

Summary of Investigation Results

Carboplatin

Non-proprietary name Brand name	Non-proprietary name	Brand name (marketing authorization holder)
	Carboplatin	Paraplatin injection 50 mg, 150 mg, 450 mg (CHEPLAPHARM K.K.) and others
Japanese market launch	May 1990	
Indications	○ Head and neck cancer, small cell lung cancer, testicular tumor, ovarian cancer, cervical cancer, malignant lymphoma, non-small cell lung cancer, breast cancer, endometrial cancer ○ Combination therapy with other antineoplastic agents for the following malignant tumors: Pediatric malignant solid tumor (neuroblastoma, retinoblastoma, hepatoblastoma, central nervous system germ cell tumor, relapsed or refractory Ewing's sarcoma family of tumor, and nephroblastoma)	
Summary of revisions	“Syndrome of inappropriate antidiuretic hormone secretion (SIADH)” should be added to the 11.1 Clinically Significant Adverse Reactions section in the 11. ADVERSE REACTIONS.	
Investigation results and background of the revision	Cases involving syndrome of inappropriate antidiuretic hormone secretion (SIADH) were evaluated. Cases in which a causal relationship between carboplatin and syndrome of inappropriate antidiuretic hormone secretion (SIADH) was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.	
Reference: Number of cases ^{*1} involving syndrome of inappropriate antidiuretic hormone secretion (SIADH) ^{*2} reported in Japan	A total of 9 cases have been reported to date (including 5 cases in which a causal relationship between the drug and the event was reasonably possible). No deaths have been reported to date.	

*1: Cases collected in PMDA's safety database for drugs.

*2: Among severe cases corresponding to MedDRA ver. 28.1 PT, "Inappropriate antidiuretic hormone secretion," cases in which information on blood sodium concentration, plasma osmolality, and plasma vasopressin levels is available were retrieved.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the "Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency" (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.