

<b>Study No:</b> 112293 (ESAA)	
<b>Title:</b> Drug Use Investigation for Albenza/Escazole (albendazole).	
<b>Rationale:</b> This post-marketing surveillance (PMS) collected safety and efficacy data of albendazole administered in the Japanese target population per the requirements of the Japanese Pharmaceuticals and Medical Devices Agency (PMDA).	
<b>Phase:</b> Post-Marketing Surveillance (PMS).	
<b>Period:</b> 15 April 1994 ~ 18 January 2004	
<b>Design:</b> Open label, multi-centre, post-marketing surveillance.	
<b>Centres:</b> 93 centres in Japan	
<b>Indication:</b> Echinococcosis	
<b>Treatment:</b> All patients received albendazole according to the prescribing information in the locally approved label by PMDA.	
<b>Objectives:</b> The study was designed to detect adverse drug reactions (particularly clinically significant adverse drug reactions) occurring in clinical settings, to examine factors likely to affect the safety and efficacy of albendazole, and to discuss the need of special investigation and postmarketing clinical study.	
<b>Safety Outcome/Variable(s):</b> Safety outcomes were incidence of adverse events in Japanese echinococcosis patients treated with albendazole based on prescribing information under the conditions of general clinical practice.	
<b>Efficacy Outcome/Variable(s):</b> Efficacy was assessed on a four-point scale (Significantly effective, Effective, Not effective, Not able to judge) on the basis of the patients' overall condition following the initiation of albendazole therapy. The subjects treated for other than the approved indication, were excluded from the efficacy analysis.	
<b>Statistical Method:</b> Since this surveillance was not designed to test any statistical hypothesis, basic descriptive statistics were presented.	
<b>Study population:</b> Male and female subjects who were considered appropriate to prescribe sumatriptan according to the prescribing information were eligible for this surveillance study.	
<b>Number of Subjects:</b>	<b>albendazole</b>
Planned, N	All patients for whom Eskazole was prescribed
Entered, N	149
Completed, n (%)	147 (98.7%)
<b>Demographics</b>	
N (ITT safety population)	147
Female (%): Male (%)	49.7: 50.3
Age, years, n (%)	
<15 (children)	8 (5.4%)
≥15 ~ <65 (adults)	90 (61.2%)
≥65 (elderly)	49 (33.3%)
Japanese, n (%)	147 (100.0%)
Diagnosis, n (%)	
Alveolar/unilocular hydatid disease	87 (59.2%)
Others	60 (40.8%)
Concomitant disease, n (%)	
Yes	50 (34.0%)
No	95 (64.6%)
Unknown	2 (1.4%)
Concomitant medication, n (%)	
Yes	88 (59.9%)
No	58 (39.5%)
Unknown	1 (0.7%)

<b>Safety Results: (ITT Safety population)</b>		
Overall incidence of adverse drug reaction, n (%)	53 events, 38 patients (25.85%)	
Unexpected adverse events, n (%)	9 events (6.12%)	
Serious adverse events, n (%)	13 events, 10 patients (6.80%)	
<b>Safety Outcome Variable(s):</b>		
Summary of risk factors by incidence of adverse events	<b>Adverse events, n(%)</b>	
<b>Covariates</b>	Yes (N=38)	No (N=109)
Gender, n (%)		
Male	18 (24.32%)	56 (75.68%)
Female	20 (27.40%)	53 (72.60%)
Diagnosis, n (%)		
Alveolar/unilocular hydatid disease	29 (33.33%)	58 (66.67%)
Others	9 (15.00%)	51 (85.00%)
<b>Most Frequent Adverse Events – On-Therapy, n(%)</b>	<b>sumatriptan (n=147)</b>	
Subjects with any AE(s), n (%)		
Hepatic function abnormal	22 (14.97%)	
Alanine aminotransferase increased	3 (2.04%)	
Aspartate aminotransferase increased	3 (2.04%)	
Nausea	3 (2.04%)	
<b>Serious Adverse Events –On -Therapy n(%, [n considered by the investigator to be related to study medication])</b>	<b>sumatriptan (n=147)</b>	
	13 events, 10 patients (6.80%) [8 events, 6 patients]	
<b>Subjects with fatal SAE(s)</b>	0 (0.0%)	
<p><b>Safety:</b> Of the 147 patients included in the Safety Analysis Set, 38 patients had 53 adverse events whose causal relationship to albendazole was not ruled out by the reporting physician. The most common ADRs were "Hepatic function abnormal" (22 events) and "Alanine aminotransferase increased", "Aspartate aminotransferase increased" and "Nausea" (each 3 events). Eight (8) ADRs (hepatic function abnormal [3 events], liver function test abnormal, acute respiratory failure, Interstitial lung disease, epatelet count decreased, and white blood cell count decrease [each 1 event]) reported in 5 patients were assessed as serious by the reporting physician. Nine (9) ADRs unexpected from the precautions for use of albendazole were reported. These ADRs consisted of "pruritus" (2 events), and "gastritis", "anorexia", "decreased appetite", "insomnia", "acute respiratory failure" and "interstitial lung disease" (each 1 event).</p>		

<b>Efficacy Results:</b>		
	Effective	Not Effective
<b>Overall Efficacy Results, n (%)</b>	40 (63.49%)	9 (14.29%)
Alveolar/unilocular hydatid disease, n (%)	40 (63.49%)	9 (14.29%)
<b>Efficacy Outcome Variable (s)</b>		
Gender, n (%)		
Male	19 (63.33%)	4 (13.33%)
Female	21 (63.64%)	5 (15.15%)
Concomitant medications, n (%)		
Yes	26 (63.41%)	5 (12.20%)
No	14 (63.64%)	4 (18.18%)
<p><b>Efficacy:</b> Of the 63 patients included in the Efficacy Analysis Set, 40 patients were assessed as "Effective", 9 patients as "Not effective" and 14 patients as "Not able to judge", resulting in the efficacy rate (percentage of "Effective") of 63.49% (40/63 patients). The efficacy results assured</p>		

the approved(70.00%[14/20patients]) label.

**Conclusion:** Adverse events were reported in 38 subjects, the most frequent being hepatic function abnormal. The overall incidence of adverse events was 25.85%. There were eight serious adverse events to be related to albendazole (hepatic function abnormal [3 events], liver function test abnormal , acute respiratory failure, Interstitial lung disease, epatelet count decreased, and white blood cell count decreased [each 1 event]), and nine unexpected adverse events were reported. The efficacy results assured the approved label.

**Publication:** No publication