



## 苦碟子注射液(碟脉灵)安全性文献分析报告

投稿时间: 2012-07-15 责任编辑: [点此下载全文](#)

引用本文: 廖星,申浩,谢雁鸣,张雯,杨薇,吕志国.苦碟子注射液(碟脉灵)安全性文献分析报告[J].中国中药杂志,2012,37(18):2786.

DOI: 10.4268/cjmm20121828

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基金项目:国家“重大新药创制”科技重大专项(2009ZX09502-030)“中药上市后评价关键技术研究”;中国科学院第6批自主选题项目(Z0215)

中文摘要:目的:通过对苦碟子注射液安全性文献的整理和分析,获得有关其上市后临床安全性方面的信息,为临床医生、研究者提供相关决策帮助。方法:该文通过检索相关文献库,获得有关苦碟子注射液安全性报道的文献96篇,并获取全文。筛选出关于苦碟子注射液发生不良反应的22篇报告,24个案例。通过对24个案例做5个方面的分析:严重不良反应5例;苦碟子注射液的不不良反应在24篇文献报道中的具体表现;不良事件发生时间;关于发生不良反应后的处理;联合用药情况。结果:分析发现文献中的不良反应报告均欠规范;对于其真正的因果关系判断的过程不明确,且临床实际应对处理也存在不合理现象;对于联合用药的分析均未涉及。结论:虽然22篇报告均是来自于临床实践的真实报告,但是由于不良事件/反应发生过程存在多种影响因素,且报告者对于因果关系的判断以及报告的不规范,在很大程度上影响了苦碟子注射液在临床使用过程中发生不良反应发生的真实程度。

中文关键词:苦碟子注射液 安全性评价 文献分析 不良反应

### Literature review report on safety evaluation about Kudiezi injection

**Abstract:Objective:** To explore safety evaluation information about Kudiezi injection used in the clinical practice. **Method:** Three Chinese literature databases were searched and 96 articles were downloaded.Safety information about the study question was extracted by researchers in the Excel form.Finally, 22 articles including 24 case reports were analyzed in this article.Five aspects about safety information were summarized. **Result:** It was found that all the adverse drug reaction reports in the literature were improper. There was no clear causality relation inference.It was inaccurate that those reports were identified as adverse drug reactions. **Conclusion:** Although 24 case reports were identified as adverse drug reaction the evidence for each report was insufficient.There is no scientific causality judgment among these reports,which were implied little significance to future health decision about Kudiezi injection.

**keywords:**Kudiezi safety report literature review adverse drug reaction

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