Your Patients Now Have A **Bioequivalent** Alternative To Synthroid® And Levoxyl®.

The Summary Results of the Levothyroxine Biostudy are Below:

Study Synopsis

Title: Comparative, Randomized, Single-Dose, 2-Way Crossover Bioavailability Study of Synthroid® as well as Sandoz Levothyroxine and Levoxyl® 300 mcg Levothyroxine Sodium Tablets in Healthy Adult Volunteers Under Fasting Conditions Following Administration of a 600 mcg Dose.

Objective: The objective of this study was to compare the single-dose relative bioavailability of Synthroid® as well as Sandoz Levothyroxine and Levoxyl® 300mcg levothyroxine sodium tablets under fasting conditions following a 600 mcg dose.

Study Design: Open-label, randomized, single-dose, 2-way crossover bioavailability study performed in 24 healthy adult volunteers and 4 alternates (19 males and 9 females). A total of 26 subjects (17 males and 9 females) completed the crossover for the study comparing Synthroid®and Sandoz Levothyroxine. A total of 27 subjects (19 females and 8 males) completed the crossover for the study comparing Sandoz Levothyroxine and Levoxyl®. Each dose was separated by a washout period of 35 days.

Methods: The AUC 0-72, AUC 0-48, AUC 0-24, Cmax and tmax pharmacokinetic parameters were calculated for baseline-adjusted and levothyroxine (Total T_4). Analysis of variance (ANOVA) and analysis of covariance (ANCOVA) were performed on the ln-transformed baseline-adjusted pharmacokinetic parameters AUC 0-24, AUC 0-48, AUC 0-72 and Cmax.

Results: The pharmacokinetic results are listed below for Total T_4 in serum:

Sandoz Levothyroxine (A) vs Synthroid® (B)
Ratios of LSM (A/B)% (90% Confidence Intervals) (ANOVA)

Parameter	Total T_4 – Baseline Adjusted
AUC 0-24	111.3% (103.5 - 119.6%)
AUC 0-48	112.5% (103.3 - 122.5%)
AUC 0-72	109.7% (100.8 - 119.4%)
Cmax	107.9% (100.9 - 115.4%)

Sandoz Levothyroxine (A) vs Levoxyl® (B)
Ratios of LSM (A/B)% (90% Confidence Intervals) (ANOVA)

Parameter	Total T_4 – Baseline Adjusted
AUC 0-24	99.6% (90.5 - 109.6%)
AUC 0-48	97.7% (87.8 - 108.8%)
AUC 0-72	97.0% (85.8 - 110.4%)
Cmax	101.4% (95.0 - 108.2%)

Sandoz Levothyroxine (A) vs Synthroid® (B)
Ratios of LSM (A/B)% (90% Confidence Intervals) (ANCOVA)

Parameter	Total T_4 – Baseline Adjusted
AUC 0-24	110.2% (103.0 - 118.1%)
AUC 0-48	111.1% (102.8 - 120.1%)
AUC 0-72	108.2% (100.4 - 116.7%)
Cmax	108.2% (101.0 - 116.0%)

Sandoz Levothyroxine (A) vs Levoxyl® (B)
Ratios of LSM (A/B)% (90% Confidence Intervals) (ANCOVA)

Parameter	Total T_4 – Baseline Adjusted
AUC 0-24	98.3% (90.1 - 107.3%)
AUC 0-48	96.4% (87.3 - 106.4%)
AUC 0-72	95.1% (85.1 - 106.3%)
Cmax	101.1% (94.6 - 108.0%)

