STUDY REPORT

ON

SINGLE ARM, ONE MONTH STUDY ON HEALTHY POPULATION WITH FREQUENT RECURRENT INFECTIONS & WEIGHT LOSS PAST HISTORY TO DETERMINE THE EFFICACY & SAFETY OF RECEPTOL® ORAL SPRAY USED AS A STAND-ALONE MONO THERAPY

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SPONSOR:

BIOMIX NETWORK LIMITED

1. INTRODUCTION

Infectious diseases are disorders caused by organisms — such as bacteria, viruses, fungi or parasites. Many organisms live in and on our bodies. They're normally harmless or even helpful, but under certain conditions, some organisms may cause disease.

Some infectious diseases can be passed from person to person. Some are transmitted by bites from insects or animals. And others are acquired by ingesting contaminated food or water or being exposed to organisms in the environment.

Signs and symptoms vary depending on the organism causing the infection, but often include fever and fatigue. Mild complaints may respond to rest and home remedies, while some life-threatening infections may require hospitalization

The incidence of emerging infectious diseases in humans has increased within the recent past or threatens to increase in the near future. Over 30 new infectious agents have been detected worldwide in the last three decades; 60 per cent of these are of zoonotic origin. Developing countries such as India suffer disproportionately from the burden of infectious diseases given the

confluence of existing environmental, socio-economic, and demographic factors.

In the recent past, India has seen outbreaks of eight organisms of emerging and re-emerging diseases in various parts of the country, six of these are of zoonotic origin. Prevention and control of emerging infectious diseases will increasingly require the application of sophisticated epidemiologic and molecular biologic technologies, changes in human behaviour, a national policy on early detection of and rapid response to emerging infections and a plan of action. WHO has made several recommendations for national response mechanisms. Many of these are in various stages of implementation in India. However, for a country of size and population of India, the emerging infections remain a real and present danger. A meaningful response must approach the problem at the systems level. A comprehensive national strategy on infectious diseases cutting across all relevant sectors with emphasis on strengthened surveillance, rapid response, partnership building and research to guide public policy is needed.

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:** 10,000 cases

c) **Methods:** This trial was a 1-Month, Stand-Alone, single arm study to evaluate the Efficacy and Safety/Tolerability of RECEPTOL® oral spray in Healthy subjects. 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.

4. RESULT

Table 1:

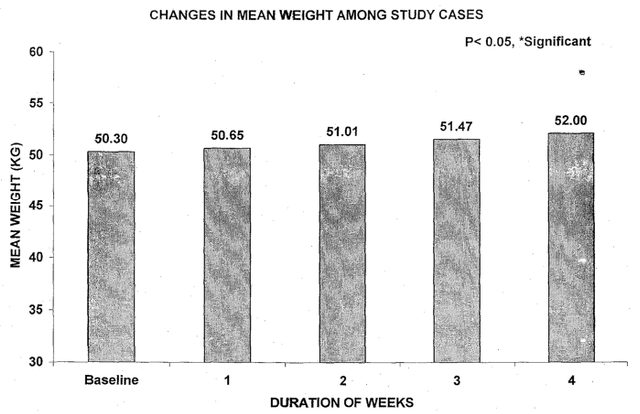
CHANGES IN MEAN WEIGHT AMONG STUDY CASES

Duration (Weeks)	Mean weight ($\bar{X} \pm$ SD) (N = 10000)
Baseline	50.30 ± 10.02
1	50.65 ± 10.01
2	51.01 ± 09.96
3	51.47 ± 09.94
4	52.00 ± 09.96
Mean Diff. (Baseline – Wk1) (P value)	*00.35 ± 00.66 (0.001)
Mean Diff. (Baseline – Wk2) (P value)	*00.71 ± 01.24 (0.001)
Mean Diff. (Baseline – Wk3) (P value)	*01.17 ± 01.95 (0.001)
Mean Diff. (Baseline – Wk4) (P value)	*01.70 ± 02.15 (0.001)

By ANOVA * Significant

- As per this data mean weight at baseline was **50.30 kg.**
- 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:

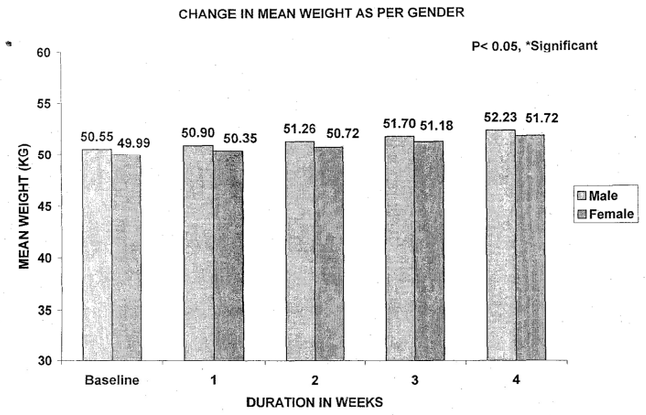
CHANGE IN MEAN WEIGHT AS PER GENDER

Duration (Weeks)	Mean weight ($\bar{X} \pm SD$)		P Value
	Male (N = 5462)	Female (N = 4538)	
Baseline	50.55 ± 10.00	49.99 ± 10.04	0.582 NS
1	50.90 ± 09.97	50.35 ± 10.05	
2	51.26 ± 09.93	50.72 ± 09.98	
3	51.70 ± 09.89	51.18 ± 09.98	
4	52.23 ± 09.95	51.72 ± 09.96	
Mean Diff. (Baseline – Wk1) (P value)	*00.35 ± 00.55 (0.001)	*00.36 ± 00.77 (0.001)	0.627 NS
Mean Diff. (Baseline – Wk2) (P value)	*00.71 ± 01.10 (0.001)	*00.73 ± 01.38 (0.001)	0.600 NS
Mean Diff. (Baseline – Wk3) (P value)	*01.15 ± 01.68 (0.001)	*01.19 ± 02.24 (0.001)	0.368 NS
Mean Diff. (Baseline – Wk4) (P value)	*01.68 ± 02.33 (0.001)	*01.73 ± 01.91 (0.001)	0.175 NS

By ANOVA * Significant NS = Not Significant

- Above data states that mean weight at baseline was **50.55kg** in males which was comparable to **49.99kg** 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 shows that after treatment with RECEPTOL, there is a significant change in weight in both the genders from baseline till 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 till end of treatment and these changes were observed in both the genders.

Hence, these results showed that RECEPTOL oral spray is very effective and safe to use in healthy population with frequent recurrent infections and weight loss cases to increase the weight and 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.