



Summary of investigation results

Carboplatin

Aug 6, 2014

Non-proprietary Name

Carboplatin

Brand Name (Marketing Authorization Holder)

PARAPLATIN injection 50 mg, 150 mg, 450 mg, (Bristol-Myers K.K.) and the others

Indications

- Head and neck cancer, small cell lung cancer, testicular tumour, ovarian cancer, cervical cancer, malignant lymphoma, non-small cell lung cancer, and breast cancer
- Combination therapy with other antineoplastics for the following malignant tumours:
Pediatric malignant solid tumour (neuroblastoma, retinoblastoma, hepatoblastoma, central nervous system germ cell tumour, relapsed or refractory Ewing's sarcoma family of tumour, and nephroblastoma)

Summary of revision

'Tumour lysis syndrome' should be added in Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of tumour lysis syndrome have been reported in patients treated with carboplatin in Japan and foreign countries. Following an investigation result based on opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reaction and fatal cases in the last 3 fiscal years in Japan

A tumour lysis syndrome case has been reported. No causal relationship with carboplatin was established in the case. No fatality has been reported.