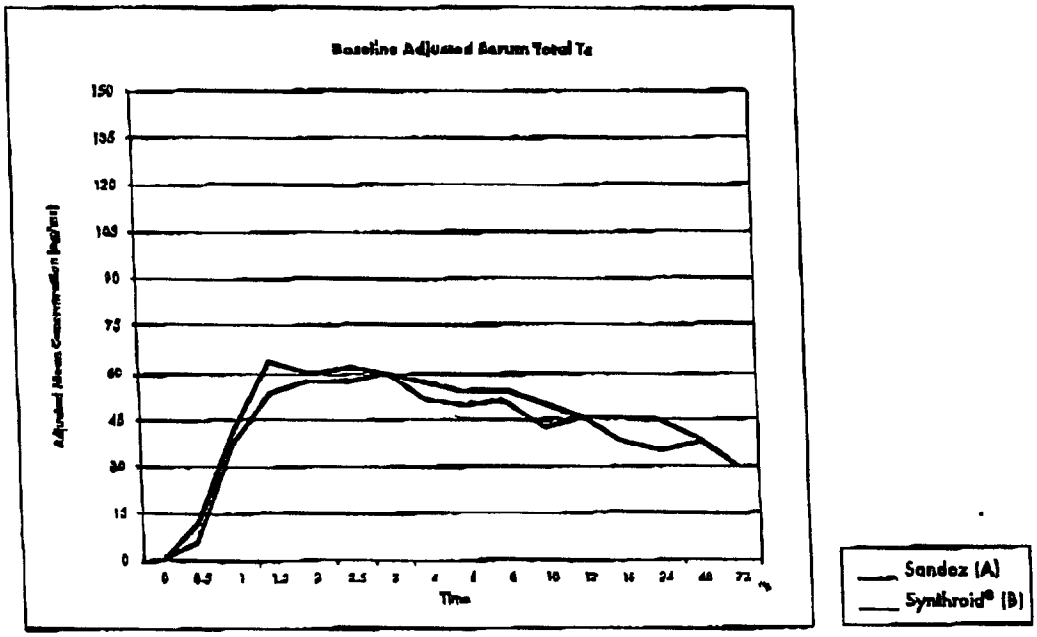
Conclusions: From the ANOVA and the ANCOVA, the ratios of least-squares means and 90% confidence intervals derived from the analysis of the ln-transformed baseline-adjusted pharmacokinetic parameters AUC 0-24, AUC 0-48, AUC 0-72 and Cmax for Total T_4 were within the 80-125% FDA acceptance range.

Results showed that the ratios of least-square means and 90% confidence intervals were also within the 80-125% FDA usual acceptance range. Based on these results, the Synthroid® and Sandoz Levothyroxine, and the Sandoz Levothyroxine and Levoxyl® 300 mcg levothyroxine sodium tablets are bioequivalent under fasting conditions, following a 600 mcg oral dose.

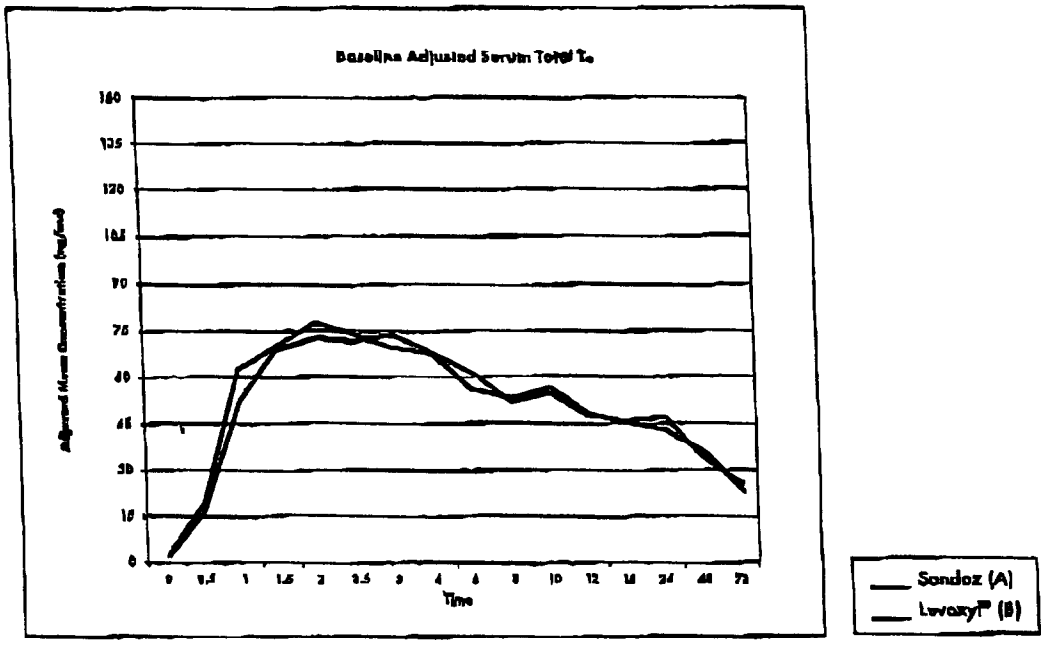
REFERENCES

Studies conducted by MDS Pharma Services

COMPARING SANDOZ LEVOTHYROXINE TO SYNTHROID®



COMPARING SANDOZ LEVOTHYROXINE TO LEVOXYL®



Sandoz Levothyroxine has been evaluated by the Food and Drug Administration and has been approved for marketing. FDA is satisfied that it is safe, effective and therapeutically equivalent to Synthroid® and Levoxyl®.

Please see full prescribing information in packet.