

Italfarmaco S.p.A. study no: DSC/13/2984/05

Page 1 of 8

Table 14.2.5.2 Summary of Subjects Showing Improvement in Signs and Symptoms of Acromegaly
(Intent-to-treat Analysis Set)

Sign/Symptom: Headache

Period		Treatment			
		100 mcg Octreotide (N=41) n (%)	500 mcg ITF2984 (N=43) n (%)	1000 mcg ITF2984 (N=47) n (%)	2000 mcg ITF2984 (N=42) n (%)
1	Yes	3 (7.3)	5 (11.6)	4 (8.5)	7 (16.7)
	No	8 (19.5)	7 (16.3)	5 (10.6)	5 (11.9)
2	Yes	3 (7.3)	3 (7.0)	5 (10.6)	3 (7.1)
	No	9 (22.0)	5 (11.6)	7 (14.9)	8 (19.0)
3	Yes	2 (4.9)	2 (4.7)	4 (8.5)	0
	No	9 (22.0)	9 (20.9)	8 (17.0)	8 (19.0)
4	Yes	0	4 (9.3)	4 (8.5)	2 (4.8)
	No	7 (17.1)	7 (16.3)	7 (14.9)	9 (21.4)
Overall	Yes	8 (19.5)	14 (32.6)	17 (36.2)	12 (28.6)
	No	33 (80.5)	28 (65.1)	27 (57.4)	30 (71.4)

N = the number of subjects in the analysis set.

n = the number of subjects with an assessment.

(%) = n/N*100.

Source: Listing 16.2.6.2

PROGRAM NAME:T_ACROM_02.SAS

DATE OF RUN:12SEP2016

TIME OF RUN: 12:12:22

DATE OF EXTRACTION:25MAY2016

Italfarmaco S.p.A. study no: DSC/13/2984/05

Page 2 of 8

Table 14.2.5.2 Summary of Subjects Showing Improvement in Signs and Symptoms of Acromegaly
(Intent-to-treat Analysis Set)

Sign/Symptom: Excessive sweating

Period		Treatment			
		100 mcg Octreotide (N=41) n (%)	500 mcg ITF2984 (N=43) n (%)	1000 mcg ITF2984 (N=47) n (%)	2000 mcg ITF2984 (N=42) n (%)
1	Yes	3 (7.3)	6 (14.0)	4 (8.5)	8 (19.0)
	No	8 (19.5)	6 (14.0)	5 (10.6)	3 (7.1)
2	Yes	4 (9.8)	1 (2.3)	4 (8.5)	3 (7.1)
	No	8 (19.5)	7 (16.3)	8 (17.0)	8 (19.0)
3	Yes	0	4 (9.3)	4 (8.5)	4 (9.5)
	No	11 (26.8)	7 (16.3)	8 (17.0)	4 (9.5)
4	Yes	2 (4.9)	2 (4.7)	4 (8.5)	4 (9.5)
	No	5 (12.2)	9 (20.9)	7 (14.9)	7 (16.7)
Overall	Yes	9 (22.0)	13 (30.2)	16 (34.0)	19 (45.2)
	No	32 (78.0)	29 (67.4)	28 (59.6)	22 (52.4)

N = the number of subjects in the analysis set.

n = the number of subjects with an assessment.

(%) = n/N*100.

Source: Listing 16.2.6.2

PROGRAM NAME:T_ACROM_02.SAS

DATE OF RUN:12SEP2016

TIME OF RUN: 12:12:22

DATE OF EXTRACTION:25MAY2016

Italfarmaco S.p.A. study no: DSC/13/2984/05

Page 3 of 8

Table 14.2.5.2 Summary of Subjects Showing Improvement in Signs and Symptoms of Acromegaly
(Intent-to-treat Analysis Set)

Sign/Symptom: Joint pain

Period		Treatment			
		100 mcg Octreotide (N=41) n (%)	500 mcg ITF2984 (N=43) n (%)	1000 mcg ITF2984 (N=47) n (%)	2000 mcg ITF2984 (N=42) n (%)
1	Yes	7 (17.1)	6 (14.0)	3 (6.4)	7 (16.7)
	No	4 (9.8)	6 (14.0)	6 (12.8)	4 (9.5)
2	Yes	3 (7.3)	1 (2.3)	5 (10.6)	6 (14.3)
	No	9 (22.0)	7 (16.3)	7 (14.9)	5 (11.9)
3	Yes	3 (7.3)	5 (11.6)	3 (6.4)	3 (7.1)
	No	8 (19.5)	6 (14.0)	9 (19.1)	5 (11.9)
4	Yes	2 (4.9)	4 (9.3)	5 (10.6)	3 (7.1)
	No	5 (12.2)	7 (16.3)	6 (12.8)	8 (19.0)
Overall	Yes	15 (36.6)	16 (37.2)	16 (34.0)	19 (45.2)
	No	26 (63.4)	26 (60.5)	28 (59.6)	22 (52.4)

N = the number of subjects in the analysis set.

n = the number of subjects with an assessment.

