

Supplementary Material 9

Concomitant Medication

D.9 Concomitant Medications

Table S328 shows a summary of the number of concomitant medication taken by patients by trial visit. Trial visit was categorised according to start date of the concomitant medication.

Table S328: Number of concomitant medications taken by patient and trial visit.

PAT_TNO	Pre-screening	Screening visit 1	Screening visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Follow up visit 10	Follow up visit 11	Other	Total
1	8 (8.16%)	0 (0.00%)	0 (0.00%)	4 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	12 (5.17%)
2	2 (2.04%)	0 (0.00%)	0 (0.00%)	2 (4.55%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (1.72%)
3	9 (9.18%)	0 (0.00%)	0 (0.00%)	5 (11.36%)	0 (0.00%)	0 (0.00%)	2 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	16 (6.90%)
4	1 (1.02%)	0 (0.00%)	0 (0.00%)	4 (9.09%)	2 (16.67%)	2 (22.22%)	2 (14.29%)	0 (0.00%)	1 (14.29%)	1 (12.50%)	1 (6.67%)	0 (0.00%)	0 (0.00%)	14 (6.03%)
5	3 (3.06%)	0 (0.00%)	0 (0.00%)	11 (25.00%)	1 (8.33%)	0 (0.00%)	3 (21.43%)	1 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	20 (8.62%)
6	3 (3.06%)	1 (33.33%)	0 (0.00%)	1 (2.27%)	1 (8.33%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	8 (3.45%)
7	3 (3.06%)	0 (0.00%)	0 (0.00%)	2 (4.55%)	3 (25.00%)	0 (0.00%)	1 (7.14%)	1 (20.00%)	1 (14.29%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	13 (5.60%)
8	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (1.29%)
9	7 (7.14%)	0 (0.00%)	0 (0.00%)	1 (2.27%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (25.00%)	1 (6.67%)	1 (50.00%)	0 (0.00%)	12 (5.17%)
10	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	1 (0.43%)
11	4 (4.08%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	0 (0.00%)	6 (2.59%)
12	3 (3.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (8.33%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (20.00%)	0 (0.00%)	0 (0.00%)	8 (3.45%)
13	1 (1.02%)	0 (0.00%)	0 (0.00%)	3 (6.82%)	0 (0.00%)	0 (0.00%)	3 (21.43%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	7 (3.02%)

Table S328: Number of concomitant medications taken by patient and trial visit. (continued)

14	2	0	0	0	0	0	0	1	0	0	0	0	0	3
	(2.04%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(20.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(1.29%)
15	11	0	1	1	2	2	0	0	1	0	0	0	10	28
	(11.22%)	(0.00%)	(100.00%)	(2.27%)	(16.67%)	(22.22%)	(0.00%)	(0.00%)	(14.29%)	(0.00%)	(0.00%)	(0.00%)	(71.43%)	(12.07%)
16	6	0	0	3	0	0	1	0	1	0	2	0	0	13
	(6.12%)	(0.00%)	(0.00%)	(6.82%)	(0.00%)	(0.00%)	(7.14%)	(0.00%)	(14.29%)	(0.00%)	(13.33%)	(0.00%)	(0.00%)	(5.60%)
17	8	0	0	0	1	0	1	0	0	0	1	0	0	11
	(8.16%)	(0.00%)	(0.00%)	(0.00%)	(8.33%)	(0.00%)	(7.14%)	(0.00%)	(0.00%)	(0.00%)	(6.67%)	(0.00%)	(0.00%)	(4.74%)
18	5	0	0	3	0	0	0	0	1	3	1	0	0	13
	(5.10%)	(0.00%)	(0.00%)	(6.82%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(14.29%)	(37.50%)	(6.67%)	(0.00%)	(0.00%)	(5.60%)
19	5	1	0	4	0	0	0	2	0	0	1	0	0	13
	(5.10%)	(33.33%)	(0.00%)	(9.09%)	(0.00%)	(0.00%)	(0.00%)	(40.00%)	(0.00%)	(0.00%)	(6.67%)	(0.00%)	(0.00%)	(5.60%)
20	4	0	0	0	0	0	0	0	0	0	0	0	0	4
	(4.08%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(1.72%)
21	7	0	0	0	0	0	1	0	0	0	2	1	1	12
	(7.14%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(7.14%)	(0.00%)	(0.00%)	(0.00%)	(13.33%)	(50.00%)	(7.14%)	(5.17%)
22	5	0	0	0	0	2	0	0	0	0	0	0	0	7
	(5.10%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(22.22%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(3.02%)
23	1	0	0	0	0	0	0	0	1	0	2	0	0	4
	(1.02%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(0.00%)	(14.29%)	(0.00%)	(13.33%)	(0.00%)	(0.00%)	(1.72%)
Total	98	3	1	44	12	9	14	5	7	8	15	2	14	232
	(100.00%)	(100.00%)	(100.00%)	(100.00%)	(100.00%)	(100.00%)	(100.00%)	(100.00%)	(100.00%)	(100.00%)	(100.00%)	(100.00%)	(100.00%)	(100.00%)

Table S329 shows the names of concomitant medications taken by each patient according to trial visit.

Table S329: Names of concomitant medications taken by patient and trial visit.

