

Fact-Finding Survey and Exploration of Preventive Drugs for Antineoplastic Drug-Induced Oral Mucositis Using the Japanese Adverse Drug Event Report Database

	Adverse event of interest	All other adverse events	Total
Drug of interest	a	b	a+b
All other drugs of interest	c	d	c+d
Total	a+c	b+d	a+b+c+d
Reporting odds ratio (ROR) = (a/c) / (b/d) = ad/bc			
95% Confidence interval (CI) = $\exp \left[\ln(\text{ROR}) \pm 1.96 \sqrt{\left(\frac{1}{a}\right) + \left(\frac{1}{b}\right) + \left(\frac{1}{c}\right) + \left(\frac{1}{d}\right)} \right]$			

Supplementary Figure S1. Two-by-two contingency table for calculating the reporting odds ratio and 95% confidence interval of oral mucositis

Supplementary Table S1. Definition of oral mucositis

PT code	PT name
10002959	Aphthous ulcer
10018386	Glossitis
10024572	Lip ulceration
10028034	Mouth ulceration
10030094	Odynophagia
10030995	Oral mucosal blistering
10031009	Oral pain
10034834	Pharyngeal ulceration
10042128	Stomatitis
10042132	Stomatitis hemorrhagic
10042135	Stomatitis necrotizing
10043942	Tongue blistering
10043991	Tongue Ulceration
10051992	Lip erosion
10062773	Pharyngeal erosion
10064594	Oral mucosa erosion
10065716	Pharyngeal inflammation
10067950	Oropharyngeal blistering
10068319	Oropharyngeal pain
10077519	Palatal ulcer

Oral mucositis was defined as a condition associated with several Medical Dictionary for Regulatory Activities (MedDRA/J, ver. 25.1) preferred terms. PT, Preferred terms.

Supplementary Table S2. Characteristics of antineoplastic drugs-treated case population

	Total (N = 210,822)		With oral mucositis (N = 2,922)	
	Number of cases	%	Number of cases	%
Sex				
Female	84,870	40.3	1,375	47.1
Male	115,164	54.6	1,457	49.9
Unknown	10,788	5.1	90	3.1
Age (years)				
<10	2,847	1.4	57	2.0
10–19	3,023	1.4	63	2.2
20–29	2,384	1.1	27	0.9
30–39	5,053	2.4	66	2.3
40–49	12,430	5.9	190	6.5
50–59	28,480	13.5	411	14.1
60–69	58,946	28.0	850	29.1
70–79	61,312	29.1	843	28.9
80–89	16,162	7.7	185	6.3
90–99	595	0.3	9	0.3
100≤	12	0.0	0	0.0
Other / Unknown	19,578	9.3	221	7.6
Drug classification (ATC code)				
Alkylating agents (L01A)	19,748	9.4	313	10.7
Antimetabolites (L01B)	60,677	28.8	1,496	51.2
Plant alkaloids and other natural products (L01C)	47,529	22.5	581	19.9
Cytotoxic antibiotics and related substances (L01D)	17,549	8.3	269	9.2
Protein kinase inhibitors (L01E)	54,546	25.9	782	26.8
Monoclonal antibodies and antibody-drug conjugates (L01F)	76,503	36.3	687	23.5
Other antineoplastic agents (L01X)	59,322	28.1	716	24.5