(%) = n/N*100.

Source: Listing 16.2.6.2

PROGRAM NAME:T_ACROM_02.SAS

DATE OF RUN:12SEP2016

TIME OF RUN: 12:12:22

DATE OF EXTRACTION:25MAY2016

Italfarmaco S.p.A. study no: DSC/13/2984/05

Page 4 of 8

Table 14.2.5.2 Summary of Subjects Showing Improvement in Signs and Symptoms of Acromegaly
(Intent-to-treat Analysis Set)

Sign/Symptom: Fatigue

Period		Treatment			
		100 mcg Octreotide (N=41) n (%)	500 mcg ITF2984 (N=43) n (%)	1000 mcg ITF2984 (N=47) n (%)	2000 mcg ITF2984 (N=42) n (%)
1	Yes	6 (14.6)	4 (9.3)	4 (8.5)	6 (14.3)
	No	5 (12.2)	8 (18.6)	5 (10.6)	6 (14.3)
2	Yes	5 (12.2)	3 (7.0)	3 (6.4)	4 (9.5)
	No	7 (17.1)	5 (11.6)	9 (19.1)	7 (16.7)
3	Yes	3 (7.3)	5 (11.6)	4 (8.5)	0
	No	8 (19.5)	6 (14.0)	8 (17.0)	8 (19.0)
4	Yes	2 (4.9)	5 (11.6)	3 (6.4)	5 (11.9)
	No	5 (12.2)	6 (14.0)	8 (17.0)	6 (14.3)
Overall	Yes	16 (39.0)	17 (39.5)	14 (29.8)	15 (35.7)
	No	25 (61.0)	25 (58.1)	30 (63.8)	27 (64.3)

N = the number of subjects in the analysis set.

n = the number of subjects with an assessment.

(%) = n/N*100.

Source: Listing 16.2.6.2

PROGRAM NAME:T_ACROM_02.SAS

DATE OF RUN:12SEP2016

TIME OF RUN: 12:12:22

DATE OF EXTRACTION:25MAY2016

Italfarmaco S.p.A. study no: DSC/13/2984/05

Page 5 of 8

Table 14.2.5.2 Summary of Subjects Showing Improvement in Signs and Symptoms of Acromegaly
(Intent-to-treat Analysis Set)

Sign/Symptom: Soft tissue swelling

Period		Treatment			
		100 mcg Octreotide (N=41) n (%)	500 mcg ITF2984 (N=43) n (%)	1000 mcg ITF2984 (N=47) n (%)	2000 mcg ITF2984 (N=42) n (%)
1	Yes	4 (9.8)	4 (9.3)	4 (8.5)	4 (9.5)
	No	7 (17.1)	8 (18.6)	5 (10.6)	8 (19.0)
2	Yes	9 (22.0)	2 (4.7)	3 (6.4)	5 (11.9)
	No	3 (7.3)	6 (14.0)	9 (19.1)	6 (14.3)
3	Yes	0	4 (9.3)	5 (10.6)	2 (4.8)
	No	11 (26.8)	7 (16.3)	7 (14.9)	6 (14.3)
4	Yes	1 (2.4)	2 (4.7)	5 (10.6)	3 (7.1)
	No	6 (14.6)	9 (20.9)	6 (12.8)	8 (19.0)
Overall	Yes	14 (34.1)	12 (27.9)	17 (36.2)	14 (33.3)
	No	27 (65.9)	30 (69.8)	27 (57.4)	28 (66.7)

N = the number of subjects in the analysis set.

n = the number of subjects with an assessment.

(%) = n/N*100.

Source: Listing 16.2.6.2

PROGRAM NAME:T_ACROM_02.SAS

DATE OF RUN:12SEP2016

TIME OF RUN: 12:12:22

DATE OF EXTRACTION:25MAY2016

Italfarmaco S.p.A. study no: DSC/13/2984/05

Page 6 of 8

Table 14.2.5.2 Summary of Subjects Showing Improvement in Signs and Symptoms of Acromegaly
(Intent-to-treat Analysis Set)

Sign/Symptom: Numbness or tingling of the extremities

Period		Treatment			
		100 mcg Octreotide (N=41) n (%)	500 mcg ITF2984 (N=43) n (%)	1000 mcg ITF2984 (N=47) n (%)	2000 mcg ITF2984 (N=42) n (%)
1	Yes	4 (9.8)	3 (7.0)	5 (10.6)	2 (4.8)
	No	7 (17.1)	9 (20.9)	4 (8.5)	10 (23.8)
2	Yes	3 (7.3)	1 (2.3)	3 (6.4)	2 (4.8)
	No	9 (22.0)	7 (16.3)	9 (19.1)	9 (21.4)
3	Yes	3 (7.3)	1 (2.3)	1 (2.1)	1 (2.4)
	No	8 (19.5)	10 (23.3)	11 (23.4)	7 (16.7)
4	Yes	3 (7.3)	3 (7.0)	4 (8.5)	3 (7.1)
	No	4 (9.8)	8 (18.6)	7 (14.9)	8 (19.0)
Overall	Yes	13 (31.7)	8 (18.6)	13 (27.7)	8 (19.0)
	No	28 (68.3)	34 (79.1)	31 (66.0)	34 (81.0)

N = the number of subjects in the analysis set.

n = the number of subjects with an assessment.

(%) = n/N*100.

Source: Listing 16.2.6.2

PROGRAM NAME:T_ACROM_02.SAS

DATE OF RUN:12SEP2016

TIME OF RUN: 12:12:22

DATE OF EXTRACTION:25MAY2016

Italfarmaco S.p.A. study no: DSC/13/2984/05

Page 7 of 8

Table 14.2.5.2 Summary of Subjects Showing Improvement in Signs and Symptoms of Acromegaly
(Intent-to-treat Analysis Set)

Sign/Symptom: Overall health status

Period		Treatment			
		100 mcg Octreotide (N=41) n (%)	500 mcg ITF2984 (N=43) n (%)	1000 mcg ITF2984 (N=47) n (%)	2000 mcg ITF2984 (N=42) n (%)
1	Yes	4 (9.8)	7 (16.3)	6 (12.8)	6 (14.3)
	No	7 (17.1)	5 (11.6)	3 (6.4)	6 (14.3)
2	Yes	4 (9.8)	1 (2.3)	7 (14.9)	4 (9.5)
	No	8 (19.5)	7 (16.3)	5 (10.6)	7 (16.7)
3	Yes	2 (4.9)	4 (9.3)	6 (12.8)	4 (9.5)
	No	9 (22.0)	7 (16.3)	6 (12.8)	4 (9.5)
4	Yes	0	4 (9.3)	5 (10.6)	4 (9.5)
	No	7 (17.1)	7 (16.3)	6 (12.8)	7 (16.7)
Overall	Yes	10 (24.4)	16 (37.2)	24 (51.1)	18 (42.9)
	No	31 (75.6)	26 (60.5)	20 (42.6)	24 (57.1)

N = the number of subjects in the analysis set.

n = the number of subjects with an assessment.

(%) = n/N*100.

Source: Listing 16.2.6.2

PROGRAM NAME:T_ACROM_02.SAS

DATE OF RUN:12SEP2016

TIME OF RUN: 12:12:22

DATE OF EXTRACTION:25MAY2016

Italfarmaco S.p.A. study no: DSC/13/2984/05

Page 8 of 8

Table 14.2.5.2 Summary of Subjects Showing Improvement in Signs and Symptoms of Acromegaly
(Intent-to-treat Analysis Set)

Sign/Symptom: Across All Signs and Symptoms

Period		Treatment			
		100 mcg Octreotide (N=41) n (%)	500 mcg ITF2984 (N=43) n (%)	1000 mcg ITF2984 (N=47) n (%)	2000 mcg ITF2984 (N=42) n (%)
1	Yes	10 (24.4)	10 (23.3)	8 (17.0)	11 (26.2)
	No	1 (2.4)	2 (4.7)	1 (2.1)	1 (2.4)
2	Yes	12 (29.3)	4 (9.3)	10 (21.3)	10 (23.8)
	No	0	4 (9.3)	2 (4.3)	1 (2.4)
3	Yes	6 (14.6)	8 (18.6)	10 (21.3)	7 (16.7)
	No	5 (12.2)	3 (7.0)	2 (4.3)	1 (2.4)
4	Yes	4 (9.8)	9 (20.9)	10 (21.3)	11 (26.2)
	No	3 (7.3)	2 (4.7)	1 (2.1)	0
Overall	Yes	32 (78.0)	31 (72.1)	38 (80.9)	39 (92.9)
	No	9 (22.0)	11 (25.6)	6 (12.8)	3 (7.1)

N = the number of subjects in the analysis set.

n = the number of subjects with an assessment.

(%) = n/N*100.

Source: Listing 16.2.6.2

PROGRAM NAME:T_ACROM_02.SAS

DATE OF RUN:12SEP2016

TIME OF RUN: 12:12:22

DATE OF EXTRACTION:25MAY2016