Patient	Pre-screening	Screening visit 1	Screening visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Follow up visit 10	Follow up visit 11	Other
1	Multivitamins; Piriton; Lansoprazole; Ursodeoxy- cholic acid; Paracetamol; Colesevelam; Azathioprine; Mezavant			Cetirizine; Ibuprofen; Cetirizine; Ibuprofen									
2	Sulfasalazine; Simvastatin			Cetirizine; Ibuprofen									
3	Cod liver oil; Multivita- mins; Fluticasone propionate; Montelukast; Pentasa; Salbutamol; Nasonex; Ur- sodeoxycholic acid; Flu capsule			Ibuprofen; Co- amoxiclav; Chlo- raphenamine; Loratidine; E45 cream			Lansoprazole; Fucibet cream						
4	Mesalazine			Cetirizine; Ibuprofen; Cetirizine; Ibuprofen	Cetirizine; Ibuprofen	Cetirizine; Ibuprofen	Cetirizine; Ibuprofen		Beechams	Neurofen	Neurofen		

Table S329: Names of concomitant medications taken by patient and trial visit. (continued)

Patient	Pre-screening	Screening visit 1	Screening visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Follow up visit 10	Follow up visit 11	Other
5	Mesalazine; Rifampicin; Prednisolone			Ibuprofen; Hydrocortisone Cetirizine; Hartman's solution; Ciprofloxacin; Paraceta- mol; Pred- nisolone; Adrenaline; Chlor- phenamine; Paraceta- mol; Saline 0.9%; Hydrocor- tisone			Benylin; Ibuprofen Paraceto- mol; Ibuprofen						
6	Naproxen; Codeine phosphate; Ursodeoxy- cholic acid	Amoxycycline		Doxycycline	Polyfax Ointment	Doxycycline			Ranitidine				
7	Morphine solution (Oromorph); Co-codamol;			Hydrocortisone Paraceta- mol	Chlorphenamine;	Paraceta- mol	Chlorphenamin Chlorphenamin Chlorphenamin Tramadol						

tirizine;
Ibuprofen

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Table S329: Names of concomitant medications taken by patient and trial visit. (continued)

Patient	Pre-screening	Screening visit 1	Screening visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Follow up visit 10	Follow up visit 11	Other
8		Paracetamol + phenyle- phrine cold sa- chets/powder (Brand name not known)			Lidocaine 1%					Antibacterial spray (brand not known)			
9	Calcitriol; Sildenafil; Salbutamol; Ursodeoxy- cholic acid; floxonase; Asacol; Clenil			Fluconazole						Clarithromycin; LANSOPRAZOLE LANSOPRAZOLE Chole- calferol			
11	Ursodeoxycholic acid; Rifampicin; Mesalazine; Budesonide					Co- Amoxiclav					Questron		
12	Sulfasalazine; Ursodeoxy- cholic Acid; Detrunorm				Cholestyranine	Co- Codamol					Zopiclone; Predsol; olopata- dine		
13	Ursodeoxycholic Acid			Hydrocortisone; Ibuprofen; Cetirizine			Prednisolone; Naproxen; Codiene						

Table S329: Names of concomitant medications taken by patient and trial visit. (continued)

Patient	Pre-screening	Screening visit 1	Screening visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Follow up visit 10	Follow up visit 11	Other
14	Omeprazole; Rifampicin								Paracetamol				
15	Amlodipine; Nortripyline; Tramadol; Urea cream; Calcipotriol cream; Cetraben cream; Hyoscine; Ketoconazole shampoo 2%; Loratidine; Omeprazole; Zopiclone		Paracetamol / Night Nurse	Valerine	Zopiclone; Chlo- raphenamine	Chloraphenamine; E45 itch cream			Pseudoephedrine Hydrochlo- ride				Night Nurse; Night Nurse; Day Nurse; Day Nurse; Ibuprofen; Chlo- raphenamine; Chlo- raphenamine; paraceta- mol; Ibuprofen; Pseu- doephedrine Hydrochlo- ride
16	Salofalk; Ursofalk; Rifampicin; Dexametha- sone; Omega 3; Hydroxy- chloroquine			Hydrocortisone; Ibuprofen; Cetirizine			Salofalk		Salofalk		Normal Saline; Paraceta- mol		

Table S329: Names of concomitant medications taken by patient and trial visit. (continued)

Patient	Pre-screening	Screening visit 1	Screening visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Follow up visit 10	Follow up visit 11	Other
17	folic acid; vitamin D3; vitamin A + D;novorapid; lantus; bisoprolol; carbimazole; pentasa				Hydrocortizone		carbimazole					Ciprofloxacin	
18	Ursodeoxycholic Acid; Ciprofloxacin; Metronida- zole; Adcal D3; Mesalazine			Hydrocortisone; Ibuprofen; Cetirizine					Vancomycin	Prednisolone; Pred- nisolone; Pred- nisolone		Ibuprofen	
19	Metformin; Saxagliptin; Gliclazide; Atorvastatin; Glargine insulin	Ursodexoycholic Acid		Actrapid; Hydrocor- tisone; Ibuprofen; Cetirizine				Colesevelam; Aqueous Cream				Ferrous Fumarate	
20	Azathioprine; Ursodeoxy- cholic acid (UDCA); Sodium Risedronate; Adcal D3												

Table S329: Names of concomitant medications taken by patient and trial visit. (continued)

Patient	Pre-screening	Screening visit 1	Screening visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Follow up visit 10	Follow up visit 11	Other
21	UDCA; Perindropril; Lansoprazole; Aqueous cream; cetizine; Ibuprofen; Hydrocorti- sone						Chloraphenamine				Loratradene; UDCA	UDCA	
22	URSODEOXYCHOLIC ACID; Asacol; Thyroxine; Salbutamol inhaler; Be- clomethasone inhaler					Thyroxine; Thyroxine							
23	co-dydramol								Codeine/paracetamol (Zapain)		Omeprazole; E45 cream		

Finally, table S330 shows a full descriptive line listing of all concomitant medications used by patients on the BUTEO trial.

Table S330: Line listing of concomitant medications.

