STUDY REPORT

ON

AN OBSERVATIONAL STUDY OF OTHER INDICATIONS LIKE ALLERGY, ASTHMA, ARTHRITIS, DIARRHEA, FEVER, FATIGUE-MALAISE, ANEMIA, ENDOMETRIOSIS ETC. FOR EFFICACY & SAFETY OF RECEPTOL® ORAL SPRAY USED AS A STAND-ALONE MONO THERAPY

PROTOCOL NO: BNL0004

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SPONSOR:
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1. INTRODUCTION

Life is in the breath. He who half breathes half lives.

If you have allergies, asthma, or other breathing problems, this proverb may sound very familiar. But a greater understanding of your breathing problems, along with an accurate medical diagnosis and effective treatment, can help you regain control. It doesn't matter what type of breathing problem you have. Daily control is vital to living an active, productive life.

The nasal passage is a pathway for viruses and allergens to enter your lungs. So the nose and sinuses are often associated with many lung disorders. A sinus or nasal passage inflammation may trigger reflexes and cause asthma attacks. And the No. 1 trigger for asthma is allergies.

Diarrhea affects most people from time to time and is usually nothing to worry about. However, it can be distressing and unpleasant until it passes, which normally takes a few days to a week.

Most cases of diarrhoea clear up after a few days without treatment, and you may not need to see your GP.However, diarrhoea can lead to dehydration, so you should drink plenty of fluids (small, frequent sips of water) until it

passes. It's very important that babies and small children do not become dehydrated.

Infection, this is the most common cause of a fever. Infections may affect the whole body or a specific body part (localized infection).Medicines, such as antibiotics, narcotics, barbiturates, antihistamines are called drug fevers. Some medicines, such as antibiotics, raise the body temperature directly. Other medicines interfere with the body's ability to readjust its temperature when other factors cause the temperature to rise.

An abnormally low body temperature (hypothermia) can be serious, even life-threatening. Low body temperature may occur from cold exposure, shock, alcohol or drug use, or certain metabolic disorders, such as diabetes or hypothyroidism. A low body temperature may also be present with an infection, particularly in newborns, older adults, or people who are frail

2. OBJECTIVE

Primary Objective:

To evaluate the efficacy of RECEPTOL® oral spray in Healthy People in terms of weight gain as weight gain is the indication of overall wellness.

3. METHODOLOGY AND STUDY PLAN

a) **Study Design:** Observational study

b) **Population:** 5000 cases

c) **Methods:** This trial was a 1-Month, Stand-Alone, single arm, open label study to evaluate the Efficacy and Safety/Tolerability of RECEPTOL® oral spray in Healthy People. The potential subjects were screened after obtaining a written informed consent from (As per Schedule Y) the subject or LAR (Legally Acceptable Representative)/impartial witness. The study was designed to investigate efficacy of RECEPTOL® therapy in change in body weight. The study subjects received RECEPTOL® as a spray self-administered by patients on either side of the oral buccal surface 4 times daily at every 4 hour's interval. Each administration consist a metered dose of 0.75 ml spray directly on the buccal mucosa. Body weight of subjects was monitored at every visit to determine the effect of RECEPTOL® therapy on change in the weight. The subjects were

also assessed for clinical symptoms and physical findings which included Healthy Population with frequent recurrent infections related to Fatigue/Malaise, Diarrhoea, Nausea, Vomiting, Fever, Cough, Parasthesia Sleep Disturbance, Skin Rash, Herpes Zoster, Lymphadenopathy, Hair changes, oral thrush, Leukoplakia, Liver enlargement, Spleen enlargement, Weight of patient and Tuberculosis.

4. RESULT

Table 1:

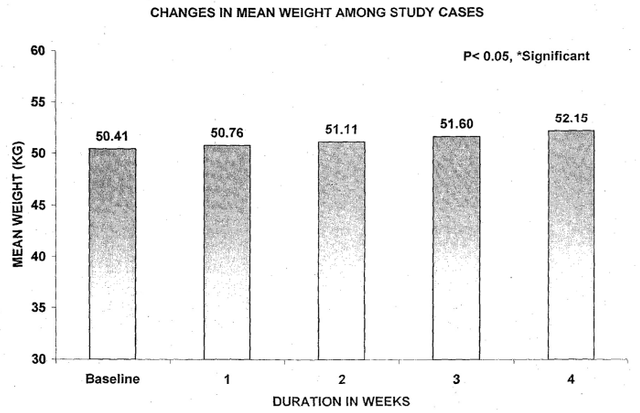
CHANGES IN MEAN WEIGHT AMONG STUDY CASES

