

承認から臨床への安全な導入—現場での対応—**

—イリノテカンの安全対策—

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Safety Measures for Irinotecan Hydrochloride in Japan

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Summary

Safety measures to reduce the risk of treatment-related deaths and severe adverse effects of irinotecan have been in place for 15 years in cooperation with the regulatory authority (Ministry of Health and Welfare) and medical institutions. We have developed and used a sales & marketing management system that focuses on safety measures, the collection of case information and communication, guidelines for appropriate use in eligible patients, and tools. We conducted a surveillance of all patients during a re-examination period of 6 years, and performed numerical and qualitative analyses of all deaths and severe adverse effects, as needed. The information from the surveillance is reflected in the label and also incorporated into the safety information for medical professionals and paramedicals. Such measures have had an impact in minimizing the risk of deaths and severe adverse effects.

Furthermore, as part of the safety measures, we cooperated in the UGT1A1 pharmacogenomics research in Japan and in the development of a diagnostic kit using the Invader® method to realize personalized medicine in relation to irinotecan chemotherapy.

Key words

Irinotecan, Safety measure, Risk management, Post marketing surveillance