Patient	Medication	Dose	Administrative Route	Frequency	Start Date	End Date	Ongoing	Medication Reason	Adverse Event
1	Paracetamol	1 G	4: Oral	q.l./prn	2007-06-15		Yes	Abdominal pain	Yes
1	Multivitamins	1 (1 tablet)	4: Oral	in d./quotid/o.d.	2011-06-15		Yes	Supplement	No
1	Piriton	10 Mg	4: Oral	q.l./prn	2011-09-01		Yes	pruritus.	Yes
1	Ursodeoxycholic acid	500 Mg	4: Oral	b.d./b.i.d	2011-09-08		Yes	PSC	No
1	Azathioprine	50 Mg	4: Oral	Alternate days	2011-12-01		Yes	Crohn's disease	No
1	Colesevelam	3 (Tablets)	4: Oral	b.d./b.i.d	2012-06-15		Yes	Itch	No
1	Mezavant	2.4 G	4: Oral	in d./quotid/o.d.	2012-06-15		Yes	Long term bowel cancer prevention	No
1	Lansoprazole	Not Known	4: Oral	in d./quotid/o.d.	2014-06-15		Yes	Prophylaxis against indigestion	No
1	Cetirizine	10 Mg	4: Oral	q.l./prn	2015-09-10	2015-11-26		BTT1023 infusion	No
1	Ibuprofen	400 Mg	4: Oral	q.l./prn	2015-09-10	2016-11-26		BTT1023 infusion	No
1	Cetirizine	10 Mg	4: Oral	q.l./prn	2015-09-10	2015-11-26		pre-infusion medication	No
1	Ibuprofen	400 Mg	4: Oral	q.l./prn	2015-09-10	2015-11-26		pre-infusion medication	No
2	Sulfasalazine	2 G	4: Oral	b.d./b.i.d	2001-10-01		Yes	IBD	No
2	Simvastatin	40 Mg	4: Oral	in d./quotid/o.d.	2015-09-01		Yes	High cholesterol	No
2	Cetirizine	10 Mg	4: Oral	Once	2015-12-09	2015-12-09		Infusion	No

Table S330: Line listing of concomitant medications. (continued)

Patient	Medication	Dose	Administrative Route	Frequency	Start Date	End Date	Ongoing	Medication Reason	Adverse Event
2	Ibuprofen	400 Mg	4: Oral	Once	2015-12-09	2015-12-09		Infusion	No
3	Cod liver oil	1 (Tablet)	4: Oral	in d./quotid/o.d.	1995-06-15		Yes	Prophylaxis	No
3	Multivitamins	1 (Tablet)	4: Oral	in d./quotid/o.d.	1995-06-15		Yes	Prophylaxis	No
3	Pentasa	500 Mg	4: Oral	t.d/t.i.d/t.d.s	1995-06-15		Yes	Crohn's disease	No
3	Salbutamol	100 µg	5: Respiratory (inhalation)	q.l./prn	1995-06-15		Yes	Asthma	No
3	Ursodeoxycholic acid	250 Mg	4: Oral	t.d/t.i.d/t.d.s	2000-06-15		Yes	PSC	No
3	Nasonex	100 µg	5: Respiratory (inhalation)	in d./quotid/o.d.	2015-04-01		Yes	Hayfever	No
3	Montelukast	10 Mg	4: Oral	q.l./prn	2015-06-15		Yes	Prophylaxis against hayfever	No
3	Fluticasone propionate	100 µg	5: Respiratory (inhalation)	b.d./b.i.d	2015-10-01		Yes	Asthma / phlegm sitting in throat intermittent	Yes
3	Flu capsule	Not Known	4: Oral	q.l./prn	2015-10-01		Yes	Prophylaxis against phlegm in throat	Yes
3	Ibuprofen	400 Mg	4: Oral	q.l./prn	2016-01-13	2016-03-31		Infusion	No
3	Loratidine	10 Mg	4: Oral	q.l./prn	2016-01-13	2016-03-31		Infusion	No
3	E45 cream	Not Known	7: Topical	q.l./prn	2016-01-14	2016-03-31		Pruritus	Yes

Table S330: Line listing of concomitant medications. (continued)

Patient	Medication	Dose	Administrative Route	Frequency	Start Date	End Date	Ongoing	Medication Reason	Adverse Event
3	Chlorphenamine	4 Mg	4: Oral	Once	2016-01-18	2016-01-18		Prophylaxis against itching / Pruritus	Yes
3	Co-amoxiclav	375 Mg	4: Oral	t.d/t.i.d/t.d.s	2016-01-20	2016-01-27		Prophylaxis against chest infection	No
3	Lansoprazole	30 Mg	4: Oral	in d./quotid/o.d.	2016-02-24		Yes	Prophylaxis against acid reflux	No
3	Fucibet cream	Not Known	7: Topical	q.l./prn	2016-02-24		Yes	Itchy skin /Sensitive skin over varicose vein on calves / Pruritus	Yes
4	Mesalazine	1.2 G	4: Oral	b.d./b.i.d	1988-06-15		Yes	Colitis	No
4	Cetirizine	10 Mg	4: Oral	q.l./prn	2016-01-18	2016-01-18		pre-infusion meds	No
4	Ibuprofen	400 Mg	4: Oral	q.l./prn	2016-01-18	2016-01-18		pre-infusion meds	No
4	Cetirizine	10 Mg	4: Oral	one off	2016-01-18	2016-01-18		pre-infusion medication	No
4	Ibuprofen	400 Mg	4: Oral	one off	2016-01-18	2016-01-18		pre-infusion medication	No
4	Cetirizine	10 Mg	4: Oral	one off	2016-01-25	2016-01-25		pre-infusion medication	No
4	Ibuprofen	400 Mg	4: Oral	one off	2016-01-25	2016-01-25		pre-infusion medication	No

Table S330: Line listing of concomitant medications. (continued)

