

RECEPTOL ORAL SPRAY: BRIEF SYNOPSIS

RECEPTOL[®] Oral Spray is an invention by Biomix Network Ltd. Proline rich polypeptides (PRPs) including Radha108 sequences are isolated through nanotechnology filtration system from bovine colostrum and formulated in a liquid oral spray to easily administer through buccal mucosa for effective penetration and effect.

RECEPTOL[®] Oral Spray is an immuno-modulatory product. It acts through regulating thymus, which in turn, modulates the function of immunity cells of the body. It increases the level of Interleukins and Cytokines. It blocks receptors of the immunity cells and restricts the entry of virus. Hence, body's own immune system improves and avoids recurrent viral infections.

RECEPTOL[®] Oral Spray was assessed as safe and effective for use in human population through clinical trials of Phase I, Phase II and Phase III in India and abroad, in the treatment of HIV and other immune disorders.

RECEPTOL[®] Oral Spray is manufactured in a controlled environment by skilled and trained personnel. Final filtration of the product through biological 0.2 μ filters ensures safe and microbial free product. Product Quality is ensured through stage-wise manufacturing and Quality Assurance controls.

RECEPTOL[®] Oral Spray containing Proline rich Polypeptides (PRPs) including Radha108 sequences shows that it is a new generation therapeutic agent, which is a highly effective, safe product for treatment of HIV and other immune disorders.

RECEPTOL[®] Oral Spray holds U.S. patent and South African patent.

BACKGROUND:

Colostrum is a pre milk substance produced from mother's breast of all mammals during first 24hrs of lactation typically first 3 milks. Colostrum has been known as immune booster since time memorial. Colostrum triggers at least 50 processes in the newborn, including transferring all immune factors and the entire immunological memory from mother's own immune system. Bovine colostrum is up to 40 times higher than human colostrum in immune factors including nano-informational peptides, Proline rich polypeptides, immunoglobulins, cytokines, interferons, lactoferrin and transfer factors. They are produced by T-lymphocytes and can transfer the ability to recognize a pathogen to naive cells. However, no one till date has been able to isolate active ingredient especially nano informational low molecular weight nano peptides and formulate a product that has a same effect as that of mother's first 3 milks after birth of child.

INTRODUCTION:

Biomix Network limited is successful in isolating active ingredients especially nano informational low molecular weight nano peptides that is Proline rich polypeptides(PRP) including Radha108 polypeptide sequences and provide a patient friendly liquid oral spray as immunomodulator.

TRIALS CONDUCTED

1) Pre clinical study (for acute and sub-chronic toxicity): Carried out as per Appendix III, Schedule Y, at Nation Institute of Nutrition, Hyderabad (Acute Toxicity report in Module 2 of the dossier submitted).

2) Phase I clinical trial: Ohio, USA. The trial was conducted to evaluate safety of Receptol[®] Oral Spray on 12 HIV patients for period of 30days.

- No serious adverse effects were reported during the study.
- Improvement observed in HIV associated clinical symptoms.
- Weight gain was observed during the trial.

3) Phase II study: Nairobi, Kenya. Trial was conducted on 30 HIV patient for 90 days treatment of Receptol[®] Oral Spray with an objective to demonstrate, under clinical conditions efficacy and safety in patients known to have advanced disease (HIV/AIDS).

- Receptol[®] Oral Spray appeared to be safe and well tolerated.
- Significant value reduction in minimizing the infection associated with HIV/AIDS.
- Weight gain as a positive response.

4) Phase III study: Rwanda, Africa. Trial was conducted in 60 HIV patients for period of 12 months using Receptol[®] Oral Spray. The objective of study was similar to Phase II study.

- Receptol[®] Oral Spray appeared to be safe and well tolerated.
- Significant value reduction in minimizing the infection associated with HIV/AIDS.
- Weight gain as a positive response.
- Moderate level of relief from fever and diarrhea was observed.

5) Phase III revalidation trial in India: At Mumbai. 50 patients with HIV were treated with Receptol[®] Oral Spray for period of 12 weeks

- Primary efficacy results indicated reduction in HIV viral load and related clinical symptoms.
- Secondary efficacy results indicated increase in absolute CD4 cell counts and Gradual disappearance of clinical symptoms of fatigue/malaise, diarrhea, fever, cough, nausea, vomiting, disturbed sleep, skin rashes and Herpes Zoster.

All the above study in HIV/AIDS infected human concluded that Receptol[®] Oral Spray containing Proline rich polypeptides and Radha108 sequences indicated that it is new generation therapeutic agent which is highly effective against HIV and other immune disorders.

CONCLUSION

Receptol[®] Oral Spray containing Proline rich polypeptide and Radha108 sequences show that it is a new generation therapeutic agent, which is highly effective and safe drug for treatment of HIV and other immune disorders.