

Listing of All Adverse Events

Actual Treatment Arm			
Subject ID ^a	AE MedDRA Preferred Term	Serious	Most Extreme Toxicity Grade
Treatment: DDI 900 mg BID + 10 mg MDZ			
12	Drug-induced liver injury	Y	4
18	Haematoma	N	1
	Fatigue	N	2
	Abdominal distension	N	1
	Eyelid haematoma	N	1
	Constipation	N	1
	Drug-induced liver injury	Y	4
	Headache	N	1
2	Headache	N	1
	Rash	N	1
	Nausea	N	1
	Headache	N	1
20	Myalgia	N	1
26	Rash	N	1
	Rash	N	1
27	Sensory disturbance	N	1
	Dizziness	N	1
	Sensory disturbance	N	1
	Disturbance in attention	N	1
	Fatigue	N	1
	Headache	N	1
	Head discomfort	N	1
	Paraesthesia	N	1
	Dizziness	N	1
	Confusional state	N	1
	Sensory disturbance	N	1
29	Limb discomfort	N	1
	Hangover	N	1
30	Contusion	N	1
	Dry mouth	N	1
	Malaise	N	1
	Abdominal discomfort	N	1
	Fatigue	N	1
	Oropharyngeal discomfort	N	1
37	Alanine aminotransferase increased	N	2
	Contusion	N	1
Treatment: FES 600 mg			
14	Skin laceration	N	1
6	Insomnia	N	1
7	Folliculitis	N	1
Treatment: FES PLB			
10	Erythema	N	1
41	Phlebitis	N	1
	Rhinitis	N	1
Treatment: MAD C1 300 mg BID			

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Treatment: MAD C1 300 mg BID			
25	Epistaxis	N	1
34	Change of bowel habit	N	1
	Upper respiratory tract infection	N	1
39	Chest pain	N	1
	Upper respiratory tract infection	N	1
9	Ear infection	N	2
	Headache	N	1
	Headache	N	1
	Upper respiratory tract infection	N	1
Treatment: MAD C1 PLB			
32	Abdominal distension	N	1
	Nasal congestion	N	1
	Liver function test increased	N	3
	Tonsillitis	N	1
Treatment: MAD C2 900 mg BID			
1	Dizziness	N	1
11	Dizziness	N	1
	Fatigue	N	1
	Fatigue	N	1
33	Abdominal pain	N	1
	Headache	N	1
	Headache	N	1
8	Lethargy	N	1
	Rash	N	1
Treatment: MAD C2 PLB			
36	Abdominal distension	N	1
	Catheter site phlebitis	N	1
Treatment: SAD C1 150 mg			
21	Oropharyngeal pain	N	1
	Constipation	N	1
23	Nausea	N	1
24	Medical device site erythema	N	1
31	Constipation	N	1
Treatment: SAD C1 PLB			
17	Erythema	N	1
28	Abdominal pain	N	1
	Nausea	N	1

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Treatment: SAD C1 PLB	Headache	N	1
Treatment: SAD C2 450 mg	Nausea	N	1
38	Upper respiratory tract infection	N	1
4	Phlebitis	N	1
40	Vomiting	N	1
	Cyclic vomiting syndrome	N	2
Treatment: SAD C2 PLB	Abdominal pain	N	1
35			
Treatment: SAD C3 900 mg	Medical device site erythema	N	1
15	Catheter site pruritus	N	1
	Upper respiratory tract infection	N	1
16	Oropharyngeal pain	N	1
19	Phlebitis	N	1
	Nausea	N	1
	Dizziness	N	1
3	Abdominal pain	N	1
Treatment: SAD C4 1800 mg	Contusion	N	1
13	Nausea	N	1
22	Dizziness	N	1
5	Muscle spasms	N	1

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