Patient	Medication	Dose	Administrative Route	Frequency	Start Date	End Date	Ongoing	Medication Reason	Adverse Event
4	Cetirizine	10 Mg	4: Oral	one off	2016-02-08	2016-02-08		pre-infusion medication	No
4	Ibuprofen	400 Mg	4: Oral	one off	2016-02-08	2016-02-08		pre-infusion medication	No
4	Cetirizine	10 Mg	4: Oral	one off	2016-02-24	2016-02-24		pre-infusion medication	No
4	Ibuprofen	400 Mg	4: Oral	one off	2016-02-24	2016-02-24		pre-infusion medication	No
4	Beechams	Not Known	4: Oral	once	2016-03-25	2016-03-25		cold / flu like symptoms	Yes
4	Neurofen	200 Mg	4: Oral	q.l./prn	2016-04-19	2016-04-19		right shoulder pain	Yes
4	Neurofen	200 Mg	4: Oral	q.l./prn	2016-05-07	2016-05-07		Right shoulder pain	Yes
5	Mesalazine	1 G	4: Oral	t.d./t.i.d./t.d.s	2010-06-15		Yes	Colitis	No
5	Rifampicin	300 Mg	4: Oral	b.d./b.i.d	2015-11-25		Yes	For itch	No
5	Prednisolone	5 Mg	8: Suppository	once daily	2015-11-25		Yes	For coli- tis/tenesmus	No
5	Ibuprofen	400 Mg	4: Oral	once a week	2016-02-11		Yes	pre-infusion medication	No
5	Cetirizine	10 Mg	4: Oral	once a week	2016-02-11		Yes	pre-infusion medication	No
5	Hartman's solution	1000 Ml	3: Intravenous	one off	2016-02-11	2016-02-12		infusion reaction	Yes
5	Ciprofloxacin	500 Mg	4: Oral	b.d./b.i.d	2016-02-11	2016-02-12		antibiotic cover	Yes

Table S330: Line listing of concomitant medications. (continued)

Patient	Medication	Dose	Administrative Route	Frequency	Start Date	End Date	Ongoing	Medication Reason	Adverse Event
5	Paracetamol	1000 Mg	4: Oral	q.d.s prn	2016-02-11	2016-02-12		For pyrexia post-infusion reaction	Yes
5	Prednisolone	30 Mg	4: Oral	once daily	2016-02-11	2016-02-14		Post infusion reaction	Yes
5	Adrenaline	500 Units	97: Other	one off	2016-02-11	2016-02-11		Intramuscular, infusion reaction. Hypotension	Yes
5	Chlorphenamine	10 Mg	3: Intravenous	one off	2016-02-11	2016-02-11		Intravenous, infusion reaction	Yes
5	Paracetamol	1000 Mg	3: Intravenous	one off	2016-02-11	2016-02-11		Infusion reaction. Pyrexia	Yes
5	Saline 0.9%	1000 Ml	3: Intravenous	One off	2016-02-11	2016-02-11		Infusion reaction. Peripheral shutdown	Yes
5	Hydrocortisone	100 Mg	97: Other	one off	2016-02-11	2016-02-11		Intramuscular. Infusion reaction	Yes
5	Hydrocortisone	100 Mg	3: Intravenous	in d./quotid/o.d.	2016-02-18	2016-02-18		pre IMP, antihistamine cover	
5	Benylin	10 Ml	4: Oral	q.l./prn	2016-03-19	2016-03-23		cough	
5	Paracetamol	1 G	4: Oral	q.l./prn	2016-03-30	2016-03-30		viral infection	
5	Ibuprofen	400 Mg	4: Oral	q.l./prn	2016-03-30	2016-03-30		viral infection	

Table S330: Line listing of concomitant medications. (continued)

Patient	Medication	Dose	Administrative Route	Frequency	Start Date	End Date	Ongoing	Medication Reason	Adverse Event
5	Ibuprofen	400 Mg	4: Oral	q.l./prn	2016-04-09	2016-04-14		chest pain whilst coughing	
5									
6	Naproxen	500 Mg	4: Oral	in d./quotid/o.d.	2011-01-01		Yes	Back pain	
6	Codeine phosphate	30 Mg	4: Oral	in d./quotid/o.d.	2011-01-01		Yes	back pain	
6	Ursodeoxycholic acid	750 Mg	4: Oral	in d./quotid/o.d.	2013-04-10		Yes	PSC treatment	
6	Amoxycycline	500 Mg	4: Oral	t.d/t.i.d/t.d.s	2016-05-16	2016-05-26		Chest infection	
6	Doxycycline	100 Mg	4: Oral	t.d/t.i.d/t.d.s	2016-05-27	2016-06-02		Chest infection	
6	Polyfax Ointment	Not Known	7: Topical	b.d./b.i.d	2016-06-02	2016-06-20		Infected Psoriasis to hands	Yes
6	Doxycycline	150 Mg	4: Oral	o.m.	2016-06-27	2016-07-06		Chest infection.	
6	Ranitidine	150 Mg	4: Oral	o.m.	2016-07-28		Yes	acid reflux	
7	Morphine solution (Oromorph)	5 Mg	4: Oral	q.l./prn	2005-06-15		Yes	Back pain	No
7	Co-codamol codeine and 500mg paracetamol per tablet)	8 (8mg codeine and 500mg paracetamol per tablet)	4: Oral	q.l./prn	2005-06-15		Yes	neck and back pain	Yes

Table S330: Line listing of concomitant medications. (continued)

