

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

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Table 14.2.3.2 Summary of Reduction of GH Level < 1.0 (mcg/litre) at the End of the Treatment Period
(Intent-to-treat Analysis Set)

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	0	0	0	1 (2.4)
	No	11 (26.8)	12 (27.9)	9 (19.1)	11 (26.2)
2	Yes	1 (2.4)	0	1 (2.1)	1 (2.4)
	No	11 (26.8)	8 (18.6)	11 (23.4)	10 (23.8)
3	Yes	0	0	0	0
	No	11 (26.8)	11 (25.6)	11 (23.4)	8 (19.0)
4	Yes	0	0	0	0
	No	7 (17.1)	11 (25.6)	11 (23.4)	11 (26.2)
Overall	Yes	1 (2.4)	0	1 (2.1)	2 (4.8)
	No	40 (97.6)	42 (97.7)	42 (89.4)	40 (95.2)

N = the number of subjects in the analysis set receiving the specified treatment.

n = the number of subjects with a measurement.

(%) = n/N*100.

Source: Listing 16.2.6.1

PROGRAM NAME:T_REDGH_02.SAS

DATE OF RUN:12SEP2016

TIME OF RUN: 11:52:42

DATE OF EXTRACTION:25MAY2016