Duration (Weeks)	**Mean weight ($\bar{X} \pm$ SD) (N = 5000)**
Baseline	50.41 ± 10.03
1	50.76 ± 10.01
2	51.11 ± 09.94
3	51.60 ± 09.91
4	52.15 ± 09.91
Mean Diff. (Baseline – Wk1) (P value)	*00.35 ± 00.57 (0.001)
Mean Diff. (Baseline – Wk2) (P value)	*00.70 ± 01.05 (0.001)
Mean Diff. (Baseline – Wk3) (P value)	*01.19 ± 01.77 (0.001)
Mean Diff. (Baseline – Wk4) (P value)	*01.74 ± 01.95 (0.001)

By ANOVA * Significant

- This analysis states that mean weight at baseline was **50.41kg.**
- After 1 week of treatment, mean weight showed a significant rise of **0.7%** from baseline.
- After 2 week of treatment, mean weight showed a significant rise of **1.4%** from baseline. Same trend was observed till the end of 4 weeks.

- **Figure1**



According to above figure, after RECEPTOL treatment mean weight significantly increases from week 2 onwards till end of treatment with respect to baseline

Table 2:

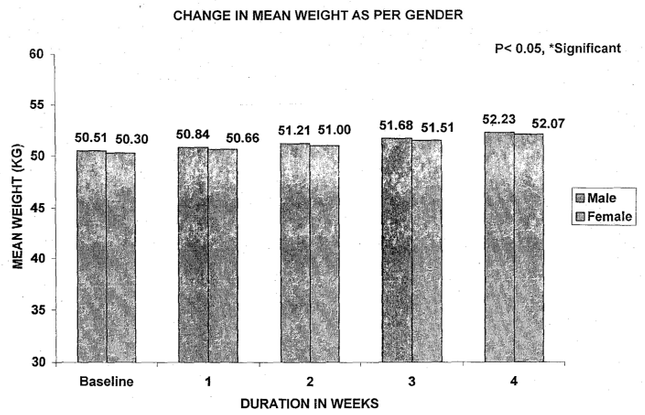
CHANGE IN MEAN WEIGHT AS PER GENDER

Duration (Weeks)	Mean weight ($\bar{X} \pm SD$)		P Value
	Male (N = 2693)	Female (N = 2307)	
Baseline	50.51 ± 09.96	50.30 ± 10.11	0.461 NS
1	50.84 ± 09.93	50.66 ± 10.10	
2	51.21 ± 09.88	51.00 ± 10.02	
3	51.68 ± 09.84	51.51 ± 10.00	
4	52.23 ± 09.87	52.07 ± 09.95	
Mean Diff. (Baseline – Wk1) (P value)	*00.33 ± 00.57 (0.001)	*00.36 ± 00.57 (0.001)	0.077 NS
Mean Diff. (Baseline – Wk2) (P value)	*00.70 ± 00.86 (0.001)	*00.70 ± 01.24 (0.001)	0.866 NS
Mean Diff. (Baseline – Wk3) (P value)	*01.17 ± 01.39 (0.001)	*01.21 ± 02.13 (0.001)	0.475 NS
Mean Diff. (Baseline – Wk4) (P value)	*01.72 ± 02.13 (0.001)	*01.77 ± 01.72 (0.001)	0.327 NS

By ANOVA * Significant NS = Not Significant

- This analysis reveals that mean weight at baseline was **50.51kg** in males which was comparable to **50.33kg** in females and the difference was not significant.
- After 1 week of treatment, mean weight showed a significant increase of **0.7%** among male and female each from baseline. If compared the increase was same among both the Group and difference was not significant.
- Same trend was observed till the end of 4 weeks.

Figure 2:



Above figure showed after treatment with RECEPTOL, there was significant change in weight among both the genders from baseline upto the end of treatment.

5. CONCLUSION

This observation study reveals that after RECEPTOL oral spray therapy, mean weight of study cases showed significant increase from baseline to end of treatment and that change were in both the genders.

Hence these results showed that RECEPTOL oral spray is very effective and safe among cases with other indications like Allergy, Asthma, Arthritis, Diarrhea, Fever, Fatigue-Malaise, Anemia, Endometriosis etc. to increase the weight and for overall wellness.

Disclaimer

All studies with Receptol as Standalone Mono-therapy resolved all clinical and physical
symptoms with 100% efficacy & safety.

Weight gain was used as a common denominator across different ailments only for meta analysis purpose.