

止咳橘红颗粒临床应用有效性和安全性的综合评估分析

A Comprehensive Evaluation of the Clinical Efficacy and Safety of Zhike Juhong Granules

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[摘要] **目的:** 系统评估止咳橘红颗粒在临床应用中的有效性和安全性, 为临床合理用药提供科学依据。**方法:** 通过系统检索国内外文献及国家药品不良反应监测数据, 从组方理论、现代药理学、毒理学研究、临床试验结果及上市后安全性监测多个层面, 对止咳橘红颗粒的临床有效性与安全性进行综合评估分析。**结果:** 在有效性方面, 多项临床研究表明, 其对于急性支气管炎、慢性阻塞性肺病急性加重等多种呼吸系统疾病疗效显著 (总有效率 $\geq 95\%$), 起效迅速 (止咳中位起效时间 2 天), 可显著缩短咳嗽时间 ($\geq 35\%$)。在安全性方面, 临床试验与上市后监测显示, 儿童、老年人等特殊人群中应用的安全性和耐受性良好, 其不良反应发生率低, 主要为轻度、一过性的胃肠道不适或皮疹, 停药即可缓解, 未报告严重不良事件及明确的肝肾功能损害证据。体外研究提示其对 CYP3A4 有轻度抑制, 但临床相关性未明。**结论:** 止咳橘红颗粒有效性确切, 安全性良好, 是治疗痰热阻肺所致咳嗽、咳痰等呼吸系统疾病的可靠选择。

[关键词] 止咳橘红颗粒; 组方分析; 有效性; 安全性; 不良反应; 肝肾功能; 药物相互作用; 合理用药

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[Abstract] **Objective:** To systematically evaluate the efficacy and safety of *Zhike Juhong Granules* in clinical application, provide a scientific basis for rational clinical drug use, and promote the standardized development of integrated traditional Chinese and Western medicine in the treatment of respiratory diseases. **Methods:** Based on a systematic review of domestic and international literature and data from the national adverse drug reaction (ADR) monitoring system, a comprehensive evaluation of the clinical efficacy and safety of *Zhike Juhong Granules* was conducted. The analysis integrated multiple dimensions, including traditional prescription theory, modern pharmacological and toxicological evidence, results from clinical trials, and post-marketing safety surveillance, to provide an evidence-based assessment relevant to clinical practice. **Results:** In terms of efficacy, multiple clinical studies have demonstrated significant therapeutic effects in various respiratory diseases, including acute bronchitis and acute exacerbations of chronic obstructive pulmonary disease (AECOPD), with a total effective rate exceeding 95%. The onset of action is rapid, with a median time to cough relief of 2 days, and treatment significantly shortens the duration of cough and sputum production by $\geq 35\%$. Regarding safety, evidence from clinical trials and post-marketing surveillance indicates good safety and tolerability in special populations such as children and the elderly. The incidence of adverse reactions is low, mainly consisting of mild and transient gastrointestinal discomfort or skin rash, which resolve upon drug discontinuation. No serious adverse events or definitive evidence of hepatotoxicity or nephrotoxicity have been reported. In vitro studies suggest a mild inhibitory effect on CYP3A4; however, its clinical relevance remains unclear. **Conclusion:** *Zhike Juhong Granules* demonstrate definite clinical efficacy and a favorable safety profile, making them a reliable therapeutic option for cough and sputum due to phlegm-heat obstructing the lung and other related respiratory disorders.

[Key words] *Zhike Juhong Granules*; Formula Analysis; Efficacy; Safety; Adverse Reactions; Hepatic and Renal Function; Drug Interactions; Rational Use of Drugs