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首页 | 编委会 | 期刊简介 | 下载专区 | 稿约 | 杂志栏目 | 当期目录 | 过刊浏览 | 专委会动态 | 药物警戒 | 学科知识 | 合理用药常识

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29例肾康注射液不良反应/事件分析

## Analysis of 29 Cases of Adverse Drug Reactions /Events of Shenkang Injection

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中文关键词: 肾康注射液 药品不良反应 药品不良事件

英文关键词:Shenkang injection Adverse drug reactions Adverse drug event

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中文摘要:

摘 要 目的:分析29例肾康注射液所致不良反应(ADR)或不良事件(ADE)发生情况及其相关因素,为临床合理用药提供参考。方法: 索1994年1月~2012年4月中国医药期刊全文数据库、中文科技期刊全文数据库及中国生物医学文献数据库关于肾康注射液的临床研究。 DR/ADE报告,提取纳入文献中ADR/ADE病例原患疾病、性别、年龄及无过敏史情况,肾康注射液用药剂量、溶媒、ADR/ADE出现时| 类型、处理及转归等进行分析。结果:检索到162篇文献,其中12篇描述了ADR,本院1例,共有29例肾康注射液ADR/ADE病例;ADF DE主要集中于血管刺激症状、全身反应(发热、过敏性休克),无死亡病例;79.31% ADR/ADE病例未按说明书选用溶媒;首次用药者 R/ADE病例占总ADR/ADE的 68.97%。结论: 肾康注射液ADR/ADE的发生是由多因素导致, 临床使用须以说明书为参照, 辨证使用, 格掌握用药剂量禁忌,慎重选用溶媒,临床医生和药师同时应加强其应用的监测,以减少不良反应的发生。

## 英文摘要:

ABSTRACT Objective: To analyze the adverse drug reactions (ADR) or adverse drug events (ADE) and the related factors of shenkan injection to provide reference for clinical medication. Methods: All the clinical studies and adverse reaction reports of shenkang injection from January 1994 to April 2012 in the CNKI, VIP and CBM database were retrieved for analysis. The information of the ADR/ADE cases such as original diseases, dosage and menstruum of the shenkang injection, patients age and gender, the occurring time and type of ADR/ADE were extracted and analyzed. Results:29 ADR/ADE cases of the 162 clinical studies were reported in 12 articles and 1 ADR/ADE case, reported in our hospital. Those ADR/ADE were mainly centered on vascular irritation and systemic reactions (fever. anaphylactic shock), but no death case was found.79.31% ADR/ADE cases used shenkang injection with other menstruum. the total ADR/ADE cases occurred in the first time medication. **Conclusion:** Shenkang injection ADR/ADE resulted from many factors. The clinical application of shenkang injection should follow its instruction file, guidance of TCM theory, warning of contraindications and careful selection of menstruum to make effort to process monitoring and follow-up. Clinicians and pharmacists should strictly monitor on its application to reduce the incidences of ADR/ADE.