Patient	Medication	Dose	Administrative Route	Frequency	Start Date	End Date	Ongoing	Medication Reason	Adverse Event
7	Paracetamol	1 G	4: Oral	q.l./prn	2005-06-15	2016-06-29		Pain in lower spine	No
7	Hydrocortisone	100 Mg	3: Intravenous	q.l./prn	2016-06-15	2016-07-06		Pre-infusion medication for Buteo trial	No
7	Paracetamol	1 G	4: Oral	q.l./prn	2016-06-17	2016-06-19		Headache	Yes
7	Certirizine	10 Mg	4: Oral	q.l./prn	2016-06-24		Yes	Given pre-infusion as part of Buteo trial. Also taken prn for Pruritus	Yes
7	Ibuprofen	400 Mg	4: Oral	q.l./prn	2016-06-24	2016-08-31		Pre infusion as part of Buteo trial	No
7	Chlorphenamine	10 Mg	4: Oral	q.l./prn	2016-07-04	2016-07-05		Itching	Yes
7	Chlorphenamine	10 Mg	4: Oral	q.l./prn	2016-07-21	2016-07-24		itching	No
7	Chlorphenamine	10 Mg	4: Oral	q.l./prn	2016-08-06	2016-08-08		itching	No
7	Chlorphenamine	10 Mg	4: Oral	q.l./prn	2016-08-17		Yes	Itching	Yes
7	Tramadol	50 Mg	4: Oral	q.l./prn	2016-09-14	2016-09-21		Neck and back pain	Yes
7									
8	Paracetamol + phenylephrine cold sachets/powder (Brand name not known)	1 (sachet)	4: Oral	q.l./prn	2017-02-26	2017-03-04		Cold	Yes

Table S330: Line listing of concomitant medications. (continued)

Patient	Medication	Dose	Administrative Route	Frequency	Start Date	End Date	Ongoing	Medication Reason	Adverse Event
8	Lidocaine 1%	5 Ml	6: Subcutaneous	one off	2017-03-15	2017-03-15		Routine dental work	No
8	Antibacterial spray (brand not known)	1 (spray)	7: Topical	q.l./prn	2017-06-08		Yes	redness around umbilicus	Yes
9	Calcitriol	Not Known	7: Topical	b.d./b.i.d	1980-06-15		Yes	Psoriasis	Yes
9	Ursodeoxycholic acid	250 Mg	4: Oral	t.d/t.i.d/t.d.s	1994-06-01		Yes	Ulcerative Colitis	No
9	Asacol	1.6 G	4: Oral	t.d/t.i.d/t.d.s	1994-06-01	2017-04-17		Ulcerative Colitis	No
9	Sildenafil	25 Mg	4: Oral	q.l./prn	2010-08-01		Yes	erectile dysfunction	Yes
9	Salbutamol	Not Known	5: Respiratory (inhalation)	q.l./prn	2014-05-01		Yes	Asthma	No
9	flixonase	200 µg	5: Respiratory (inhalation)	in d./quotid/o.d.	2014-05-01		Yes	Rhinitis	No
9	Clenil	2 Puffs	5: Respiratory (inhalation)	b.d./b.i.d	2014-05-01		Yes	Asthma	No
9	Fluconazole	50 Mg	4: Oral	daily	2017-03-12	2017-03-18		Oesophageal candidiasis	Yes
9	Clarithromycin	500 Mg	4: Oral	b.d./b.i.d	2017-05-24	2017-05-31		Staphylococcus Aurous infection in Left shin wound	Yes
9	Cholecalferol	20 Units	4: Oral	twice weekly	2017-05-25		Yes	Vitamin D deficiency	Yes

Table S330: Line listing of concomitant medications. (continued)

Patient	Medication	Dose	Administrative Route	Frequency	Start Date	End Date	Ongoing	Medication Reason	Adverse Event
9	LANSOPRAZOLE	30 Mg	4: Oral	b.d./b.i.d	2017-06-20	2017-07-11		Portal hypertensive gastropathy.	Yes
9	LANSOPRAZOLE	30 Mg	4: Oral	in d./quotid/o.d.	2017-07-12		Yes	portal Gastropathy as shown on endoscopy	Yes
10									
11	Ursodeoxycholic acid	250 Mg	4: Oral	b.d./b.i.d	2007-11-01		Yes	Ulcerative Colitis	
11	Mesalazine	1 G	4: Oral	Not known	2007-11-01		Yes	Ulcerative colitis	
11	Budesonide	3 Mg	4: Oral	in d./quotid/o.d.	2015-11-01		Yes	Ulcerative Colitis	
11	Rifampicin	300 Mg	4: Oral	in d./quotid/o.d.	2017-03-01		Yes	ulcerative colitis	
11	Co-Amoxiclav	625 Mg	4: Oral	t.d/t.i.d/t.d.s	2017-06-12	2017-07-05		Abdominal pain	Yes
11	Questron	1 G	4: Oral	t.d/t.i.d/t.d.s	2017-07-19		Yes	Abdominal pain	Yes
12	Sulfasalzine	500 Mg	4: Oral	q.d./q.i.d/q.d.s.	1988-06-15		Yes	Ulcerative colitis	No
12	Detrunorm	45 Mg	4: Oral	in d./quotid/o.d.	2015-06-15		Yes	urinary frequency	No
12	Ursodeoxycholic Acid	500 Mg	4: Oral	q.d./q.i.d/q.d.s.	2016-06-15		Yes	PSC	No
12	Cholestyranine	4 G	4: Oral	b.d./b.i.d	2017-05-23	2017-05-23		Puritis	Yes
12	Co-Codamol	30 Mg	4: Oral	q.l./prn	2017-06-15		Yes	Pain relief	

Table S330: Line listing of concomitant medications. (continued)

Patient	Medication	Dose	Administrative Route	Frequency	Start Date	End Date	Ongoing	Medication Reason	Adverse Event
12	Predsol	1 Mg	9: Intra-ocular	t.d/t.i.d/t.d.s	2017-08-24		Yes	allergic retinitis	Yes
12	olopatadine	1 Not known	9: Intra-ocular	b.d./b.i.d	2017-08-24		Yes	allergic retinitis	Yes
12	Zopiclone	7.5 Mg	4: Oral	in d./quotid/o.d.	2017-09-08		Yes	depression	Yes
13	Ursodeoxycholic Acid	1000 Mg	4: Oral	in d./quotid/o.d.	2010-01-01		Yes	PSC treatment	No
13	Hydrocortisone	100 Mg	3: Intravenous	q.l./prn	2017-05-12	2017-07-27		Pre infusion	No
13	Ibuprofen	400 Mg	4: Oral	q.l./prn	2017-05-12	2017-07-27		Pre infusion	No
13	Cetirizine	10 Mg	4: Oral	q.l./prn	2017-05-12	2017-07-27		Pre infusion	No
13	Prednisolone	10 Mg	4: Oral	in d./quotid/o.d.	2017-06-22		Yes	Steroids for treatment of PSC	No
13	Naproxen	500 Mg	4: Oral	in d./quotid/o.d.	2017-06-24	2017-06-26		Polyarthralgia	No
13	Codiene	60 Mg	4: Oral	q.l./prn	2017-06-27	2017-06-27		Polyarthralgia	No
14	Rifampicin	150 Mg	4: Oral	o.m.	2005-01-01		Yes	Previous itch due to PSC	No
14	Omeprazole	20 Mg	4: Oral	o.m.	2008-01-01		Yes	Acid reflux	No
14	Paracetamol	1000 Mg	4: Oral	one dose only	2017-08-07	2017-08-07		shivers and temperature (not recorded temperature)	Yes
15	Zopiclone	7.5 Mg	4: Oral	at night	2010-06-15	2017-08-19		to aid sleeping	Yes
15	Amlodipine	5 Mg	4: Oral	in d./quotid/o.d.	2013-06-15		Yes	Hypertension	No
15	Nortriptyline	10 Mg	4: Oral	b.d./b.i.d	2013-06-15		Yes	depression	No

Table S330: Line listing of concomitant medications. (continued)

Patient	Medication	Dose	Administrative Route	Frequency	Start Date	End Date	Ongoing	Medication Reason	Adverse Event
15	Tramadol	100 Mg	4: Oral	at night	2013-06-15		Yes	abdominal pain	Yes
15	Hyoscine	10 Mg	4: Oral	q.l./prn	2013-06-15		Yes	Irritable bowel syndrome	No
15	Loratidine	10 Mg	4: Oral	q.l./prn	2013-06-15		Yes	Pruritus	Yes
15	Omeprazole	40 Mg	4: Oral	in d./quotid/o.d.	2013-06-15		Yes	acid reflux	No
15	Urea cream	1 (application)	7: Topical	q.l./prn	2015-06-15		Yes	sore skin on hands	No
15	Calcipotriol cream	1 (application)	7: Topical	q.l./prn	2015-06-15		Yes	sore skin on hands	No
15	Cetaben cream	1 (application)	7: Topical	in d./quotid/o.d.	2015-06-15		Yes	sore skin on hands	No
15	Ketoconazole shampoo 2%	1 (application)	7: Topical	q.l./prn	2015-06-15		Yes	sore skin	No
15	Paracetamol / Night Nurse	10 mg/ml	4: Oral	at night	2017-08-20	2017-08-20		Cold	Yes
15	Valerine	5 Mg	4: Oral	at night	2017-08-22	2017-08-31		to aid sleeping, fatigue	Yes
15	Zopiclone	7.5 Mg	4: Oral	at night	2017-08-31		Yes	to aid sleeping	Yes
15	Chloraphenamine	4 Mg	4: Oral	frequency varied	2017-08-31	2017-09-14		itching post infusion	Yes
15	Chloraphenamine	4 Mg	4: Oral	t.d/t.i.d/t.d.s	2017-09-14	2017-10-06		itching post infusion	Yes
15	E45 itch cream	1 (application)	7: Topical	in d./quotid/o.d.	2017-09-18	2017-09-23		Pruritus	Yes
15	Chloraphenamine	4 Mg	4: Oral	at night	2017-10-06	2017-10-15		itching	Yes

Table S330: Line listing of concomitant medications. (continued)

Patient	Medication	Dose	Administrative Route	Frequency	Start Date	End Date	Ongoing	Medication Reason	Adverse Event
15	Night Nurse	Not Known	4: Oral	Not known	2017-10-07	2017-10-09		aching body / cough	Yes
15	Day Nurse	Not Known	4: Oral	Not known	2017-10-07	2017-10-09		aching body / cough	Yes
15	Ibuprofen	400 Mg	4: Oral	t.d/t.i.d/t.d.s	2017-10-11	2017-10-12		aching body / cough	Yes
15	Night Nurse	Not Known	4: Oral	Not known	2017-10-12	2017-10-14		aching body / cough	Yes
15	Day Nurse	Not Known	4: Oral	Not known	2017-10-12	2017-10-14		Aching body cough	Yes
15	paracetamol	1000 Mg	4: Oral	b.d./b.i.d	2017-10-16	2017-10-20		cough / body ache	Yes
15	Ibuprofen	800 Mg	4: Oral	b.d./b.i.d	2017-10-16	2017-10-20		cough / body ache	Yes
15	Pseudoephedrine Hydrochloride	60 Mg	4: Oral	b.d./b.i.d	2017-10-16	2017-10-20		cough / body ache	Yes
15	Chlorphenamine	4 Mg	4: Oral	at night	2017-10-21		Yes	itching	Yes
15	Pseudoephedrine Hydrochloride	60 Mg	4: Oral	in d./quotid/o.d.	2017-11-07	2017-11-08		Cold	Yes
16	Salofalk	1.5 G	4: Oral	in d./quotid/o.d.	1999-01-01	2017-10-23		UC	No
16	Omega 3	500 Mg	4: Oral	t.d/t.i.d/t.d.s	1999-01-01		Yes		No
16	Ursofalk	500 Mg	4: Oral	q.d./q.i.d/q.d.s.	2002-01-01		Yes	PSC	No
16	Rifampicin	150 Mg	4: Oral	o.m.	2002-01-01		Yes	PSC	No
16	Dexamethasone	0.4 Mg	97: Other	q.l./prn	2002-01-01		Yes	Sjorgens	No
16	Hydroxychloroquine	200 Mg	4: Oral	in d./quotid/o.d.	2002-01-01		Yes	Sjorgens	No
16	Hydrocortisone	100 Mg	3: Intravenous	q.l./prn	2017-09-08	2017-11-23		Pre infusion	No

Table S330: Line listing of concomitant medications. (continued)

Patient	Medication	Dose	Administrative Route	Frequency	Start Date	End Date	Ongoing	Medication Reason	Adverse Event
16	Ibuprofen	400 Mg	4: Oral	q.l./prn	2017-09-08	2017-11-23		Pre infusion	No
16	Cetirizine	10 Mg	4: Oral	q.l./prn	2017-09-08	2017-11-23		Pre infusion	No
16	Salofalk	1.5 G	4: Oral	b.d./b.i.d	2017-10-23	2017-11-20		AE - bloody, loose stools	Yes
16	Salofalk	1.5 G	4: Oral	in d./quotid/o.d.	2017-11-20		Yes	UC maintenance	
16	Normal Saline	2000 (ml)	3: Intravenous	Stat	2017-12-18	2017-12-20		Vomiting and diarrhoea AE	Yes
16	Paracetamol	1 G	4: Oral	q.l./prn	2017-12-18	2017-12-20		Gastrointestinal pain AE	Yes
17	pentasa	500 Mg	4: Oral	t.d/t.i.d/t.d.s	2006-06-15		Yes	ulcerative colitis	No
17	novorapid	22 mg/ml	6: Subcutaneous	t.d/t.i.d/t.d.s	2013-06-15		Yes	type 1 diabetes	Yes
17	lantus	22 (units)	6: Subcutaneous	in d./quotid/o.d.	2013-06-15		Yes	type 1 diabetes	No
17	folic acid	5 Mg	4: Oral	in d./quotid/o.d.	2014-06-15		Yes	vitamin supplement	No
17	vitamin D3	1600 (IU)	4: Oral	in d./quotid/o.d.	2016-06-15		Yes	vitamin supplement	No
17	vitamin A + D	Not Known	4: Oral	alternate days to Vitamin D3	2016-06-15		Yes	Vitamin supplement	No
17	bisoprolol	2.5 Mg	4: Oral	in d./quotid/o.d.	2016-06-15	2017-10-23		Hyperthyroidism	No
17	carbimazole	5 Mg	4: Oral	t.d/t.i.d/t.d.s	2016-06-15	2017-11-09		hyperthyroid	Yes
17	Hydrocortizone	50 Mg	3: Intravenous	in d./quotid/o.d.	2017-10-05	2017-10-05		pre BTT1023 infusion	No
17	carbimazole	5 Mg	4: Oral	b.d./b.i.d	2017-11-10		Yes	hyperthyroid	Yes

Table S330: Line listing of concomitant medications. (continued)

Patient	Medication	Dose	Administrative Route	Frequency	Start Date	End Date	Ongoing	Medication Reason	Adverse Event
17	Ciprofloxacin	500 Mg	4: Oral	b.d./b.i.d	2018-01-24	2018-01-29		cholangitis: gallbladder infection	Yes
18	Ursodeoxycholic Acid	750 Mg	4: Oral	b.d./b.i.d	2005-09-01		Yes	PSC	No
18	Mesalazine	1 G	8: Suppository	q.l./prn	2005-09-01		Yes	Ulcerative colitis	No
18	Ciprofloxacin	250 Mg	4: Oral	b.d./b.i.d	2017-09-01		Yes	Pouchitis	No
18	Metronidazole	200 Mg	4: Oral	b.d./b.i.d	2017-09-01		Yes	Pouchitis	No
18	Adcal D3	1 (Tablet)	4: Oral	o.m.	2017-09-01		Yes	Thin bones/diet low in calcium	No
18	Hydrocortisone	100 Mg	3: Intravenous	q.l./prn	2017-12-11	2018-01-02		Pre infusion	No
18	Ibuprofen	400 Mg	4: Oral	q.l./prn	2017-12-11	2018-01-02		Pre infusion	No
18	Cetirizine	10 Mg	4: Oral	q.l./prn	2017-12-11	2018-01-02		Pre infusion	No
18	Vancomycin	125 Mg	4: Oral	b.d./b.i.d	2018-02-13	2018-02-27		?pouchitis	Yes
18	Prednisolone	40 Mg	4: Oral	in d./quotid/o.d.	2018-02-26	2018-03-04		Cuffitis/Pouchitis	Yes
18	Prednisolone	30 Mg	4: Oral	in d./quotid/o.d.	2018-03-05	2018-03-11		Cuffitis/Pouchitis	Yes
18	Prednisolone	20 Mg	4: Oral	in d./quotid/o.d.	2018-03-12		Yes	Cuffitis/Pouchitis	Yes
18	Ibuprofen	800 Mg	4: Oral	Stat	2018-04-07	2018-04-07		Pain caused by constipation	Yes
19	Metformin	500 Mg	4: Oral	q.d./q.i.d/q.d.s.	2017-01-01		Yes	Type 2 Diabetes	No

Table S330: Line listing of concomitant medications. (continued)

