

Generic and originator immunosuppressants - comparative list prices and bioequivalence data

	NHS List price (MIMS)	Bioequivalence assessment vs. originator				Mean ratios of test product to originator and 90% CIs - from public domain data	
	Date: October 2013		Study design	Fasting/ fed state?	Subjects in final assessment: n=	Cmax	AUC
Ciclosporin							
Neoral (Novartis)	10mg capsule, 60=£19.40 25mg capsule, 30=£19.52 50mg capsule, 30=£38.23 100mg capsule, 30=£72.57 100mg/ml oral soln, 50ml=£108.73.	n/a					
Capimune (Mylan)	25mg cap, 30=£13.50 50mg, 30=£26.80 100mg, 30=£51.30.	PL 04569/0939-41	Randomised, two-way crossover study of 2 x 100mg Capimune versus 2 x 100mg Neoral	Fasting	34	99 (94-104%)	99 (96-103%)
		PL 04569/0939-41	Randomised, two-way crossover study of 2 x 100mg Capimune versus 2 x 100mg Neoral	Fed	31	104 (88-123%)	97 (88-108%)

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Capsorin (Morningside/ TEVA)	25mg cap, 30=£13.11, 50 mg cap, 30=£25.65 , 100mg cap, 30=£48.93	PL 20117/0036-8	Randomised, two-way, crossover study of 2 x 100mg Capsorin versus 2 x 100mg Neoral	Fasting	? Not stated	99 (94-104%)	99 (96-103%)
		PL 20117/0036-8	Randomised, two-way, crossover study of 2 x 100mg Capsorin versus 2 x 100mg Neoral	Fed	? Not stated	104 (88-123%)	97 (88-108%)
Deximune (Dexcel)	25mg cap, 30=£13.50 50mg, 30=£26.80 100mg, 30=£51.30.	PL 14017/0144-6	Randomised, two-way crossover study of 2 x 100mg Deximune versus 2 x 100mg Neoral	Fasting	24	99 (90-109%)	101 (93-109%)
		PL 14017/0144-6	Randomised, two-way crossover study of 2 x 100mg Deximune versus 2 x 100mg Neoral	Fed - standard high-fat high- calorie breakfast	39	113 (105-122%)	106 (103-110%)
Vanquoral (Teva)	25mg cap, 30, 50mg cap, 30, 100mg cap,30	PL 00289/1404-07	Randomised, single-dose crossover study of 100mg Vanquoral versus 100mg Sandimmun (German Neoral)	Fasting	62	104 (100-108%)	102 (99-104%)
		PL 00289/1404-07	Randomised, single-dose crossover study of 100mg Vanquoral versus 100mg Sandimmun (German Neoral)	Fed - high fat high calorie breakfast	?	102 (97-108%)	102 (100-105%)

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Tacrolimus							
Prograf (Astellas)	0.5mg cap, 50=£61.88 1mg, 50=£80.28; 100=£160.54 5mg, 50=£296.58	n/a					
Advagraf (SR, Astellas)	0.5mg cap, 50=£35.79 1mg, 50=£71.59; 100=£143.17 3mg, 50=£214.76 5mg, 50=£266.92.	n/a					
Modigraf (Granules, Astellas)	0.2 mg sachet, 50=£71.30 1mg, 50=£356.65.	n/a					
Adoport (Sandoz)	0.5mg cap, 50=£50.50 1mg, 50=£65.52; 100=£131.02 5mg, 50=£242.05.	PL 04416/0939-41	Open label, single dose, two-way crossover PK assessment of Adoport versus Prograf	Fasting	42 (5mg) 207 (0.5mg)	5mg - 100 (92-111%). 0.5mg - 103 (94-111%)	5mg - 104 (99-110%). 0.5mg - 110 (101-119%)
Capexion (Mylan)	0.5mg cap, 50=£52.50 1mg, 50=£68.20; 100=£136.20 5mg, 50=£252.00.	PL 23022/0078-80	Randomised, two treatment, two-period, single dose crossover PK assessment of 5mg Capexion versus 5mg Prograf	Fasting	141	116 (106-118%)	99 (93-105%)

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Tacni (TEVA)	0.5mg cap, 50=£50.48 1mg, 50=£65.49; 100=£130.99 5mg, 50=£242.01.	PL 00289/1620-2	Randomised, two treatment, two period, single dose crossover PK assessment of 5mg Tacni versus 5mg Prograf	Fasting	141	116 (106-118%)	99 (93-105%)
Vivadex (Dexcel)	0.5mg cap, 50=£46.41 1mg, 50=£60.21; 100=£122.41 5mg, 50=£222.44.	PL 14017/0225-7	Randomised, two treatment, two-period, single dose crossover PK assessment of 5mg Vivadex versus 5mg Prograf	Fasting	141	116 (106-118%)	99 (93-105%)

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Mycophenolate mofetil							
CellCept (Roche)	250mg cap, 100=£82.26 500mg cap-shaped tab, 50=£82.26 1g per 5ml powder for oral susp, 175ml=£115.16	n/a					
Arzip (Winthrop/Zentiva)	Not listed	PL 17780/0301	Open label, randomised, two-treatment, two period, two sequence crossover PK assessment of 500mg Arzip versus CellCept	Fasting	45	107 (96-118%)	99 (96-102%)
Myfenax (TEVA)	Not listed	EU/1/07/438/003_5 EU/1/07/438/001_2 EU/1/07/438/006	Open label, single dose, two period, two sequence studies. Assessment of 250 mg Myfenax capsules and 500 mg tablets in both fasting and fed states versus CellCept.	Fasting and Fed	78 (250mg fasting), 38 (250mg fed), 77 (500mg fasting), 112 (500mg fed)	96 (89-103%), 95 (86-106%), 99 (87-113%), 94 (87-102%) respectively	102 (100-105%), 104 (99-108%), 98 (95-102%), 101 (98-103%) respectively

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Also unbranded versions from Mylan, Sandoz, Dr. Reddy, Accord, Waymade, Cubic, AAH, Sigma, Actavis, Colorama, JMMcGill, Phoenix, Wockhardt	Not listed						
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