Table 2.1: Summary of baseline characteristics 27SEP2007
Analysis Set = Safety Population (N=200)

&COLVAR

Variable	Medisan 20 mg N=100	Novomed 100 mg N=100
Sex		
Male	12 (13%)	19 (19%)
Female	84 (88%)	81 (81%)
Missing	4	0
Weight (kg)		
N	99	100
Median	68.0	69.5
Mean	71.1	71.5
SD	19.2	16.2
Min	49	44
Max	179	134
Missing	1	0

&VARLIST

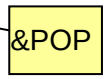

Table 2.2: Demographic characteristics 27SEP2007
Analysis Set = ITT Population (N=193)

Variable	Medisan 20 mg N=98	Novomed 100 mg N=95
Sex		
Male	12 (13%)	18 (19%)
Female	83 (87%)	77 (81%)
Missing	3	0
Weight (kg)		
N	97	95
Median	68.0	70.0
Mean	71.1	71.8
SD	19.3	16.4
Min	49	44
Max	179	134
Missing	1	0

vs.weight is selected when VSBLFL='Y'

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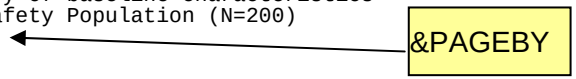
Table 2.3: Summary of baseline characteristics 05OCT2007
Analysis Set = Safety Population (N=200)
Sex = Male (N=31)



Variable	Medisan 20 mg N=12	Novomed 100 mg N=19
Race		
ASIAN	2 (17%)	1 (5%)
NEGROID	1 (8%)	0 (0%)
WHITE	9 (75%)	18 (95%)
Missing	0	0
Weight (kg)		
N	11	19
Median	70.0	75.0
Mean	72.3	74.9
SD	17.8	17.1
Min	49	49
Max	107	112
Missing	1	0

Table 2.3: Summary of baseline characteristics 05OCT2007
Analysis Set = Safety Population (N=200)
Sex = Female (N=165)

&PAGEBY

Variable	Medisan 20 mg N=84	Novomed 100 mg N=81
Race		
ASIAN	7 (8%)	9 (11%)
NEGROID	3 (4%)	5 (6%)
WHITE	74 (88%)	67 (83%)
Missing	0	0
Weight (kg)		
N	84	81
Median	67.0	69.0
Mean	70.4	70.7
SD	19.8	16.0
Min	49	44
Max	179	134
Missing	0	0

Table 2.4: Summary of baseline characteristics 16OCT2007
Analysis Set = Safety Population (N=200)

Variable	Medisan 20 mg N=100	Novomed 100 mg N=100	TOTAL N=200
Race			
ASIAN	9 (9%)	10 (10%)	19 (10%)
NEGROID	4 (4%)	5 (5%)	9 (5%)
WHITE	87 (87%)	85 (85%)	172 (86%)
Missing	0	0	0
Weight (kg)			
N	99	100	199
Median	68.0	69.5	69.0
Mean	71.1	71.5	71.3
SD	19.2	16.2	17.7
Min	49	44	44
Max	179	134	179
Missing	1	0	1

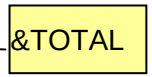
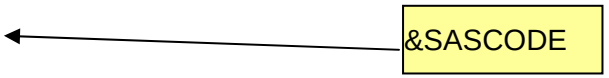


Table 2.5: Summary of baseline characteristics 16OCT2007
Females age>30 only
Analysis Set = Safety Population (N=124)



Variable	Medisan 20 mg N=65	Novomed 100 mg N=59
Race		
ASIAN	4 (6%)	4 (7%)
NEGROID	1 (2%)	2 (3%)
WHITE	60 (92%)	53 (90%)
Missing	0	0
Weight (kg)		
N	65	59
Median	66.0	68.0
Mean	70.0	70.3
SD	21.1	15.6
Min	49	44
Max	179	106
Missing	0	0

Table 3.1: Stratified summary of baseline characteristics 27SEP2007
Analysis Set = Safety Population (N=200)

Variable	ASIAN		NEGROID		WHITE	
	Medisan 20 mg N=9	Novomed 100 mg N=10	Medisan 20 mg N=4	Novomed 100 mg N=5	Medisan 20 mg N=87	Novomed 100 mg N=85
Sex						
Male	2 (22%)	1 (10%)	1 (25%)	0 (0%)	9 (11%)	18 (21%)
Female	7 (78%)	9 (90%)	3 (75%)	5 (100%)	74 (89%)	67 (79%)
Missing	0	0	0	0	4	0
Weight (kg)						
N	9	10	4	5	86	85
Median	70.0	68.0	70.0	74.0	67.5	69.0
Mean	70.0	70.5	69.5	73.0	71.2	71.5
SD	8.6	15.6	7.7	18.1	20.4	16.4
Min	58	48	61	54	49	44
Max	84	92	77	100	179	134
Missing	0	0	0	0	1	0

&COLBY

&COLVAR

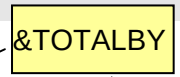


Table 3.2: Demographic characteristics strafied by race 27SEP2007
Analysis Set = ITT Population (N=193)

	ASIAN			NEGROID			WHITE		
Variable	Medisan 20 mg N=9	Novomed 100 mg N=9	TOTAL N=18	Medisan 20 mg N=4	Novomed 100 mg N=4	TOTAL N=8	Medisan 20 mg N=85	Novomed 100 mg N=82	TOTAL N=167
Sex									
Male	2 (22%)	1 (11%)	3 (2%)	1 (25%)	0 (0%)	1 (1%)	9 (11%)	17 (21%)	26 (14%)
Female	7 (78%)	8 (89%)	15 (8%)	3 (75%)	4 (100%)	7 (4%)	73 (89%)	65 (79%)	138 (73%)
Missing	0	0	0	0	0	0	3	0	3
Weight (kg)									
N	9	9	18	4	4	8	84	82	166
Median	70.0	65.0	69.5	70.0	76.0	74.5	67.5	69.5	69.0
Mean	70.0	70.0	70.0	69.5	77.8	73.6	71.2	71.7	71.5
SD	8.6	16.5	12.8	7.7	16.9	13.0	20.6	16.5	18.6
Min	58	48	48	61	59	59	49	44	44
Max	84	92	92	77	100	100	179	134	179
Missing	0	0	0	0	0	0	1	0	1

vs.weight is selected when VSBLFL='Y'

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Listing 2.1: Listing of baseline characteristics 27SEP2007
Analysis Set = Safety Population (N=200)
Treatment Group = Medisan 20 mg (N=100)

Usubjid	Height (cm)	Weight (kg)
001/0002	165	65
001/0004	169	61
001/0006	179	75
001/0008	171	77
001/0010	183	81
001/0012	167	98
001/0014	175	56
001/0016	168	78
001/0018	169	179
001/0020	167	49
001/0022	163	60
001/0024	169	83
001/0026	157	69
001/0028	168	77
001/0030	175	83
001/0032	164	59
001/0034	161	84
001/0036	167	58
001/0038	168	81
001/0040	166	71
001/0042	172	69
001/0044	160	70
001/0046	170	67
001/0048	165	71
001/0050	186	70
002/0002	166	59
002/0004	161	68
002/0006	179	57
002/0008	188	86
002/0010	162	51
002/0012	157	70
002/0014	157	60
002/0016	165	63
002/0018	172	69
002/0020	160	66
002/0022	153	66
002/0024	182	74
002/0026	165	100
002/0028	182	56
002/0030	171	70
002/0032	183	54
002/0034	165	66
002/0036	-	55
002/0038	161	59
002/0040	162	-
002/0042	55	63
002/0044	154	72
002/0046	170	72
002/0048	151	96
002/0050	166	89
003/0002	170	59

Table 15.1: Summary of concomitant medication and procedures &AGGVAR 27SEP2007
Analysis Set = Safety Population (N=200)

Treatment Class / Treatment/Procedure as Coded	Number (%) of Subjects Medisan 20 mg N=100	 Novomed 100 mg N=100
Subjects with any Treatment	33 (33)	35 (35)
ALPHA- AND BETA-ADRENORECEPTOR AGONISTS	8 (8)	5 (5)
EPINEPHRINE	4 (4)	0 (0)
EPINEPHRINE HYDROCHLORIDE	4 (4)	5 (5)
ANILIDES	6 (6)	5 (5)
PARACETAMOL	6 (6)	5 (5)
ANTIBIOTICS	2 (2)	2 (2)
AMPICILLIN	0 (0)	1 (1)
ANTIBIOTICS	1 (1)	1 (1)
ERYTHROMYCIN	1 (1)	0 (0)
BARBITURATES AND DERIVATIVES	1 (1)	0 (0)
PHENOBARBITAL	1 (1)	0 (0)
CARBAMATES	0 (0)	1 (1)
MEPROBAMATE	0 (0)	1 (1)
CARIES PROPHYLACTIC AGENTS	1 (1)	0 (0)
D-FLUORETTEN	1 (1)	0 (0)
CEPHALOSPORINS AND RELATED SUBSTANCES	0 (0)	1 (1)
CEFUROXIME	0 (0)	1 (1)
CONTACT LAXATIVES	0 (0)	1 (1)
BRYONIA	0 (0)	1 (1)
CORTICOSTEROIDS	2 (2)	3 (3)
BUDESONIDE	1 (1)	1 (1)
PREDNISOLONE	0 (0)	1 (1)
PREDNISOLONE SODIUM SUCCINATE	1 (1)	1 (1)
CORTICOSTEROIDS FOR LOCAL USE	1 (1)	0 (0)
PREDNISONE	1 (1)	0 (0)
EXPECTORANTS	0 (0)	1 (1)
BRONCHICUM	0 (0)	1 (1)
GLUCOCORTICOIDS	1 (1)	0 (0)
PREDNISONE	1 (1)	0 (0)
IMIDAZOLE DERIVATIVES	1 (1)	0 (0)
CLOTRIMAZOLE	1 (1)	0 (0)
MUCOLYTICS	3 (3)	6 (6)
ACETYLCYSTEINE	0 (0)	2 (2)

Listing 4.1: Other treatments (incl. medical procedures) by trial treatment and subject number 27SEP2007
Analysis Set = Safety Population (N=200)
Treatment Group = Medisan 20 mg (N=100)

Usubjid	Sex	Age (yr)	Treatment Class	Treatment/ Procedure as Coded	Dosage	Day of Onset	Stop Day	Reason Indication
001/0004	M	38	SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS	TERBUTALINE SULFATE	P Andere	235	235	HUSTEN
001/0012	F	45	SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS	FENOTEROL HYDROBROMIDE	1 Hub	382	382	PSEUDOCROUP
001/0018	F	52	ANTIBIOTICS	ANTIBIOTICS	U U	227	237	SUPERINFIZIERTE WINDPOCKEN
			OPIUM ALKALOIDS AND DERIVATIVES	CODIPRONT /OLD FORM/	1 Teelöffel	131	134	HUSTEN
001/0020	M	61	MUCOLYTICS	AMBROXOL HYDROCHLORIDE	4 Milliliter	156	-	KRUPP-HUSTEN
001/0030	F	44	OTHER NASAL PREPARATIONS	SODIUM CHLORIDE	8 Milliliter	154	155	BRONCHITIS
001/0040	F	39	ANILIDES	PARACETAMOL	250 mg	184	184	FIEBER
001/0046	F	27	ALPHA- AND BETA-ADRENORECEPTOR AGONISTS	EPINEPHRINE	2 Hub	-37	-37	PSEUDO-KRUPP
			GLUCOCORTICOIDS	PREDNISONE	100 mg	-37	-37	PSEUDO-KRUPP
002/0004	F	61	IMIDAZOLE DERIVATIVES	CLOTRIMAZOLE	P Andere	239	-	WINDELSOOR
			OTHER NASAL PREPARATIONS	SODIUM CHLORIDE	2 Milliliter	229	229	PSEUDOCROUP
002/0028	F	46	ALPHA- AND BETA-ADRENORECEPTOR AGONISTS	EPINEPHRINE	2 Hub	57	58	KEINE AUSREICHENDE BESSERUNG DURCH PRÜFMEDIKATION
002/0030	F	36	ANILIDES	PARACETAMOL	250 mg	-135	-135	FIEBER
			ANILIDES	PARACETAMOL	1000 mg	121	122	FIEBER
002/0034	F	37	ALPHA- AND BETA-ADRENORECEPTOR AGONISTS	EPINEPHRINE HYDROCHLORIDE	4 mg	321	321	STRIDOR, INSPIRATORISCH
			SYMPATHOMIMETICS, PLAIN	XYLOMETAZOLINE HYDROCHLORIDE	2 Tropfen	239	242	RHINITIS
002/0036	F	44	SYMPATHOMIMETICS, PLAIN	XYLOMETAZOLINE HYDROCHLORIDE	P Tropfen	27	-	KRUPP-EPISODEN
002/0038	F	42	CORTICOSTEROIDS	BUDESONIDE	1 mg	234	234	CROUPHUSTEN
002/0042	F	36	OPIUM ALKALOIDS AND DERIVATIVES	NOSCAPINE RESIN	P Andere	331	331	HUSTEN
002/0050	F	23	CORTICOSTEROIDS FOR LOCAL USE	PREDNISONE	1 Zäpfchen	324	324	PSEUDOKRUPP
003/0004	F	35	ANTIBIOTICS	ERYTHROMYCIN	10 Milliliter	299	-	BRONCHITIS
003/0006	F	34	ANILIDES	PARACETAMOL	250 mg	-52	-52	FIEBER
003/0012	F	21	SYMPATHOMIMETICS, PLAIN	XYLOMETAZOLINE HYDROCHLORIDE	P Andere	164	-	PSEUDOKRUPP

Table 50.1: Summary of extent of exposure to trial treatment 27SEP2007
Analysis Set = Safety Population (N=200)

	Medisan 20 mg N=100	Novomed 100 mg N=100
Number of Treatment Days		
N	100	100
Median	5.0	5.0
Mean	5.0	5.0
SD	0.1	0.0
Q1	5.0	5.0
Q3	5.0	5.0
Min	4	5
Max	5	5
Missing	0	0

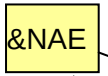
Listing 10.1: Exposure to trial treatment 27SEP2007
Analysis Set = Safety Population (N=200)
Treatment Group = Medisan 20 mg (N=100)

Usubjid	Sex	Age (yr)	Start Day	Stop Day	Treatment	Dose	Unit	Cumulative Dose
001/0002	F	61	1	1	Medisan 20 mg	250	ML	250 ML
			94	94	Medisan 20 mg	250	ML	500 ML
			182	182	Medisan 20 mg	250	ML	750 ML
			275	275	Medisan 20 mg	250	ML	1000 ML
			360	360	Medisan 20 mg	250	ML	1250 ML
001/0004	M	38	1	1	Medisan 20 mg	250	ML	250 ML
			86	86	Medisan 20 mg	250	ML	500 ML
			180	180	Medisan 20 mg	250	ML	750 ML
			270	270	Medisan 20 mg	250	ML	1000 ML
			366	366	Medisan 20 mg	250	ML	1250 ML
001/0006	F	26	1	1	Medisan 20 mg	400	ML	400 ML
			88	88	Medisan 20 mg	250	ML	650 ML
			174	174	Medisan 20 mg	250	ML	900 ML
			264	264	Medisan 20 mg	250	ML	1150 ML
			368	368	Medisan 20 mg	250	ML	1400 ML
001/0008	F	24	1	1	Medisan 20 mg	250	ML	250 ML
			94	94	Medisan 20 mg	250	ML	500 ML
			181	181	Medisan 20 mg	400	ML	900 ML
			275	275	Medisan 20 mg	250	ML	1150 ML
			364	364	Medisan 20 mg	250	ML	1400 ML
001/0010	F	64	1	1	Medisan 20 mg	250	ML	250 ML
			84	84	Medisan 20 mg	250	ML	500 ML
			176	176	Medisan 20 mg	250	ML	750 ML
			265	265	Medisan 20 mg	250	ML	1000 ML
			368	368	Medisan 20 mg	250	ML	1250 ML
001/0012	F	45	1	1	Medisan 20 mg	250	ML	250 ML
			83	83	Medisan 20 mg	250	ML	500 ML
			185	185	Medisan 20 mg	250	ML	750 ML
			267	267	Medisan 20 mg	250	ML	1000 ML
			363	363	Medisan 20 mg	250	ML	1250 ML
001/0014	F	19	1	1	Medisan 20 mg	250	ML	250 ML
			84	84	Medisan 20 mg	250	ML	500 ML
			182	182	Medisan 20 mg	250	ML	750 ML
			266	266	Medisan 20 mg	250	ML	1000 ML
			368	368	Medisan 20 mg	250	ML	1250 ML
001/0016	-	-	1	1	Medisan 20 mg	250	ML	250 ML
			93	93	Medisan 20 mg	250	ML	500 ML
			179	179	Medisan 20 mg	250	ML	750 ML
			269	269	Medisan 20 mg	250	ML	1000 ML
			364	364	Medisan 20 mg	250	ML	1250 ML

Table 51.1: Overall summary of adverse events 27SEP2007
Analysis Set = Safety Population (N=200)

	Number (%) of Subjects	
Subjects with	Medisan 20 mg N=100	Novomed 100 mg N=100
Any AE	90 (90)	93 (93)
Related AE	57 (57)	69 (69)
Serious AE	7 (7)	12 (12)
Serious Related AE	2 (2)	4 (4)
AE Resulting in Death	1 (1)	0 (0)
Related AE Resulting in Death	0 (0)	0 (0)
AE Causing Action on Study Drug:		
NONE	88 (88)	90 (90)
DISCONTINUED	9 (9)	5 (5)
INTERRUPTED	24 (24)	13 (13)
DECREASED	0 (0)	0 (0)
INCREASED	0 (0)	0 (0)
OTHER	0 (0)	0 (0)
Related AE Causing Action on Study Drug:		
NONE	45 (45)	63 (63)
DISCONTINUED	7 (7)	4 (4)
INTERRUPTED	15 (15)	12 (12)
DECREASED	0 (0)	0 (0)
INCREASED	0 (0)	0 (0)
OTHER	0 (0)	0 (0)

Table 51.2: Overall summary of adverse events 27SEP2007
Analysis Set = Safety Population (N=200)



	Number (%) of Subjects / AEs					
	Medisan 20 mg		Novomed 100 mg		TOTAL	
Subjects with	N=100	nAE=278	N=100	nAE=273	N=200	nAE=551
Any AE	90 (90)	278 (100)	93 (93)	273 (100)	183 (92)	551 (100)
Related AE	57 (57)	86 (31)	69 (69)	109 (40)	126 (63)	195 (35)
Serious AE	7 (7)	7 (3)	12 (12)	14 (5)	19 (10)	21 (4)
Serious Related AE	2 (2)	2 (1)	4 (4)	4 (1)	6 (3)	6 (1)
AE Resulting in Death	1 (1)	1 (0)	0 (0)	0 (0)	1 (1)	1 (0)
Related AE Resulting in Death	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
AE Causing Action on Study Drug:						
NONE	88 (88)	235 (85)	90 (90)	252 (92)	178 (89)	487 (88)
DISCONTINUED	9 (9)	12 (4)	5 (5)	5 (2)	14 (7)	17 (3)
INTERRUPTED	24 (24)	28 (10)	13 (13)	15 (5)	37 (19)	43 (8)
DECREASED	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INCREASED	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
OTHER	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Related AE Causing Action on Study Drug:						
NONE	45 (45)	57 (21)	63 (63)	91 (33)	108 (54)	148 (27)
DISCONTINUED	7 (7)	7 (3)	4 (4)	4 (1)	11 (6)	11 (2)
INTERRUPTED	15 (15)	19 (7)	12 (12)	13 (5)	27 (14)	32 (6)
DECREASED	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
INCREASED	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
OTHER	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Table 52.1: Overall stratified summary of adverse events 27SEP2007
Analysis Set = Safety Population (N=200)

	Number (%) of Subjects			
	Male		Female	
Subjects with	Medisan 20 mg N=12	Novomed 100 mg N=19	Medisan 20 mg N=84	Novomed 100 mg N=81
Any AE	11 (92)	19 (100)	75 (89)	74 (91)
Related AE	9 (75)	12 (63)	46 (55)	57 (70)
Serious AE	2 (17)	2 (11)	5 (6)	10 (12)
Serious Related AE	0 (0)	0 (0)	2 (2)	4 (5)
AE Resulting in Death	0 (0)	0 (0)	1 (1)	0 (0)
Related AE Resulting in Death	0 (0)	0 (0)	0 (0)	0 (0)
AE Causing Action on Study Drug:				
NONE	10 (83)	19 (100)	74 (88)	71 (88)
DISCONTINUED	1 (8)	1 (5)	8 (10)	4 (5)
INTERRUPTED	3 (25)	2 (11)	20 (24)	11 (14)
DECREASED	0 (0)	0 (0)	0 (0)	0 (0)
INCREASED	0 (0)	0 (0)	0 (0)	0 (0)
OTHER	0 (0)	0 (0)	0 (0)	0 (0)
Related AE Causing Action on Study Drug:				
NONE	7 (58)	11 (58)	36 (43)	52 (64)
DISCONTINUED	1 (8)	1 (5)	6 (7)	3 (4)
INTERRUPTED	0 (0)	2 (11)	15 (18)	10 (12)
DECREASED	0 (0)	0 (0)	0 (0)	0 (0)
INCREASED	0 (0)	0 (0)	0 (0)	0 (0)
OTHER	0 (0)	0 (0)	0 (0)	0 (0)

Table 53.1: Summary of adverse events 27SEP2007
Analysis Set = Safety Population (N=200)

System Organ Class / Preferred Term	Number (%) of Subjects Medisan 20 mg N=100	 Novomed 100 mg N=100
Subjects with any AE	90 (90)	93 (93)
Infections and infestations	11 (11)	2 (2)
Abscess	0 (0)	1 (1)
Candiduria	1 (1)	0 (0)
Fungal infection	1 (1)	0 (0)
Helicobacter gastritis	2 (2)	0 (0)
Herpes simplex	1 (1)	0 (0)
Herpes zoster	4 (4)	0 (0)
Influenza	2 (2)	1 (1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (1)	1 (1)
Infected epidermal cyst	1 (1)	1 (1)
Immune system disorders	2 (2)	0 (0)
Dermatitis allergic	2 (2)	0 (0)
Endocrine disorders	1 (1)	1 (1)
Goitre haemorrhage	1 (1)	1 (1)
Metabolism and nutrition disorders	0 (0)	2 (2)
Oedema peripheral	0 (0)	2 (2)
Psychiatric disorders	5 (5)	9 (9)
Decreased interest	2 (2)	0 (0)
Depression	1 (1)	1 (1)
Disturbance in attention	0 (0)	1 (1)
Nightmare	1 (1)	4 (4)
Sleep disorder	1 (1)	3 (3)
Nervous system disorders	59 (59)	54 (54)
Carpal tunnel syndrome	3 (3)	0 (0)
Dizziness	5 (5)	5 (5)
Dizziness postural	0 (0)	1 (1)
Headache	25 (25)	26 (26)
Insomnia	1 (1)	5 (5)
Migraine	43 (43)	29 (29)
Tension headache	1 (1)	0 (0)
Trigeminal neuralgia	0 (0)	1 (1)
Ear and labyrinth disorders	3 (3)	2 (2)
Middle ear effusion	2 (2)	1 (1)
Tinnitus	1 (1)	1 (1)
Cardiac disorders	4 (4)	4 (4)
Angina pectoris	1 (1)	0 (0)
Bradycardia	0 (0)	1 (1)
Cardiac disorder	1 (1)	2 (2)

Table 53.2: Summary of adverse events with incidence >= 5% 27SEP2007
Females only
Analysis Set = Safety Population (N=165)

	Number (%) of Subjects		
Preferred Term	Medisan 20 mg N=84	Novomed 100 mg N=81	Total N=165
Subjects with any AE	75 (89)	74 (91)	149 (90)
Migraine	35 (42)	27 (33)	62 (38)
Headache	20 (24)	21 (26)	41 (25)
Fatigue	12 (14)	8 (10)	20 (12)
Back pain	8 (10)	9 (11)	17 (10)
Haematoma	7 (8)	9 (11)	16 (10)
Musculoskeletal pain	7 (8)	6 (7)	13 (8)
Haemodynamic instability	3 (4)	8 (10)	11 (7)
Nausea	6 (7)	4 (5)	10 (6)
Rhinitis	3 (4)	6 (7)	9 (5)

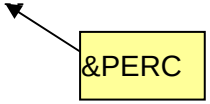


Table 55.1: Stratified summary of adverse events 27SEP2007
Analysis Set = Safety Population (N=200)

System Organ Class / Preferred Term	Male: Medisan 20 mg N=12	Male: Novomed 100 mg N=19	Female: Medisan 20 mg N=84	Female: Novomed 100 mg N=81
	Number (%) of Subjects			
Subjects with any AE	11 (92)	19 (100)	75 (89)	74 (91)
Infections and infestations	2 (17)	1 (5)	8 (10)	1 (1)
Abscess	0 (0)	0 (0)	0 (0)	1 (1)
Candiduria	0 (0)	0 (0)	1 (1)	0 (0)
Fungal infection	0 (0)	0 (0)	0 (0)	0 (0)
Helicobacter gastritis	0 (0)	0 (0)	2 (2)	0 (0)
Herpes simplex	1 (8)	0 (0)	0 (0)	0 (0)
Herpes zoster	1 (8)	0 (0)	3 (4)	0 (0)
Influenza	0 (0)	1 (5)	2 (2)	0 (0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0 (0)	1 (5)	1 (1)	0 (0)
Infected epidermal cyst	0 (0)	1 (5)	1 (1)	0 (0)
Immune system disorders	0 (0)	0 (0)	2 (2)	0 (0)
Dermatitis allergic	0 (0)	0 (0)	2 (2)	0 (0)
Endocrine disorders	0 (0)	0 (0)	1 (1)	1 (1)
Goitre haemorrhage	0 (0)	0 (0)	1 (1)	1 (1)
Metabolism and nutrition disorders	0 (0)	1 (5)	0 (0)	1 (1)
Oedema peripheral	0 (0)	1 (5)	0 (0)	1 (1)
Psychiatric disorders	1 (8)	1 (5)	4 (5)	8 (10)
Decreased interest	0 (0)	0 (0)	2 (2)	0 (0)
Depression	1 (8)	0 (0)	0 (0)	1 (1)
Disturbance in attention	0 (0)	0 (0)	0 (0)	1 (1)
Nightmare	0 (0)	1 (5)	1 (1)	3 (4)
Sleep disorder	0 (0)	0 (0)	1 (1)	3 (4)
Nervous system disorders	8 (67)	8 (42)	47 (56)	46 (57)
Carpal tunnel syndrome	1 (8)	0 (0)	2 (2)	0 (0)
Dizziness	2 (17)	0 (0)	3 (4)	5 (6)
Dizziness postural	0 (0)	0 (0)	0 (0)	1 (1)
Headache	3 (25)	5 (26)	20 (24)	21 (26)
Insomnia	0 (0)	2 (11)	1 (1)	3 (4)
Migraine	6 (50)	2 (11)	35 (42)	27 (33)
Tension headache	0 (0)	0 (0)	1 (1)	0 (0)
Trigeminal neuralgia	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	1 (5)	3 (4)	1 (1)
Middle ear effusion	0 (0)	0 (0)	2 (2)	1 (1)
Tinnitus	0 (0)	1 (5)	1 (1)	0 (0)
Cardiac disorders	1 (8)	1 (5)	3 (4)	3 (4)
Angina pectoris	0 (0)	0 (0)	1 (1)	0 (0)

Protocol: N12345 (Sponsor: Schmidt & CO KG)
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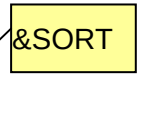
Table 54.1: Summary of adverse events 27SEP2007
Analysis Set = Safety Population (N=200)

System Organ Class / Preferred Term	Medisan 20 mg N=100	Novomed 100 mg N=100	P-Value*
	Number (%) of Subjects		
Subjects with any AE	90 (90)	93 (93)	0.6133
Infections and infestations	11 (11)	2 (2)	0.0184
Abscess	0 (0)	1 (1)	1.0000
Candiduria	1 (1)	0 (0)	1.0000
Fungal infection	1 (1)	0 (0)	1.0000
Helicobacter gastritis	2 (2)	0 (0)	0.4975
Herpes simplex	1 (1)	0 (0)	1.0000
Herpes zoster	4 (4)	0 (0)	0.1212
Influenza	2 (2)	1 (1)	1.0000
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (1)	1 (1)	1.0000
Infected epidermal cyst	1 (1)	1 (1)	1.0000
Immune system disorders	2 (2)	0 (0)	0.4975
Dermatitis allergic	2 (2)	0 (0)	0.4975
Endocrine disorders	1 (1)	1 (1)	1.0000
Goitre haemorrhage	1 (1)	1 (1)	1.0000
Metabolism and nutrition disorders	0 (0)	2 (2)	0.4975
Oedema peripheral	0 (0)	2 (2)	0.2790
Psychiatric disorders	5 (5)	9 (9)	0.4068
Decreased interest	2 (2)	0 (0)	0.4975
Depression	1 (1)	1 (1)	1.0000
Disturbance in attention	0 (0)	1 (1)	1.0000
Nightmare	1 (1)	4 (4)	0.3687
Sleep disorder	1 (1)	3 (3)	0.6212
Nervous system disorders	59 (59)	54 (54)	0.5684
Carpal tunnel syndrome	3 (3)	0 (0)	0.2462
Dizziness	5 (5)	5 (5)	1.0000
Dizziness postural	0 (0)	1 (1)	1.0000
Headache	25 (25)	26 (26)	1.0000
Insomnia	1 (1)	5 (5)	0.2116
Migraine	43 (43)	29 (29)	0.0551
Tension headache	1 (1)	0 (0)	1.0000
Trigeminal neuralgia	0 (0)	1 (1)	1.0000
Ear and labyrinth disorders	3 (3)	2 (2)	1.0000
Middle ear effusion	2 (2)	1 (1)	1.0000
Tinnitus	1 (1)	1 (1)	1.0000
Cardiac disorders	4 (4)	4 (4)	1.0000
Angina pectoris	1 (1)	0 (0)	1.0000
Bradycardia	0 (0)	1 (1)	1.0000

* Fisher's exact test

Table 54.2: Summary of adverse events with incidence >= 5% 16OCT2007
Females only
Analysis Set = Safety Population (N=165)



	Number (%) of Subjects		
Preferred Term	Medisan 20 mg N=84	Novomed 100 mg N=81	P-Value*
Subjects with any AE	75 (89)	74 (91)	1.0000
Haemodynamic instability	3 (4)	8 (10)	0.2134
Migraine	35 (42)	27 (33)	0.2845
Fatigue	12 (14)	8 (10)	0.4804
Rhinitis	3 (4)	6 (7)	0.4977
Nausea	6 (7)	4 (5)	0.7475
Haematoma	7 (8)	9 (11)	0.7953
Back pain	8 (10)	9 (11)	1.0000
Headache	20 (24)	21 (26)	1.0000
Musculoskeletal pain	7 (8)	6 (7)	1.0000

* Fisher's exact test
This output was produced with MAKS
MAKS is a library of SAS Macros

Table 64.1: Summary of serious adverse events 27SEP2007
Analysis Set = Safety Population (N=200)

System Organ Class / Preferred Term	Medisan 20 mg N=100		Novomed 100 mg N=100	
	Number (%) of Subjects			
	Serious AEs	All AEs	Serious AEs	All AEs
Subjects with any AE	7 (7)	90 (90)	12 (12)	93 (93)
Infections and infestations	0 (0)	11 (11)	1 (1)	2 (2)
Abscess	0 (0)	0 (0)	1 (1)	1 (1)
Candiduria	0 (0)	1 (1)	0 (0)	0 (0)
Fungal infection	0 (0)	1 (1)	0 (0)	0 (0)
Helicobacter gastritis	0 (0)	2 (2)	0 (0)	0 (0)
Herpes simplex	0 (0)	1 (1)	0 (0)	0 (0)
Herpes zoster	0 (0)	4 (4)	0 (0)	0 (0)
Influenza	0 (0)	2 (2)	0 (0)	1 (1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0 (0)	1 (1)	0 (0)	1 (1)
Infected epidermal cyst	0 (0)	1 (1)	0 (0)	1 (1)
Immune system disorders	0 (0)	2 (2)	0 (0)	0 (0)
Dermatitis allergic	0 (0)	2 (2)	0 (0)	0 (0)
Endocrine disorders	0 (0)	1 (1)	0 (0)	1 (1)
Goitre haemorrhage	0 (0)	1 (1)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	2 (2)
Oedema peripheral	0 (0)	0 (0)	0 (0)	2 (2)
Psychiatric disorders	0 (0)	5 (5)	0 (0)	9 (9)
Decreased interest	0 (0)	2 (2)	0 (0)	0 (0)
Depression	0 (0)	1 (1)	0 (0)	1 (1)
Disturbance in attention	0 (0)	0 (0)	0 (0)	1 (1)
Nightmare	0 (0)	1 (1)	0 (0)	4 (4)
Sleep disorder	0 (0)	1 (1)	0 (0)	3 (3)
Nervous system disorders	0 (0)	59 (59)	4 (4)	54 (54)
Carpal tunnel syndrome	0 (0)	3 (3)	0 (0)	0 (0)
Dizziness	0 (0)	5 (5)	1 (1)	5 (5)
Dizziness postural	0 (0)	0 (0)	0 (0)	1 (1)
Headache	0 (0)	25 (25)	2 (2)	26 (26)
Insomnia	0 (0)	1 (1)	1 (1)	5 (5)
Migraine	0 (0)	43 (43)	0 (0)	29 (29)
Tension headache	0 (0)	1 (1)	0 (0)	0 (0)
Trigeminal neuralgia	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	3 (3)	0 (0)	2 (2)
Middle ear effusion	0 (0)	2 (2)	0 (0)	1 (1)
Tinnitus	0 (0)	1 (1)	0 (0)	1 (1)
Cardiac disorders	0 (0)	4 (4)	0 (0)	4 (4)
Angina pectoris	0 (0)	1 (1)	0 (0)	0 (0)
Bradycardia	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorder	0 (0)	1 (1)	0 (0)	2 (2)

Table 65.1: Criteria for serious adverse events 27SEP2007
Analysis Set = Safety Population (N=200)

Seriousness Criterion	Number (%) of Subjects Medisan 20 mg N=100	 Novomed 100 mg N=100
Subjects with any SAE	7 (7)	12 (12)
INVOLVES CANCER	5 (5)	7 (7)
CONGENITAL ANOMALY / BIRTH DEFECT	2 (2)	6 (6)
PERSISTS SIGNIFICANT DISABILITY / INCAPACITY	5 (5)	7 (7)
DEATH	2 (2)	6 (6)
REQUIRING / PROLONGING HOSPITALIZATION	5 (5)	7 (7)
LIFE THREATENING	2 (2)	6 (6)
OCCURRED WITH OVERDOSE	5 (5)	7 (7)
OTHER MEDICAL IMPORTANCE	2 (2)	6 (6)

Table 66.1: Stratified criteria for serious adverse events 27SEP2007
Analysis Set = Safety Population (N=200)

	Number (%) of Subjects					
	ASIAN		NEGROID		WHITE	
Seriousness Criterion	Medisan 20 mg N=9	Novomed 100 mg N=10	Medisan 20 mg N=4	Novomed 100 mg N=5	Medisan 20 mg N=87	Novomed 100 mg N=85
Subjects with any SAE	0 (0)	2 (20)	0 (0)	0 (0)	7 (8)	10 (12)
INVOLVES CANCER	0 (0)	1 (10)	0 (0)	0 (0)	5 (6)	6 (7)
CONGENITAL ANOMALY / BIRTH DEFECT	0 (0)	1 (10)	0 (0)	0 (0)	2 (2)	5 (6)
PERSISTS SIGNIFICANT DISABILITY / INCAPACITY	0 (0)	1 (10)	0 (0)	0 (0)	5 (6)	6 (7)
DEATH	0 (0)	1 (10)	0 (0)	0 (0)	2 (2)	5 (6)
REQUIRING / PROLONGING HOSPITALIZATION	0 (0)	1 (10)	0 (0)	0 (0)	5 (6)	6 (7)
LIFE THREATENING	0 (0)	1 (10)	0 (0)	0 (0)	2 (2)	5 (6)
OCCURRED WITH OVERDOSE	0 (0)	1 (10)	0 (0)	0 (0)	5 (6)	6 (7)
OTHER MEDICAL IMPORTANCE	0 (0)	1 (10)	0 (0)	0 (0)	2 (2)	5 (6)

Table 63.1: Summary of related adverse events 27SEP2007
Analysis Set = Safety Population (N=200)

System Organ Class / Preferred Term	Number (%) of Subjects			
	Medisan 20 mg N=100		Novomed 100 mg N=100	
	Related AEs	All AEs	Related AEs	All AEs
Subjects with any AE	57 (57)	90 (90)	69 (69)	93 (93)
Infections and infestations	1 (1)	11 (11)	1 (1)	2 (2)
Abscess	0 (0)	0 (0)	0 (0)	1 (1)
Candiduria	0 (0)	1 (1)	0 (0)	0 (0)
Fungal infection	0 (0)	1 (1)	0 (0)	0 (0)
Helicobacter gastritis	0 (0)	2 (2)	0 (0)	0 (0)
Herpes simplex	0 (0)	1 (1)	0 (0)	0 (0)
Herpes zoster	0 (0)	4 (4)	0 (0)	0 (0)
Influenza	1 (1)	2 (2)	1 (1)	1 (1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0 (0)	1 (1)	0 (0)	1 (1)
Infected epidermal cyst	0 (0)	1 (1)	0 (0)	1 (1)
Immune system disorders	1 (1)	2 (2)	0 (0)	0 (0)
Dermatitis allergic	1 (1)	2 (2)	0 (0)	0 (0)
Endocrine disorders	0 (0)	1 (1)	0 (0)	1 (1)
Goitre haemorrhage	0 (0)	1 (1)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	2 (2)
Oedema peripheral	0 (0)	0 (0)	0 (0)	2 (2)
Psychiatric disorders	4 (4)	5 (5)	6 (6)	9 (9)
Decreased interest	2 (2)	2 (2)	0 (0)	0 (0)
Depression	0 (0)	1 (1)	0 (0)	1 (1)
Disturbance in attention	0 (0)	0 (0)	1 (1)	1 (1)
Nightmare	1 (1)	1 (1)	2 (2)	4 (4)
Sleep disorder	1 (1)	1 (1)	3 (3)	3 (3)
Nervous system disorders	14 (14)	59 (59)	20 (20)	54 (54)
Carpal tunnel syndrome	0 (0)	3 (3)	0 (0)	0 (0)
Dizziness	4 (4)	5 (5)	3 (3)	5 (5)
Dizziness postural	0 (0)	0 (0)	1 (1)	1 (1)
Headache	5 (5)	25 (25)	7 (7)	26 (26)
Insomnia	0 (0)	1 (1)	2 (2)	5 (5)
Migraine	7 (7)	43 (43)	6 (6)	29 (29)
Tension headache	0 (0)	1 (1)	0 (0)	0 (0)
Trigeminal neuralgia	0 (0)	0 (0)	1 (1)	1 (1)
Ear and labyrinth disorders	1 (1)	3 (3)	1 (1)	2 (2)
Middle ear effusion	0 (0)	2 (2)	0 (0)	1 (1)
Tinnitus	1 (1)	1 (1)	1 (1)	1 (1)
Cardiac disorders	3 (3)	4 (4)	4 (4)	4 (4)
Angina pectoris	0 (0)	1 (1)	0 (0)	0 (0)
Bradycardia	0 (0)	0 (0)	1 (1)	1 (1)
Cardiac disorder	1 (1)	1 (1)	2 (2)	2 (2)

Table 62.1: Summary of adverse events by intensity (all occurences) 27SEP2007
Analysis Set = Safety Population (N=200)

System Organ Class / Preferred Term	Number (%) of Subjects					
	Medisan 20 mg N=100			Novomed 100 mg N=100		
	MILD	MODERATE	SEVERE	MILD	MODERATE	SEVERE
Subjects with any AE	77 (77)	55 (55)	24 (24)	71 (71)	64 (64)	24 (24)
Infections and infestations	4 (4)	6 (6)	1 (1)	0 (0)	1 (1)	1 (1)
Abscess	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Candiduria	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Fungal infection	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Helicobacter gastritis	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Herpes simplex	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Herpes zoster	1 (1)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)
Influenza	0 (0)	1 (1)	1 (1)	0 (0)	1 (1)	0 (0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Infected epidermal cyst	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Immune system disorders	1 (1)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Dermatitis allergic	1 (1)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Endocrine disorders	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Goitre haemorrhage	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Oedema peripheral	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Psychiatric disorders	4 (4)	2 (2)	0 (0)	6 (6)	3 (3)	0 (0)
Decreased interest	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Depression	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)
Disturbance in attention	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Nightmare	1 (1)	1 (1)	0 (0)	2 (2)	2 (2)	0 (0)
Sleep disorder	1 (1)	0 (0)	0 (0)	3 (3)	0 (0)	0 (0)
Nervous system disorders	40 (40)	28 (28)	12 (12)	29 (29)	28 (28)	9 (9)
Carpal tunnel syndrome	0 (0)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)
Dizziness	2 (2)	3 (3)	0 (0)	4 (4)	0 (0)	1 (1)
Dizziness postural	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Headache	19 (19)	7 (7)	3 (3)	17 (17)	7 (7)	5 (5)
Insomnia	0 (0)	1 (1)	0 (0)	2 (2)	2 (2)	0 (0)
Migraine	25 (25)	17 (17)	9 (9)	13 (13)	19 (19)	3 (3)
Tension headache	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Trigeminal neuralgia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	2 (2)	2 (2)	0 (0)	1 (1)	1 (1)	0 (0)
Middle ear effusion	1 (1)	2 (2)	0 (0)	0 (0)	1 (1)	0 (0)
Tinnitus	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Cardiac disorders	2 (2)	2 (2)	0 (0)	1 (1)	3 (3)	0 (0)
Angina pectoris	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bradycardia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)

Table 61.1: Summary of adverse events by intensity (most severe occurrence) 27SEP2007
Analysis Set = Safety Population (N=200)

System Organ Class / Preferred Term	Number (%) of Subjects					
	Medisan 20 mg N=100			Novomed 100 mg N=100		
	MILD	MODERATE	SEVERE	MILD	MODERATE	SEVERE
Subjects with any AE	70 (70)	54 (54)	24 (24)	65 (65)	63 (63)	24 (24)
Infections and infestations	4 (4)	6 (6)	1 (1)	0 (0)	1 (1)	1 (1)
Abscess	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Candiduria	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Fungal infection	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Helicobacter gastritis	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Herpes simplex	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Herpes zoster	1 (1)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)
Influenza	0 (0)	1 (1)	1 (1)	0 (0)	1 (1)	0 (0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Infected epidermal cyst	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Immune system disorders	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Dermatitis allergic	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Endocrine disorders	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Goitre haemorrhage	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Oedema peripheral	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Psychiatric disorders	3 (3)	2 (2)	0 (0)	6 (6)	3 (3)	0 (0)
Decreased interest	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Depression	0 (0)	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)
Disturbance in attention	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Nightmare	0 (0)	1 (1)	0 (0)	2 (2)	2 (2)	0 (0)
Sleep disorder	1 (1)	0 (0)	0 (0)	3 (3)	0 (0)	0 (0)
Nervous system disorders	32 (32)	27 (27)	12 (12)	24 (24)	26 (26)	9 (9)
Carpal tunnel syndrome	0 (0)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)
Dizziness	2 (2)	3 (3)	0 (0)	4 (4)	0 (0)	1 (1)
Dizziness postural	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Headache	15 (15)	7 (7)	3 (3)	14 (14)	7 (7)	5 (5)
Insomnia	0 (0)	1 (1)	0 (0)	2 (2)	2 (2)	0 (0)
Migraine	18 (18)	15 (15)	9 (9)	9 (9)	17 (17)	3 (3)
Tension headache	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Trigeminal neuralgia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	1 (1)	2 (2)	0 (0)	1 (1)	1 (1)	0 (0)
Middle ear effusion	0 (0)	2 (2)	0 (0)	0 (0)	1 (1)	0 (0)
Tinnitus	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Cardiac disorders	2 (2)	2 (2)	0 (0)	1 (1)	3 (3)	0 (0)
Angina pectoris	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

*In case of multiple AEs with identical MedDRA level term only the most severe occurrence is counted

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Listing 12.1: Adverse events by trial treatment and subject number 27SEP2007
Analysis Set = Safety Population (N=200)
Treatment Group = Medisan 20 mg (N=100)

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Usubjid / Adverse Event as Coded	Sex	Age (yr)	Weight (kg)	Severity	Onset Day	Days since Last Study Treatment	Duration (Days)	Relationship to Study Treatment	Action on Study Treatment	Other Action	Outcome
001/0002	F	61	65								
Middle ear effusion				MODERATE	91	90	17	UNRELATED	NONE	COUNTERACTIVE MEDICATION	RESOLVED WITH SEQUELAE
Middle ear effusion				MILD	91	90	17	UNRELATED	NONE	COUNTERACTIVE MEDICATION	RESOLVED WITH SEQUELAE
Middle ear effusion				MILD	91	90	17	UNRELATED	NONE	COUNTERACTIVE MEDICATION	RESOLVED WITH SEQUELAE
001/0004	M	38	61								
Haematoma				MODERATE	62	61	198	UNRELATED	NONE	NONE	RESOLVED WITH SEQUELAE
Haematoma				MILD	62	61	198	UNRELATED	NONE	NONE	RESOLVED WITH SEQUELAE
Haematoma				MILD	62	61	198	UNRELATED	NONE	NONE	RESOLVED WITH SEQUELAE
Haemodynamic instability				MODERATE	218	37	123	POSSIBLY	NONE	NONE	RESOLVED WITH SEQUELAE
Haemodynamic instability				MILD	218	37	123	POSSIBLY	NONE	NONE	RESOLVED WITH SEQUELAE
Haemodynamic instability				MILD	218	37	123	POSSIBLY	NONE	NONE	RESOLVED WITH SEQUELAE
001/0006	F	26	75								
Condition aggravated				MODERATE	43	42	93	POSSIBLY	DISCONTINUED	COUNTERACTIVE MEDICATION	RESOLVED WITH SEQUELAE
Condition aggravated				MILD	43	42	93	POSSIBLY	DISCONTINUED	COUNTERACTIVE MEDICATION	RESOLVED WITH SEQUELAE
Condition aggravated				MILD	43	42	93	POSSIBLY	DISCONTINUED	COUNTERACTIVE MEDICATION	RESOLVED WITH SEQUELAE
Nightmare				MODERATE	139	50	231+	UNRELATED	NONE	NONE	RESOLVED WITH SEQUELAE
Nightmare				MILD	139	50	231+	UNRELATED	NONE	NONE	RESOLVED WITH SEQUELAE
Nightmare				MILD	139	50	231+	UNRELATED	NONE	NONE	RESOLVED WITH SEQUELAE
Musculoskeletal pain				MODERATE	252	77	58	UNRELATED	NONE	OTHER	IMPROVED
Musculoskeletal pain				MILD	252	77	58	UNRELATED	NONE	OTHER	IMPROVED
Musculoskeletal pain				MILD	252	77	58	UNRELATED	NONE	OTHER	IMPROVED
Bronchitis				MODERATE	361	96	9+	PROBABLY	NONE	NONE	RESOLVED WITH SEQUELAE
Bronchitis				MILD	361	96	9+	PROBABLY	NONE	NONE	RESOLVED WITH SEQUELAE
Bronchitis				MILD	361	96	9+	PROBABLY	NONE	NONE	RESOLVED WITH SEQUELAE

! = Serious adverse event
* = Further comment available for this adverse event
+ = Ongoing at end of study

Protocol: N12345 (Sponsor: Schmidt & CO KG)
Source: T:\DMST\STUDIEN\MAKSVALIDATION\HAUPTMAKROS\DUMMYSTUDY1\PROG\MUSTERAUFRUFE\L12_LAE_1.sas

Listing 12.2: Listing of adverse events 27SEP2007
Analysis Set = Safety Population (N=200)
Treatment Group = Medisan 20 mg (N=100)

Usubjid	Sex	Age (yr)	Weight (kg)	Adverse Event as Coded	Severity	Onset Day	Time since Last Study Treatment D H:M	Duration (Time) D H:M	Relationship to Study Treatment	Action on Study Treatment	Other Action	Outcome
001/0002	F	61	65									
				Middle ear effusion	MODERATE	91	90 8:55	15 17:37	UNRELATED	NONE	COUNTERACTIVE MEDICATION	RESOLVED WITH SEQUELAE
				Middle ear effusion	MILD	91	90 8:55	15 17:37	UNRELATED	NONE	COUNTERACTIVE MEDICATION	RESOLVED WITH SEQUELAE
				Middle ear effusion	MILD	91	90 8:55	15 17:37	UNRELATED	NONE	COUNTERACTIVE MEDICATION	RESOLVED WITH SEQUELAE
001/0004	M	38	61									
				Haematoma	MODERATE	62	61 21:54	196 6:03	UNRELATED	NONE	NONE	RESOLVED WITH SEQUELAE
				Haematoma	MILD	62	61 21:54	196 6:03	UNRELATED	NONE	NONE	RESOLVED WITH SEQUELAE
				Haematoma	MILD	62	61 21:54	196 6:03	UNRELATED	NONE	NONE	RESOLVED WITH SEQUELAE
				Haemodynamic instability	MODERATE	218	37 7:22	122 5:03	POSSIBLY	NONE	NONE	RESOLVED WITH SEQUELAE
				Haemodynamic instability	MILD	218	37 7:22	122 5:03	POSSIBLY	NONE	NONE	RESOLVED WITH SEQUELAE
				Haemodynamic instability	MILD	218	37 7:22	122 5:03	POSSIBLY	NONE	NONE	RESOLVED WITH SEQUELAE
001/0006	F	26	75									
				Condition aggravated	MODERATE	43	42 4:11	92 8:42	POSSIBLY	DISCONTINUED	COUNTERACTIVE MEDICATION	RESOLVED WITH SEQUELAE
				Condition aggravated	MILD	43	42 4:11	92 8:42	POSSIBLY	DISCONTINUED	COUNTERACTIVE MEDICATION	RESOLVED WITH SEQUELAE
				Condition aggravated	MILD	43	42 4:11	92 8:42	POSSIBLY	DISCONTINUED	COUNTERACTIVE MEDICATION	RESOLVED WITH SEQUELAE
				Nightmare	MODERATE	139	50 12:38	230 11:22+	UNRELATED	NONE	NONE	RESOLVED WITH SEQUELAE
				Nightmare	MILD	139	50 12:38	230 11:22+	UNRELATED	NONE	NONE	RESOLVED WITH SEQUELAE
				Nightmare	MILD	139	50 12:38	230 11:22+	UNRELATED	NONE	NONE	RESOLVED WITH SEQUELAE
				Musculoskeletal pain	MODERATE	252	77 17:11	57 3:07	UNRELATED	NONE	OTHER	IMPROVED
				Musculoskeletal pain	MILD	252	77 17:11	57 3:07	UNRELATED	NONE	OTHER	IMPROVED
				Musculoskeletal pain	MILD	252	77 17:11	57 3:07	UNRELATED	NONE	OTHER	IMPROVED
				Bronchitis	MODERATE	361	96 2:01	8 21:59+	PROBABLY	NONE	NONE	RESOLVED WITH SEQUELAE
				Bronchitis	MILD	361	96 2:01	8 21:59+	PROBABLY	NONE	NONE	RESOLVED WITH SEQUELAE

! = Serious adverse event
* = Further comment available for this adverse event
+ = Ongoing at end of study

Listing 13.1: Adverse events by trial treatment, System Organ Class, Preferred Term and subject number 27SEP2007
Analysis Set = Safety Population (N=200)
Treatment Group = Medisan 20 mg (N=100)

System Organ Class Adverse Event as Coded Usubjid	Sex	Age (yr)	Weight (kg)	Severity	Onset Day	Days since Last Study Treatment	Duration (Days)	Relationship to Study Treatment	Action on Study Treatment	Other Action	Outcome
Infections and infestations											
Candiduria											
002/0008	F	23	86	MODERATE	227	49	145+	UNRELATED	NONE	COUNTERACTIVE MEDICATION	-
Fungal infection											
004/0040	-	-	83	MODERATE	29	28	60	UNRELATED	NONE	NONE	RESOLVED WITH SEQUELAE
Helicobacter gastritis											
001/0014	F	19	56	MILD	312	45	58+	UNRELATED	DISCONTINUED	COUNTERACTIVE MEDICATION	RESOLVED WITH SEQUELAE
002/0050	F	23	89	MILD	182	0	191+	UNRELATED	DISCONTINUED	COUNTERACTIVE MEDICATION	RESOLVED WITH SEQUELAE
Herpes simplex											
* 004/0042	M	36	55	MILD	67	66	303+	UNRELATED	NONE	NONE	RESOLVED WITH SEQUELAE
Herpes zoster											
002/0040	M	41	-	MODERATE	107	19	196	UNRELATED	INTERRUPTED	COUNTERACTIVE MEDICATION	IMPROVED
003/0012	F	21	109	MODERATE	334	54	32+	UNRELATED	INTERRUPTED	COUNTERACTIVE MEDICATION	IMPROVED
003/0026	F	39	76	MILD	363	97	3+	UNRELATED	NONE	COUNTERACTIVE MEDICATION	RESOLVED WITH SEQUELAE
* 004/0012	F	26	68	MODERATE	59	58	61	UNRELATED	INTERRUPTED	COUNTERACTIVE MEDICATION	IMPROVED
Influenza											
001/0010	F	64	81	MODERATE	253	76	74	UNRELATED	NONE	OTHER	RESOLVED WITH SEQUELAE
* 003/0028	F	50	65	SEVERE	44	43	204	POSSIBLY	NONE	COUNTERACTIVE MEDICATION	ONGOING
Neoplasms benign, malignant and unspecified (incl cysts and polyps)											
Infected epidermal cyst											
002/0018	F	28	69	MILD	201	24	76	UNRELATED	NONE	COUNTERACTIVE MEDICATION	RESOLVED WITH SEQUELAE

! = Serious adverse event
* = Further comment available for this adverse event
+ = Ongoing at end of study

Table 11.1: Summary of medical history 27SEP2007
Analysis Set = Safety Population (N=200)

System Organ Class / Preferred Term	Number (%) of Subjects Medisan 20 mg N=100	 Novomed 100 mg N=100
Subjects with any Medical Condition	20 (20)	23 (23)
RESPIRATIONSTRAKT	15 (15)	13 (13)
HUSTEN	3 (3)	5 (5)
RHINITIS	5 (5)	0 (0)
BRONCHITIS	1 (1)	2 (2)
ADENOTOMIE	0 (0)	2 (2)
REZIDIVIERENDE INFEKTE DER ATEM	0 (0)	2 (2)
TONSILLEKTOMIE	2 (2)	0 (0)
ADENEKTOMIE	1 (1)	0 (0)
ASTHMA	1 (1)	0 (0)
ASTHMA BRONCHIALE	1 (1)	0 (0)
BRONCHITIDEN	0 (0)	1 (1)
HALSSCHMERZEN MIT HUSTEN	1 (1)	0 (0)
INFEKT D. OBEREN LUFTWEGE MIT H	0 (0)	1 (1)
KRUPP-HUSTEN	1 (1)	0 (0)
OBSTRUKTIVE BRONCHITIS	1 (1)	0 (0)
PHARYNGITIS	1 (1)	0 (0)
PSEUDOKRUPP	1 (1)	0 (0)
RESPIRATORY-SYNCYTIAL-VIRUS-BRO	0 (0)	1 (1)
REZIDIVIERENDE BRONCHITIDEN BIS	1 (1)	0 (0)
REZIDIVIERENDE OBSTRUKTIVE BRON	1 (1)	0 (0)
GENERALISIERTE STOERUNGEN	3 (3)	4 (4)
FIEBER	0 (0)	4 (4)
FIEBERHAFTER INFEKT	1 (1)	0 (0)
MULTIPLE ALLERGIEN	1 (1)	0 (0)
POLYPEKTOMIE (NASENPOLYPEN)	1 (1)	0 (0)
VERAENDERUNGEN DER WIDERSTANDKRAFT	3 (3)	4 (4)
OTITIS MEDIA	0 (0)	2 (2)
ADENOTOMIE MIT PARACENTESE	0 (0)	1 (1)
GERSTENKORN-OP, RE.	1 (1)	0 (0)
INFEKT MIT FIEBER UND HUSTEN	1 (1)	0 (0)
OTITIS SEROSA	0 (0)	1 (1)
WINDELSOOR	1 (1)	0 (0)
HAUT UND HAUTANHANGSGEBILDE	3 (3)	1 (1)
NEURODERMITIS	3 (3)	0 (0)
V.A. KAWASAKI	0 (0)	1 (1)
FERTILITAETSSTOERUNGEN DES MANNES	1 (1)	1 (1)
CIRCUMCISION BEI PHIMOSE	0 (0)	1 (1)
LEISTENBRUCH-OP RE U. LI	1 (1)	0 (0)
VERDAUUNGSTRAKT	0 (0)	2 (2)
DARM OP BEI "DARMVERSCHLINGUNG"	0 (0)	1 (1)
GASTROENTERITIS	0 (0)	1 (1)

Protocol: N12345 (Sponsor: Schmidt & CO KG)
Source: T:\DMST\STUDIEN\MAKSVALIDATION\HAUPTMAKROS\DUMMYSTUDY1\PROG\MUSTERAUFRUFE\T11_MH_1.sas

Table 12.1: Summary of medical history 27SEP2007
Analysis Set = Safety Population (N=537)

Reported Term	MEDISAN 500 N=179	MEDISAN 200 N=179	PLACEBO N=179
	Number (%) of Subjects		
Subjects with any Medical Condition	164 (92)	160 (89)	161 (90)
OTHER	78 (44)	84 (47)	85 (47)
GASTROINTESTINAL DISEASE	74 (41)	79 (44)	86 (48)
CARDIOVASCULAR DISEASE	65 (36)	60 (34)	59 (33)
EARS, EYES, NOSE, MOUTH AND THROAT DISEASE	57 (32)	49 (27)	55 (31)
RESPIRATORY DISEASE	45 (25)	47 (26)	48 (27)
ENDOCRINE/METABOLIC DISEASE	41 (23)	43 (24)	44 (25)
HEMATOLOGICAL/HEMATOPOIETIC/LYMPHATIC DISEASE	40 (22)	43 (24)	44 (25)
MUSCULOSKELETAL DISEASE	40 (22)	36 (20)	37 (21)
SURGERY/ACCIDENTS	39 (22)	35 (20)	35 (20)
NEUROLOGICAL DISEASE	35 (20)	32 (18)	33 (18)
PSYCHOLOGICAL/PSYCHIATRIC DISEASE	28 (16)	26 (15)	32 (18)
ALLERGIES	24 (13)	19 (11)	25 (14)
GENITO-URINARY DISEASE	22 (12)	23 (13)	21 (12)
DERMATOLOGICAL DISEASE	10 (6)	10 (6)	12 (7)

Listing 3.1: Medical history by trial treatment and subject number 27SEP2007
Analysis Set = Safety Population (N=200)
Treatment Group = Medisan 20 mg (N=100)

Usubjid	Sex	Age (yr)	System Organ Class	Preferred Term	Day of Onset
001/0034	F	61	HAUT UND HAUTANHANGSGEBILDE	EKZEM	< -512
001/0038	F	21	RESPIRATIONSTRAKT	RHINITIS	-31
001/0040	F	39	RESPIRATIONSTRAKT	PHARYNGITIS	< -493
			RESPIRATIONSTRAKT	BRONCHITIS	< -2319
001/0050	F	36	RESPIRATIONSTRAKT	CHRONISCH OBSTRUKTIVE ATEMWEGSERK	-1464
002/0002	F	25	RESPIRATIONSTRAKT	STRIDOR	-14
002/0010	F	36	RESPIRATIONSTRAKT	BRONCHITIS	-98
002/0012	F	31	HOER- UND GLEICHGEWICHTSSTOERUNGEN	HOERVERMINDERUNG	-76
002/0016	F	37	RESPIRATIONSTRAKT	RHINITIS	-56
002/0020	F	51	GENERALISIERTE STOERUNGEN	ALLERGIE	-120
002/0022	F	32	RESPIRATIONSTRAKT	ASTHMA	-978
002/0024	M	22	RESPIRATIONSTRAKT	PHARYNGITIS	-74
002/0026	M	48	VERAENDERUNGEN DER WIDERSTANDKRAFT	INFEKTION	-29
002/0036	F	44	VERAENDERUNGEN DER WIDERSTANDKRAFT	ABSZESS	< -748
002/0042	F	36	RESPIRATIONSTRAKT	RHINITIS	-40
002/0044	F	26	RESPIRATIONSTRAKT	HUSTEN	-91
002/0046	F	40	RESPIRATIONSTRAKT	HUSTEN	-69
003/0010	F	62	RESPIRATIONSTRAKT	RHINITIS	-53
003/0012	F	21	RESPIRATIONSTRAKT	HUSTEN	-10
			RESPIRATIONSTRAKT	HUSTEN	-82
003/0046	M	44	RESPIRATIONSTRAKT	HUSTEN	-27
004/0002	F	56	VERAENDERUNGEN DER WIDERSTANDKRAFT	MONILIASIS	-57

Listing 3.2: Listing of medical history 27SEP2007
Females only
Analysis Set = Safety Population (N=165)
Treatment Group = Medisan 20 mg (N=84)

Usubjid	Sex	Age (yr)	System Organ Class	Reported Term	Day of Onset
001/0034	F	61	HAUT UND HAUTANHANGSGEBILDE	NEURODERMITIS	< -512
001/0038	F	21	RESPIRATIONSTRAKT	RHINITIS	-31
001/0040	F	39	RESPIRATIONSTRAKT	ADENEKTOMIE	< -493
			RESPIRATIONSTRAKT	REZIDIVIERENDE BRONCHITIDEN BIS 5. LBJ.	< -2319
001/0050	F	36	RESPIRATIONSTRAKT	REZIDIVIERENDE OBSTRUKTIVE BRONCHITIDEN	-1464
002/0002	F	25	RESPIRATIONSTRAKT	PSEUDOKRUPP	-14
002/0010	F	36	RESPIRATIONSTRAKT	BRONCHITIS	-98
002/0012	F	31	HOER- UND GLEICHGEWICHTSSTOERUNGEN	HÖRMINDERUNG	-76
002/0016	F	37	RESPIRATIONSTRAKT	RHINITIS	-56
002/0020	F	51	GENERALISIERTE STOERUNGEN	MULTIPLE ALLERGIEN	-120
002/0022	F	32	RESPIRATIONSTRAKT	ASTHMA BRONCHIALE	-978
002/0036	F	44	VERAENDERUNGEN DER WIDERSTANDKRAFT	GERSTENKORN-OP, RE.	< -748
002/0042	F	36	RESPIRATIONSTRAKT	RHINITIS	-40
002/0044	F	26	RESPIRATIONSTRAKT	HUSTEN	-91
002/0046	F	40	RESPIRATIONSTRAKT	HALSSCHMERZEN MIT HUSTEN	-69
003/0010	F	62	RESPIRATIONSTRAKT	RHINITIS	-53
003/0012	F	21	RESPIRATIONSTRAKT	HUSTEN	-10
			RESPIRATIONSTRAKT	HUSTEN	-82
004/0002	F	56	VERAENDERUNGEN DER WIDERSTANDKRAFT	WINDELSOOR	-57

Table 1.1: Summary of patients disposition 27SEP2007
Analysis Set = Safety Population (N=200)

	Number (%) of Subjects	
Disposition Term	Medisan 20 mg	Novomed 100 mg
INFORMED CONSENT OBTAINED	100	100
RANDOMIZATION	100 (100)	100 (100)
RANDOMIZED AND TREATED	100 (100)	100 (100)
COMPLETED	97 (97)	89 (89)
WITHDRAWN	3 (3)	11 (11)
ADVERSE EVENT	0 (0)	4 (4)
PROTOCOL VIOLATION	2 (2)	2 (2)
LOST TO FOLLOW-UP	0 (0)	3 (3)
WITHDRAWAL OF CONSENT	1 (1)	1 (1)
DEATH	0 (0)	1 (1)

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Table 72.1: Shift table for laboratory data 27SEP2007
Analysis Set = Safety Population (N=200)

Clinical Chemistry		LAST VALUE UNDER TREATMENT Abnormal	Normal	Total	Missing
	BASELINE				
Creatinine	Abnormal	104 (73%)	38 (27%)	142 (72%)	1
	Normal	40 (74%)	14 (26%)	54 (28%)	1
	Total	144 (73%)	52 (27%)	196 (100%)	2
	Missing	2	0	2	0
HDL Cholesterol	Abnormal	0 (0%)	16 (100%)	16 (8%)	0
	Normal	14 (8%)	165 (92%)	179 (92%)	3
	Total	14 (7%)	181 (93%)	195 (100%)	3
	Missing	0	2	2	0

Table 72.2: Shift table for laboratory data 16OCT2007
Analysis Set = Safety Population (N=200)

Clinical Chemistry		HIGHEST VALUE UNDER TREATMENT			
		Abnormal	Normal	Total	Missing
	BASELINE				
Creatinine	Abnormal	79 (100%)	0 (0%)	79 (60%)	64
	Normal	51 (96%)	2 (4%)	53 (40%)	2
	Total	130 (98%)	2 (2%)	132 (100%)	66
	Missing	2	0	2	0
HDL Cholesterol	Abnormal	0 (0%)	16 (100%)	16 (11%)	0
	Normal	0 (0%)	133 (100%)	133 (89%)	49
	Total	0 (0%)	149 (100%)	149 (100%)	49
	Missing	0	2	2	0

Table 71.1: Shift table for laboratory data 27SEP2007
Analysis Set = Safety Population (N=200)

Clinical Chemistry		LAST VALUE UNDER TREATMENT Low	Normal	High	Total	Missing
	BASELINE					
Cholesterol	Low	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0
	Normal	0 (0%)	99 (69%)	44 (31%)	143 (73%)	3
	High	0 (0%)	35 (67%)	17 (33%)	52 (27%)	0
	Total	0 (0%)	134 (69%)	61 (31%)	195 (100%)	3
	Missing	0	2	0	2	0

Listing 20.1: Listing of laboratory data
Analysis Set = Safety Population (N=200)
Treatment Group = Medisan 20 mg (N=100)

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16OCT2007

Usubjid	Sex	Age (yr)	Visit	Day	Clinical Chemistry: Cholesterol	Clinical Chemistry: Creatinine	Clinical Chemistry: HDL Cholesterol
001/0002	F	61	Baseline	?	180.00	0.69	61.00
			Visit 1	?	122.00	1.95 A	61.00
			End of Study	?	227.00 H	0.71	65.00
001/0004	M	38	Baseline	1	220.00 H	1.16 A	50.00
			Visit 1	87	175.00	1.00 A	39.00 A
			End of Study	367	228.00 H	0.97 A	52.00
001/0006	F	26	Baseline	1	232.00 H	0.72	61.00
			Visit 1	89	179.00	0.67	62.00
			End of Study	369	130.00	0.82	54.00
001/0008	F	24	Baseline	1	n.d.	n.d.	n.d.
			Visit 1	95	189.00	1.27 A	57.00
			End of Study	365	146.00	1.15 A	48.00
001/0010	F	64	Baseline	1	155.00	0.90	38.00 A
			Visit 1	85	186.00	1.14 A	60.00
			End of Study	369	152.00	1.08 A	46.00
001/0012	F	45	Baseline	1	148.00	1.04 A	40.00
			Visit 1	84	244.00 H	1.23 A	48.00
			End of Study	364	188.00	1.04 A	96.00
001/0014	F	19	Baseline	1	253.00 H	1.02 A	74.00
			Visit 1	85	227.00 H	0.71	65.00
			End of Study	369	198.00	1.01 A	37.00 A
001/0016	-	-	Baseline	1	193.00	0.88	51.00
			Visit 1	94	206.00 H	0.99 A	70.00
			End of Study	365	339.00 H	0.60	57.00
001/0018	F	52	Baseline	1	339.00 H	0.60	57.00
			Visit 1	92	174.00	0.93 A	48.00
			End of Study	367	170.00	1.00 A	62.00
001/0020	M	61	Baseline	1	189.00	0.73	70.00
			Visit 1	85	211.00 H	1.22 A	43.00
			End of Study	375	175.00	1.14 A	56.00
001/0022	F	33	Baseline	1	247.00 H	0.77	87.00
			Visit 1	87	200.00	0.73	67.00
			End of Study	369	164.00	0.76	48.00
001/0024	F	55	Baseline	1	137.00	1.19 A	63.00
			Visit 1	92	227.00 H	1.22 A	39.00 A
			End of Study	359	161.00	1.30 A	85.00

H: Above normal range; L: Below normal range; A: Abnormal; S: Clinically significant

Protocol: N12345 (Sponsor: Schmidt & CO KG)
Source: T:\DMST\Studien\MAKSVALIDATION\HAUPTMAKROS\DUMMYSTUDY1\PROG\MUSTERAUFRUFE\L20_LLB_1.sas

Listing 20.2: Listing of laboratory data 16OCT2007
Analysis Set = Safety Population (N=200)
Treatment Group = Medisan 20 mg (N=100)

						Hematology	
Usubjid	Sex	Age (yr)	Visit	Date	Day	Basophils	Eosinophils
001/0002	F	61	Baseline	?	?	1.20	1.50
			Visit 1	?	?	0.60	2.20
			End of Study	?	?	0.70	0.50
001/0004	M	38	Baseline	2001-04-16	1	0.50	2.40
			Visit 1	2001-07-11	87	0.50	2.50
			End of Study	2002-04-17	367	0.80	13.00 H
001/0006	F	26	Baseline	2001-06-12	1	0.80	1.30
			Visit 1	2001-09-08	89	0.70	4.60
			End of Study	2002-06-15	369	0.70	2.30
001/0008	F	24	Baseline	2001-11-07	1	n.d.	n.d.
			Visit 1	2002-02-09	95	0.50	3.70
			End of Study	2002-11-06	365	0.50	2.20
001/0010	F	64	Baseline	2001-12-14	1	0.60	1.20
			Visit 1	2002-03-08	85	0.90	1.90
			End of Study	2002-12-17	369	0.60	1.60
001/0012	F	45	Baseline	2001-01-20	1	0.30	3.00
			Visit 1	2001-04-13	84	0.70	2.20
			End of Study	2002-01-18	364	0.40	0.80
001/0014	F	19	Baseline	2001-08-08	1	0.30	6.20
			Visit 1	2001-10-31	85	0.70	0.50
			End of Study	2002-08-11	369	0.70	3.30
001/0016	-	-	Baseline	2001-08-13	1	1.00	2.80
			Visit 1	2001-11-14	94	0.70	2.60
			End of Study	2002-08-12	365	0.90	3.20
001/0018	F	52	Baseline	2001-07-14	1	0.90	3.20
			Visit 1	2001-10-13	92	0.30	1.70
			End of Study	2002-07-15	367	0.80	4.00
001/0020	M	61	Baseline	2001-05-28	1	0.40	2.10
			Visit 1	2001-08-20	85	1.30	2.90
			End of Study	2002-06-06	375	0.40	1.00
001/0022	F	33	Baseline	2001-10-25	1	1.00	1.40
			Visit 1	2002-01-19	87	1.10	6.30
			End of Study	2002-10-28	369	0.90	7.30 H
001/0024	F	55	Baseline	2001-06-14	1	0.40	3.00
			Visit 1	2001-09-13	92	0.80	4.70
			End of Study	2002-06-07	359	0.80	11.70 H

H: Above normal range; L: Below normal range; A: Abnormal; S: Clinically significant

Listing 1.1: Inclusion/exclusion exceptions by trial treatment and subject number 27SEP2007
Analysis Set = Safety Population (N=537)
Treatment Group = MEDISAN 500 (N=179)

Usubjid	Sex	Age (yr)	Exception	Inclusion/Exclusion Criterion
0039	F	51	EXCLUSION	SCHWANGERSCHAFT/STILLZEIT
0076	M	57	EXCLUSION	ALKOHOL-, MEDIKAMENTEN-, DROGENABHAENGIGKEIT
0091	M	69	EXCLUSION	UNKONTROLLIERTER BLUTHOCHDRUCK
			INCLUSION	VOLLJAEHRIG
0092	M	69	EXCLUSION	LEBERERKRANKUNG
0181	M	65	EXCLUSION	MANIFESTE ENTZUENDUNG/INFEKTIONSKRANKHEIT
0365	M	54	EXCLUSION	UNKONTROLLIERTER BLUTHOCHDRUCK
0382	M	51	EXCLUSION	INNERHALB DER LETZTEN 4 WOCHEN TEILNAHME AN EINER KLINISCHEN PRUEFUNG
0416	M	66	INCLUSION	KORONARE HERZERKRANKUNG

Table 41.1: Physical examinations 27SEP2007
Analysis Set = Safety Population (N=200)

Baseline System	Number (%) of Abnormal Results Medisan 20 mg N=100	 Novomed 100 mg N=100
Dermatological	19 (26)	13 (18)
Neurological	3 (4)	7 (9)
Genito-urinary	0 (0)	0 (0)
Head/ Neck	19 (26)	15 (20)
Pulmonary	9 (12)	11 (15)
Lymphatic	0 (0)	2 (3)
General Appearance	17 (23)	9 (12)
Musculoskeletal	7 (9)	3 (4)
Gastrointestinal	18 (24)	11 (15)
Cardiovascular	6 (8)	2 (3)

Table 21.1: Summary of repeated measurements 27SEP2007
Analysis Set = Safety Population (N=200)

Pulse (bpm)	Medisan 20 mg N=100	Novomed 100 mg N=100
Baseline		
N	95	98
Median	78.0	80.0
Mean	78.7	80.3
SD	11.3	13.3
Min	50	47
Max	119	132
Missing	5	2
Visit 1		
N	97	96
Median	80.0	80.0
Mean	80.3	79.8
SD	12.3	11.9
Min	54	52
Max	118	132
Missing	3	4
Visit 2		
N	99	97
Median	79.0	79.0
Mean	79.1	79.1
SD	11.6	11.6
Min	56	44
Max	113	106
Missing	1	3
Visit 3		
N	97	98
Median	78.0	79.0
Mean	78.8	78.8
SD	12.2	10.3
Min	52	49
Max	108	108
Missing	3	2
End of Study		
N	97	98
Median	78.0	80.0
Mean	78.5	78.4
SD	11.2	10.0
Min	50	55
Max	108	98
Missing	3	2

Table 21.2: 27SEP2007
Analysis Set = Safety Population (N=200)

Pulse (bpm)	Medisan 20 mg N=100	Novomed 100 mg N=100
Baseline		
(1 timepoint)		
N	95	98
Median	78.0	80.0
Mean	78.7	80.3
SD	11.3	13.3
Min	50	47
Max	119	132
Missing	5	2
Visit 1		
1.0 hour after intervention		
N	97	96
Median	80.0	80.0
Mean	80.3	79.8
SD	12.3	11.9
Min	54	52
Max	118	132
Missing	3	4
2.0 hours after intervention		
N	96	100
Median	79.0	78.5
Mean	80.0	79.3
SD	13.4	12.5
Min	52	51
Max	121	120
Missing	4	0
3.0 hours after intervention		
N	99	99
Median	80.0	80.0
Mean	79.2	79.7
SD	12.4	10.7
Min	47	55
Max	116	108
Missing	1	1
Visit 2		
(1 timepoint)		
N	99	97
Median	79.0	79.0
Mean	79.1	79.1
SD	11.6	11.6
Min	56	44
Max	113	106
Missing	1	3

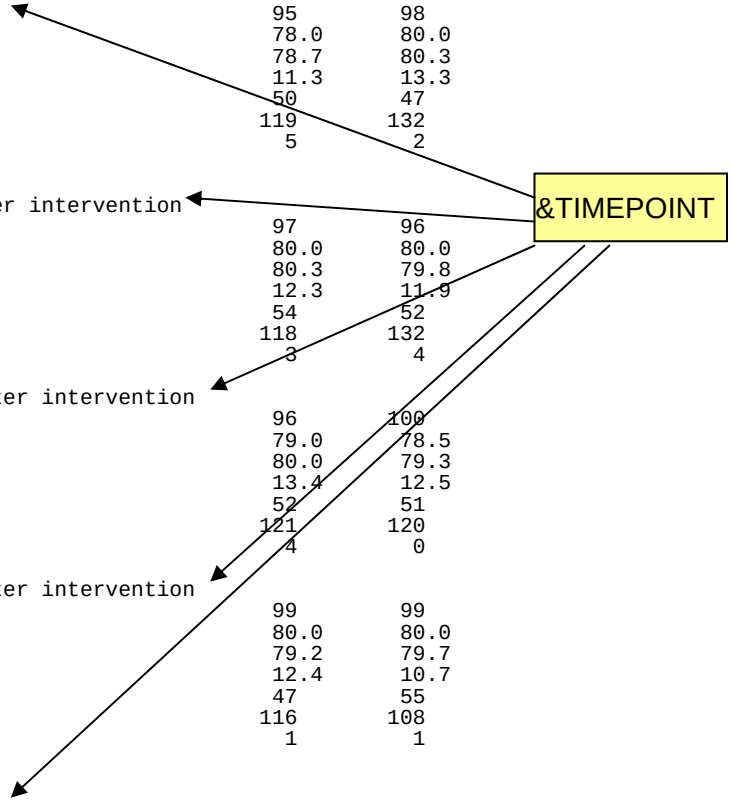
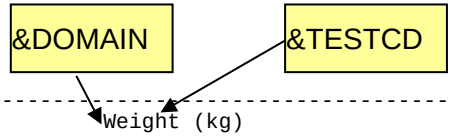


Table 22.1: Changes of time varying variables
Analysis Set = Safety Population (N=200)
Treatment Group = Medisan 20 mg (N=100)



27SEP2007

Weight (kg)

	Actual values						Change from Baseline					
Visit	N	Mean	SD	Median	Min	Max	N	Mean	SD	Median	Min	Max
Baseline	99	71.1	19.2	68.0	49	179						
Visit 1	99	72.0	19.5	69.0	49	183	99	1.0	1.5	1.0	-4	5
Visit 2	99	70.8	19.6	68.0	46	180	99	-0.3	1.5	0.0	-4	4
Visit 3	99	73.0	19.5	70.0	50	183	99	2.0	1.4	2.0	-1	5
End of Study	99	71.8	19.3	69.0	50	180	99	0.7	1.6	1.0	-3	4

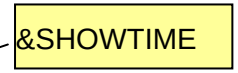
Table 22.2: Table of vital signs in females aged > 60 years 27SEP2007
Analysis Set = ITT Population (N=7)

		Pulse (bpm)											
		Actual values						Change from Baseline					
Visit	Scheduled Time	N	Mean	SD	Median	Min	Max	N	Mean	SD	Median	Min	Max
Baseline		7	84.9	10.8	90.0	67	96						
Visit 1	1.0 hour after intervention	7	83.3	8.7	84.0	73	97	7	-1.6	11.3	-1.0	-23	13
	2.0 hours after intervention	7	77.9	15.0	72.0	65	102	7	-7.0	14.6	-6.0	-25	12
	3.0 hours after intervention	7	77.4	9.0	76.0	67	94	7	-7.4	11.1	-10.0	-21	9
Visit 2		7	79.9	6.4	80.0	72	89	7	-5.0	9.2	-9.0	-17	8
Visit 3		7	82.3	7.1	81.0	74	97	7	-2.6	12.0	-7.0	-15	14
End of Study		6	81.2	1.5	80.5	80	83	6	-6.7	7.9	-7.5	-16	8

Listing 5.1: Listing of time varying variables 27SEP2007
Analysis Set = Safety Population (N=200)
Treatment Group = Medisan 20 mg (N=100)

Usubjid	Sex	Age (yr)	Visit	Day	Height (cm)	Pulse (bpm)
001/0002	F	61	Baseline	1	165	96
			Visit 1	95	-	73
				95	-	72
				95	-	81
			Visit 2	183	-	87
			Visit 3	276	-	81
			End of Study	361	-	80
001/0004	M	38	Baseline	1	169	81
			Visit 1	87	-	89
				87	-	84
				87	-	86
			Visit 2	181	-	83
			Visit 3	271	-	85
			End of Study	367	-	80
001/0006	F	26	Baseline	1	179	81
			Visit 1	89	-	80
				89	-	89
				89	-	73
			Visit 2	175	-	79
			Visit 3	265	-	72
			End of Study	369	-	79
001/0008	F	24	Baseline	1	171	71
			Visit 1	95	-	68
				95	-	67
				95	-	69
			Visit 2	182	-	68
			Visit 3	276	-	71
			End of Study	365	-	89
001/0010	F	64	Baseline	1	183	90
			Visit 1	85	-	97
				85	-	65
				85	-	69
			Visit 2	177	-	73
			Visit 3	266	-	83
			End of Study	369	-	83
001/0012	F	45	Baseline	1	167	97
			Visit 1	84	-	87
				84	-	100
				84	-	106
			Visit 2	186	-	91
			Visit 3	268	-	101
			End of Study	364	-	66

Listing 5.2: Listing of vital signs in females aged > 60 years
Analysis Set = ITT Population (N=7)
Treatment Group = Medisan 20 mg (N=5)



27SEP2007

Usubjid	Sex	Age (yr)	Visit	Day	Time	Pulse (bpm)	Systolic Bloodpressure	Diastolic Bloodpressure
001/0002	F	61	Baseline	1	8:00	96	121	78
			Visit 1	95	8:00	73	118	71
				95	9:00	72	110	80
				95	10:00	81	109	80
			Visit 2	183	0:00	87	125	76
			Visit 3	276	0:00	81	109	80
			End of Study	361	0:00	80	119	79
001/0010	F	64	Baseline	1	8:00	90	110	71
			Visit 1	85	8:00	97	120	84
				85	9:00	65	116	69
				85	10:00	69	119	80
			Visit 2	177	0:00	73	108	71
			Visit 3	266	0:00	83	119	83
			End of Study	369	0:00	83	119	80
001/0034	F	61	Baseline	1	8:00	72	122	76
			Visit 1	90	8:00	73	120	85
				90	9:00	66	119	81
				90	10:00	67	120	81
			Visit 2	173	0:00	80	135	80
			Visit 3	260	0:00	80	122	70
			End of Study	353	0:00	80	128	81
002/0004	F	61	Baseline	1	8:00	67	120	81
			Visit 1	86	8:00	80	99	70
				86	9:00	68	115	60
				86	10:00	76	109	71
			Visit 2	183	0:00	72	110	81
			Visit 3	266	0:00	81	105	61
			End of Study	365	0:00	-	130	81
003/0010	F	62	Baseline	1	8:00	89	112	69
			Visit 1	90	8:00	87	108	67
				90	9:00	96	107	75
				90	10:00	94	119	70
			Visit 2	180	0:00	78	101	56
			Visit 3	262	0:00	74	112	71
			End of Study	367	0:00	81	105	52

Table 81.1: Descriptive analyses 27SEP2007
Analysis Set = Safety Population (N=200)

Variable	Medisan 20 mg N=100	Novomed 100 mg N=100
Height (cm)		
N	99	99
Median	168.0	169.0
Q1	163.0	164.0
Q3	173.0	173.0
Min	55	150
Max	197	730
Missing	1	1
Race		
Negroid	4 (4%)	5 (5%)
Asian	9 (9%)	10 (10%)
White	87 (87%)	85 (85%)
Missing	0	0
Weight (kg)		
N	99	100
Median	68.0	69.5
Mean	71.0	71.2
SD	19.4	16.2
Min	49	43
Max	181	135
Missing	1	0

Table 83.1: Tests for differences 27SEP2007
Analysis Set = Safety Population (N=200)

Variable	Medisan 20 mg N=100	Novomed 100 mg N=100
Weight (kg)		
N	99	100
Median	68.0	69.5
Mean	71.0	71.2
SD	19.4	16.2
Min	49	43
Max	181	135
P (Wilcoxon-Test)		0.5930
Missing	1	0
Race		
Negroid	4 (4%)	5 (5%)
Asian	9 (9%)	10 (10%)
P (Fisher-Test)		1.0000
White	87 (87%)	85 (85%)
P (Fisher-Test)		0.7469
Missing	0	0

Table 84.1: Confidence intervals for odds ratios and differences 27SEP2007
Analysis Set = Safety Population (N=200)

Variable	Medisan 20 mg N=100	Novomed 100 mg N=100
Weight (kg)		
N	99	100
Median	68.0	69.5
Mean	71.0	71.2
SD	19.4	16.2
Min	49	43
Max	181	135
Mean difference		-0.2
95%-CI		-5.2 : -5.2
Missing	1	0
Race		
Negroid	4 (4%)	5 (5%)
Asian	9 (9%)	10 (10%)
OR		1.1
95%-CI		0.2 : 5.5
White	87 (87%)	85 (85%)
OR		0.8
95%-CI		0.2 : 3.0
Missing	0	0
Sex		
Male	12 (13%)	19 (19%)
Female	84 (88%)	81 (81%)
OR		1.6
95%-CI		0.7 : 3.6
Missing	4	0
Height (cm)		
N	99	99
Median	168.0	169.0
Q1	163.0	164.0
Q3	173.0	173.0
Min	55	150
Max	197	730
Mean difference		-6.9
95%-CI		-18.5 : -18.
Missing	1	1