Patient	Medication	Dose	Administrative Route	Frequency	Start Date	End Date	Ongoing	Medication Reason	Adverse Event
19	Saxagliptin	5 Mg	4: Oral	in d./quotid/o.d.	2017-01-01		Yes	Type 2 diabetes	No
19	Gliclazide	80 Mg	4: Oral	q.d./q.i.d/q.d.s.	2017-01-01		Yes	Type 2 diabetes	No
19	Atorvastatin	60 Mg	4: Oral	in d./quotid/o.d.	2017-01-01		Yes	Hypercholestraemia	Yes
19	Glargine insulin	8 Units	6: Subcutaneous	in d./quotid/o.d.	2017-01-01		Yes	Type 2 diabetes	No
19	Ursodexoycholic Acid	250 Mg	4: Oral	q.d./q.i.d/q.d.s.	2017-12-06		Yes	Primary Sclerosing Cholangitis	No
19	Actrapid	4 Units	6: Subcutaneous	Stat	2018-01-05	2018-01-05		Hyperglycaemia	Yes
19	Hydrocortisone	100 Mg	3: Intravenous	q.l./prn	2018-01-05	2018-01-25		Pre infusion	No
19	Ibuprofen	400 Mg	4: Oral	q.l./prn	2018-01-05	2018-01-25		Pre infusion	No
19	Cetirizine	10 Mg	4: Oral	q.l./prn	2018-01-05	2018-01-25		Pre infusion	No
19	Colesevelam	1250 Mg	4: Oral	b.d./b.i.d	2018-03-07		Yes	Pruritus	Yes
19	Aqueous Cream	Not Known	7: Topical	q.l./prn	2018-03-07		Yes	Pruritus	Yes
19	Ferrous Fumarate	210 Mg	4: Oral	b.d./b.i.d	2018-04-16		Yes	Anaemia	Yes
20	Azathioprine	50 Mg	4: Oral	in d./quotid/o.d.	2010-06-15		Yes	Autoimmune hepatitis	No
20	Adcal D3	2 Units	4: Oral	in d./quotid/o.d.	2010-06-15		Yes	Bone protection	No
20	Sodium Risedronate	35 Mg	4: Oral	weekly	2013-06-15		Yes	bone protection	No

Table S330: Line listing of concomitant medications. (continued)

Patient	Medication	Dose	Administrative Route	Frequency	Start Date	End Date	Ongoing	Medication Reason	Adverse Event
20	Ursodeoxycholic acid (UDCA)	500 Mg	4: Oral	b.d./b.i.d	2014-10-15		Yes	Primary sclerosing cholangitis	No
21	Perindopril	4 Mg	4: Oral	in d./quotid/o.d.	2008-06-15		Yes	Hypertension	Yes
21	UDCA	250 Mg	4: Oral	b.d./b.i.d	2015-06-15	2018-06-27		Primary Schlerosing Cholangitis	Yes
21	Aqueous cream	Not Known	7: Topical	q.l./prn	2015-06-15		Yes	itching, pruritus	Yes
21	Lansoprazole	30 Mg	4: Oral	every third day	2015-10-15		Yes	Barretts oesophagus	Yes
21	cetizine	10 Mg	4: Oral	in d./quotid/o.d.	2017-08-21	2017-08-21		anti histamine cover pre IMP	
21	Ibuprofen	400 Mg	4: Oral	in d./quotid/o.d.	2017-08-21	2017-08-21		anti histamine cover pre IMP	
21	Hydrocortisone	100 Mg	3: Intravenous	in d./quotid/o.d.	2017-08-21	2017-08-21		anti histamine cover pre IMP	
21	Chloraphenamine	4 Mg	4: Oral	once only	2018-04-16	2018-04-16		Weather change, Hay fever	Yes
21	Loratradene	4 Mg	4: Oral	in d./quotid/o.d.	2018-06-25		Yes	Hayfever	Yes
21	UDCA	250 Mg	4: Oral	in d./quotid/o.d.	2018-06-28	2018-07-05		PSC	No
21	UDCA	250 Mg	4: Oral	b.d./b.i.d	2018-07-05		Yes	PSC	No
21									

Table S330: Line listing of concomitant medications. (continued)

Patient	Medication	Dose	Administrative Route	Frequency	Start Date	End Date	Ongoing	Medication Reason	Adverse Event
22	URSODEOXYCHOLIC ACID	500 Mg	4: Oral	in d./quotid/o.d.	2002-07-04		Yes	PSC	No
22	Asacol	2400 Mg	4: Oral	in d./quotid/o.d.	2002-07-04		Yes	Ulcerative Colitis	No
22	Thyroxine	175 Mg	4: Oral	in d./quotid/o.d.	2004-10-05	2018-06-16		Hyperthyroidism	No
22	Salbutamol inhaler	2 Puffs	5: Respiratory (inhalation)	q.l./prn	2012-07-20		Yes	Asthma	No
22	Beclomethasone inhaler	2 Puffs	5: Respiratory (inhalation)	b.d./b.i.d	2012-07-20		Yes	Asthma	No
22	Thyroxine	225 Mg	4: Oral	in d./quotid/o.d.	2018-06-16	2018-06-23		Hypothyroidism	Yes
22	Thyroxine	200 Mg	4: Oral	in d./quotid/o.d.	2018-06-23		Yes	Hypothyroidism	Yes
23	co-dydramol	8.5 Mg	4: Oral	q.l./prn	2018-05-01		Yes	Osteoarthritis both knees	Yes
23	Codeine/paracetamol (Zapain)	20 Mg	4: Oral	q.l./prn	2018-09-05		Yes	Osteoarthritis both knees	No
23	Omeprazole	20 Mg	4: Oral	b.d./b.i.d	2018-10-02	2018-10-30		abdominal pain	Yes
23	E45 cream	Not Known	7: Topical	b.d./b.i.d	2018-10-10		Yes	Rash on forehead	Yes

