复）  \*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的□  \*是否非预期: 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□  \*关联性评价：  \*初始报告人评价 肯定□ 很可能□ 可能□ 可能无关□ 无法评价□  \*上市许可持有人评价 肯定□ 很可能□ 可能□ 可能无关□ 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： | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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） | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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：  \*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  \*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 | | | 其他需要说明的情况： | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |