MedDRA SOC / Preferred Term	**ADRs / Patients**	**Severity** mild / moderate / severe	**Seriousness** non-serious / serious	**Incidence**[1] (95% CI)	**Incidence rate**[2] (95% CI)	**DFP discontinuation**[3] (95% CI)
Blood and lymphatic system disorders						
Agranulocytosis	2/2	0/2/0	0/2	0.7 (0.1-2.4)	0.3 (0.0-1.0)	0.7 (0.1-2.4)
Leukopenia	3/2	3/0/0	3/0	0.7 (0.1-2.4)	0.4 (0.1-1.2)	0.3 (0.0-1.9)
Neutropenia	38/25	26/12/0	0/38	8.4 (5.5-12.2)	5.3 (3.7-7.3)	5.1 (2.9-8.2)
Thrombocytopenia	1/1	1/0/0	0/1	0.3 (0.0-1.9)	0.1 (0.0-0.8)	0.3 (0.0-1.9)
Gastrointestinal disorders						
Abdominal pain	9/8	6/3/0	9/0	2.7 (1.2-5.2)	1.3 (0.6-2.4)	1.0 (0.2-2.9)
Diarrhoea	1/1	1/0/0	1/0	0.3 (0.0-1.9)	0.1 (0.0-0.8)	none
Dyspepsia	4/4	4/0/0	4/0	1.3 (0.4-3.4)	0.6 (0.2-1.4)	0.3 (0.0-1.9)
Nausea	3/3	1/2/0	3/0	1.0 (0.2-2.9)	0.4 (0.1-1.2)	0.3 (0.0-1.9)
Salivary hypersecretion	1/1	1/0/0	1/0	0.3 (0.0-1.9)	0.1 (0.0-0.8)	none
Vomiting	14/10	3/11/0	14/0	3.4 (1.6-6.1)	2.0 (1.1-3.3)	2.7 (1.2-5.2)
General disorders and administration site conditions						
Fatigue	1/1	0/1/0	1/0	0.3 (0.0-1.9)	0.1 (0.0-0.8)	0.3 (0.0-1.9)
Investigations						
Transaminases increased	42/31	35/7/0	17/25	10.4 (7.2-14.5)	5.9 (4.2-7.9)	6.4 (3.9-9.8)
Weight increased	1/1	1/0/0	1/0	0.3 (0.0-1.9)	0.1 (0.0-0.8)	none
Musculoskeletal and connective tissue disorders						
Arthropathy	43/35	10/30/3	41/2	11.8 (8.3-16.0)	6.0 (4.3-8.1)	8.4 (5.5-12.2)
Bone pain	5/5	2/3/0	5/0	1.7 (0.5-3.9)	0.7 (0.2-1.6)	1.3 (0.4-3.4)
Renal and urinary disorders						
Chromaturia	1/1	1/0/0	1/0	0.3 (0.0-1.9)	0.1 (0.0-0.8)	none
Skin and subcutaneous tissue disorders						
Rash	2/1	2/0/0	2/0	0.3 (0.0-1.9)	0.3 (0.0-1.0)	none
Urticaria	1/1	0/1/0	1/0	0.3 (0.0-1.9)	0.1 (0.0-0.8)	none
TOTAL						
Any ADR	172/104	97/72/3	104/68	35.0 (29.6-40.7)	24.0 (20.5-27.8)	23.2 (18.6-28.5)

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Any serious ADR	68/44	48/19/1	0/68	14.8 (11.0-19.4)	9.5 (7.4-12.0)	9.1 (6.1-13.0)

[1] Number of patients with at least one ADR from the corresponding group divided by all exposed patients in percent (95% CI); [2] Number of ADR episodes divided by total observation time per 100 PY (95% CI); [3] Number of patients permanently discontinuing DFP due to the ADR divided by all exposed patients in percent (95% CI). PY: person-years; CI: confidence interval

Table 6. DEEP-3 identified adverse drug reactions to deferiprone