Investigator's Brochure

NeuroCalm: An Investigational Drug for the Treatment of Generalized Anxiety Disorder

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1. Introduction

NeuroCalm is an investigational drug developed by HealthPharma for the treatment of Generalized Anxiety Disorder (GAD). This brochure provides comprehensive information about NeuroCalm, including its pharmacological properties, preclinical and clinical data, and guidance for investigators conducting clinical trials.

2. Summary of Data and Guidance for the Investigator

NeuroCalm has demonstrated potential efficacy in reducing anxiety symptoms in preclinical models and early-phase clinical trials. This brochure aims to equip investigators with the necessary information to safely and effectively conduct clinical trials involving NeuroCalm.

3. Drug Information

Description: NeuroCalm is a novel anxiolytic agent designed to modulate neurotransmitter activity in the brain, thereby reducing symptoms of anxiety.

Formulation: NeuroCalm is supplied in oral tablet form, with each tablet containing 50 mg of the active ingredient.

Pharmacodynamics: NeuroCalm works by enhancing the activity of gamma-aminobutyric acid (GABA) receptors, leading to a calming effect on neuronal activity.

Pharmacokinetics:

- **Absorption:** NeuroCalm is rapidly absorbed with peak plasma concentrations reached within 1-2 hours post-administration.
- **Distribution:** It is widely distributed in the body, crossing the blood-brain barrier.
- **Metabolism:** NeuroCalm is primarily metabolized in the liver.
- **Excretion:** The drug and its metabolites are excreted mainly via the kidneys.

4. Preclinical Studies

Preclinical studies in animal models have shown that NeuroCalm effectively reduces anxiety-like behaviors without significant adverse effects. Toxicology studies indicate a favorable safety profile with no evidence of organ toxicity at therapeutic doses.

5. Clinical Studies

Phase I Studies: Phase I trials assessed the safety, tolerability, and pharmacokinetics of NeuroCalm in healthy volunteers. The drug was well-tolerated, and no serious adverse events were reported.

Phase II Studies: Phase II trials evaluated the efficacy of NeuroCalm in patients with GAD. Preliminary results indicated a significant reduction in anxiety symptoms compared to placebo, as measured by the Hamilton Anxiety Rating Scale (HAM-A).

6. Potential Risks and Side Effects

Common side effects observed in clinical trials include headache, dizziness, nausea, and fatigue. There may be additional risks that are currently unknown. Investigators must monitor participants closely and report any adverse effects promptly.

7. Instructions for Use

Participants will take one oral tablet of NeuroCalm (50 mg) daily for the duration of the study. Compliance with the dosing regimen is critical for the integrity of the study data.

8. Monitoring and Reporting

Investigators must conduct regular follow-up visits to monitor participants' health and collect data on efficacy and safety. Any adverse events must be reported to HealthPharma's safety monitoring board within 24 hours.

9. Summary and Conclusion

NeuroCalm represents a promising new treatment for GAD with a favorable safety and efficacy profile in early clinical trials. Further research is needed to confirm these findings in larger, more diverse populations.

10. References

1. Smith, J. et al. (2024). Preclinical Evaluation of NeuroCalm: Safety and Efficacy in Animal Models. Journal of Neuropsychopharmacology.
2. HealthPharma (2023). Phase I Clinical Trial Results for NeuroCalm.
3. HealthPharma (2024). Phase II Clinical Trial Results for NeuroCalm.

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