

Table 8: Summary of GH Level (µg/L) at baseline, end of treatment and change from baseline on the original scale (ITT Analysis Set)

	OCR 100 µg N=41		ITF2984 500 µg N=43		ITF2984 1000 µg N=47		ITF2984 2000 µg N=42	
	Observed value	Change from Baseline	Observed value	Change from Baseline	Observed value	Change from Baseline	Observed value	Change from Baseline
Period 1								
Baseline								
n	11		12		11		12	
Mean	13.68		7.99		10.17		6.28	
SD	10.551		8.263		7.142		4.591	
End of treatment								
n	11	11	12	12	9	9	12	12
Mean	11.45	-2.23	7.03	-0.96	9.19	-2.00	3.44	-2.84
SD	15.125	9.096	6.352	2.417	10.495	6.071	3.110	4.223
Period 2								
Baseline								
n	12		9		12		11	
Mean	7.32		9.99		4.73		18.51	
SD	7.174		7.094		3.324		20.771	
End of treatment								
n	12	12	8	8	12	12	11	11
Mean	4.90	-2.42	10.29	-0.13	4.29	-0.44	5.47	-13.04
SD	3.157	7.056	9.139	2.590	3.640	1.151	5.658	18.977
Period 3								
Baseline								
n	11		11		12		8	
Mean	5.17		13.29		7.63		13.34	
SD	5.562		15.244		8.366		10.042	
End of treatment								
n	11	11	11	11	11	11	8	8
Mean	6.14	0.96	11.05	-2.25	5.80	-1.95	7.35	-5.99
SD	3.842	3.375	10.675	7.290	3.650	6.617	8.873	8.316

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	OCR 100 μg N=41		ITF2984 500 μg N=43		ITF2984 1000 μg N=47		ITF2984 2000 μg N=42	
	Observed value	Change from Baseline	Observed value	Change from Baseline	Observed value	Change from Baseline	Observed value	Change from Baseline
Period 4								
Baseline								
n	7		11		11		11	
Mean	11.47		5.37		15.85		4.64	
SD	10.240		5.738		18.326		1.872	
End of treatment								
n	7	7	11	11	11	11	11	11
Mean	10.10	-1.37	4.91	-0.46	6.38	-9.47	3.85	-0.79
SD	12.389	12.357	3.514	2.501	5.166	15.874	2.966	2.204
Overall								
Baseline								
n	41		43		46		42	
Mean	9.16		9.10		9.45		10.40	
SD	8.797		9.970		11.079		12.734	
End of treatment								
n	41	41	42	42	43	43	42	42
Mean	7.88	-1.28	8.15	-1.01	6.24	-3.47	4.82	-5.57
SD	9.722	7.884	7.888	4.224	6.081	9.535	5.307	11.354

Baseline is defined as Day 0 of each period; At each time point, only subjects with a value at both Baseline and that time point were included in the change from Baseline column.

N = the number of subjects in the analysis set receiving the specified treatment; n = the number of subjects with a measurement in this time period; OCR = octreotide; SD = standard deviation

Data Source: Section 14, [Table 14.2.1.1](#)