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139例炎琥宁注射剂不良反应/事件报告分析

Analysis of 139 ADR/ADE Cases Induced by Yanhuning Injection

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中文摘要:

摘要目的:探讨炎琥宁注射剂致不良反应/事件(ADR/ADE)发生的一般规律及特点,为临床合理使用炎琥宁注射剂提供参考。方 法:对2008~2009年深圳市各单位上报的139例与炎琥宁注射剂有关的ADR/ADE报告进行分类统计、分析。结果: 139例ADR/ADE涉及 到6个厂家生产的产品,ADR/ADE在0~9岁人群构成比为 57.14% 且呈现性别差异; ADR/ADE可累及人体多个器官系统,主要累及皮 肤及附件,其次为神经系统、循环系统等,严重者可出现过敏性休克。ADR/ADE多发生在30 min以内,绝大多数ADR/ADE经治疗后转归 良好。低龄人群,特别是0~9岁婴幼儿、儿童给药剂量、浓度严重偏高。结论:炎琥宁注射剂可致过敏性休克等严重ADR/ADE发生,应提 高合理用药水平,加强炎琥宁注射剂用药监护,以减少ADR/ADE发生,保障患者用药安全。

英文摘要:

ABSTRACT Objective: To investigate the essential characteristics and regularity of adverse drug reactions/events (ADR/ADE) induced by vanhuning injection to provide references for its rational clinic use. Method: A statistical analysis of 139 cases of its ADR/ADE reports was conducted from all healthcare settings from 2008 to 2009. Result: Yanhuning injection from six manufactories was involved in 139 ADR/ADE reports.57.4% of ADR/ADE occurred in the 0-9 age's population with some extent gender discrepancy. The single ADR/ADE could lead to more than one organ/system lesion and their clinical manifestations were various. The lesions of ADR/ADE were primarily involved in skin and its accessories, followed by the nerve system, circulation system, etc. The allergic shock was observed in some severe ADR/ADE reports. The onset time of most ADRs/ADEs was within 30 min after intravenous administration and most ADR/ADE had good prognosis after withdrawal of medication and anti allergy treatment. The dosage and concentration of vanhuning administrated to the 0-9 age's population were abnormally high Conclusion: Yanhuning injection could lead to some deadly ADRs/ADEs, such as allergic shock. The rational use and monitoring of yanhuning injection should be improved and strengthened so as to decrease the occurrence of ADR/ADE cases and ensure the patient's safety.

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