

SUMMARY

Clinical study of INSUGEN – N (NPH) Insulin Injection, Isophane Ph. Eur., 40 IU / ml in Indian Diabetic subjects

1. Objectives :

To evaluate the safety and efficacy of INSUGEN – N 40 IU/ml, Human Isophane Insulin manufactured by Biocon and to demonstrate its non-inferiority to equivalent Marketed Human Isophane Insulin (40 IU/ml) in subjects with diabetes mellitus.

2. Methodology :

Study Design: A multicentric, open labeled, randomized, parallel group non-inferiority study.

Treatment Groups: 'Biocon' group which received INSUGEN – N 40 IU/ml (Human Isophane Insulin Injection) manufactured by Biocon for 12 weeks.

'Marketed' group which received equivalent Marketed Human Isophane Insulin Injection (40 IU/ml) for 12 weeks.

3. Duration of Treatment : 12 weeks.

4. Criteria for Evaluation :

Primary Efficacy Parameters :

- Change in HbA1c during the treatment period
- Change in 2-hr Post-Prandial Plasma Glucose during the treatment period
- Change in Fasting Plasma Glucose during the treatment period

Secondary Efficacy Parameter :

- 6-Point blood glucose profile (Home blood glucose monitoring) during 0, 4th, 8th and 12th week of treatment

Safety Parameters:

Physical examination, Hypoglycaemia, Adverse Events, Haematology, Biochemistry and Serology, ECG, Chest X-Ray, Fundoscopy, Lipid Profile.

5. Test Product :

INSUGEN – N, Human Isophane Insulin of Biocon 40 IU/ml, 10ml vial administered subcutaneously. {Insulin injection isophane(Human Insulin, rDNA Origin)}.

6. Reference Product :

Equivalent marketed Human Isophane Insulin Injection 40 IU/ml, 10ml vial administered subcutaneously.

7. Study Centers :

Diacon Hospital and Research Centre, Bangalore
Care Hospital, Hyderabad
Diabetes, Endocrine, Nutrition Management and Research Centre, Mumbai
Amrita Institute of Medical Science, Cochin
Madras Diabetes Research Foundation, Chennai
M.S. Ramaiah Medical College and Hospital, Bangalore
M.V. Diabetes Research Centre, Chennai
Nizam's Institute of Medical Sciences, Hyderabad
MEDIHEIGHTS Healthcare Foundation, Mumbai
Dr.V. Seshiah Diabetes Care and Research Institute, Chennai
Samatvam, Bangalore.
Kilpauk Medical College Hospital, Chennai
INSTRIDE, Pune.

8. Number of Subjects (Planned and Analyzed):

Sl.	Number of Subjects	Planned	Analyzed
1.	Planned (60 per arm)	120	
2.	Enrolled	136	
3.	Completed		126
4.	Safety Analysis		126
5.	Efficacy Analysis		122

9. EFFICACY RESULTS :

There was no significant difference between the BIOCON and MARKETED groups with respect to change from baseline in any of the primary efficacy parameters, HbA1c, FPG, and PPPG. The results pertaining to the secondary efficacy parameters based on the 6-point glucose profile were similar to those based on the primary efficacy parameters, thus confirming the robustness of the efficacy results.

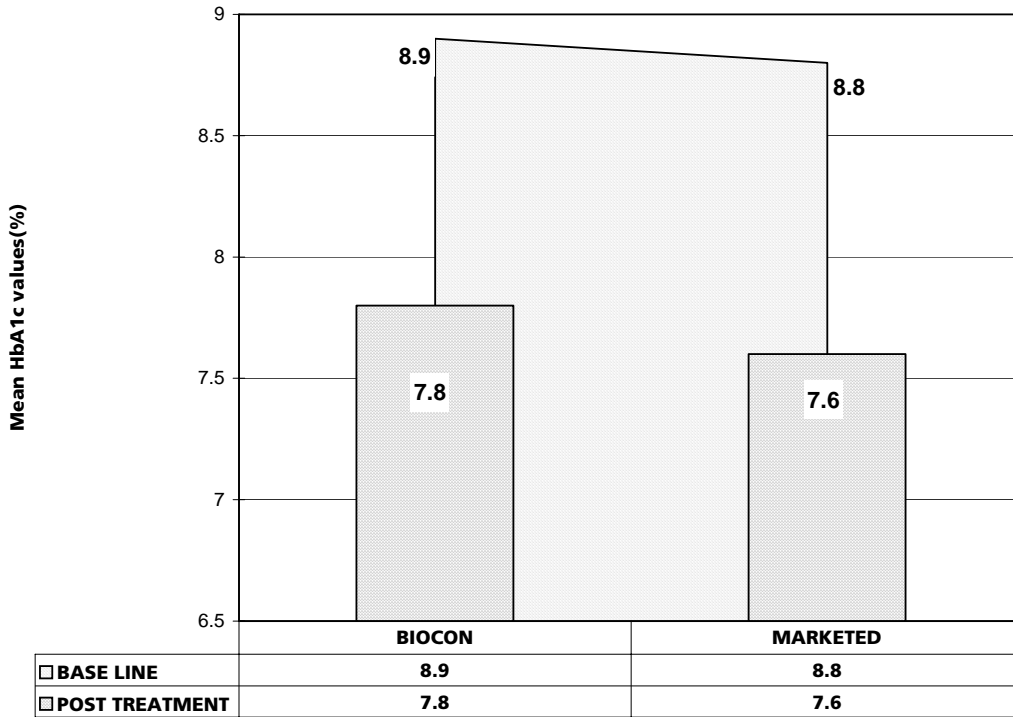
10. SAFETY RESULTS :

The incidence of adverse events during the 12-week treatment period was similar for the two treatment groups. Most of these adverse events were categorised as having a mild and unlikely relationship to the study drugs. Thus, both treatments were generally well tolerated.

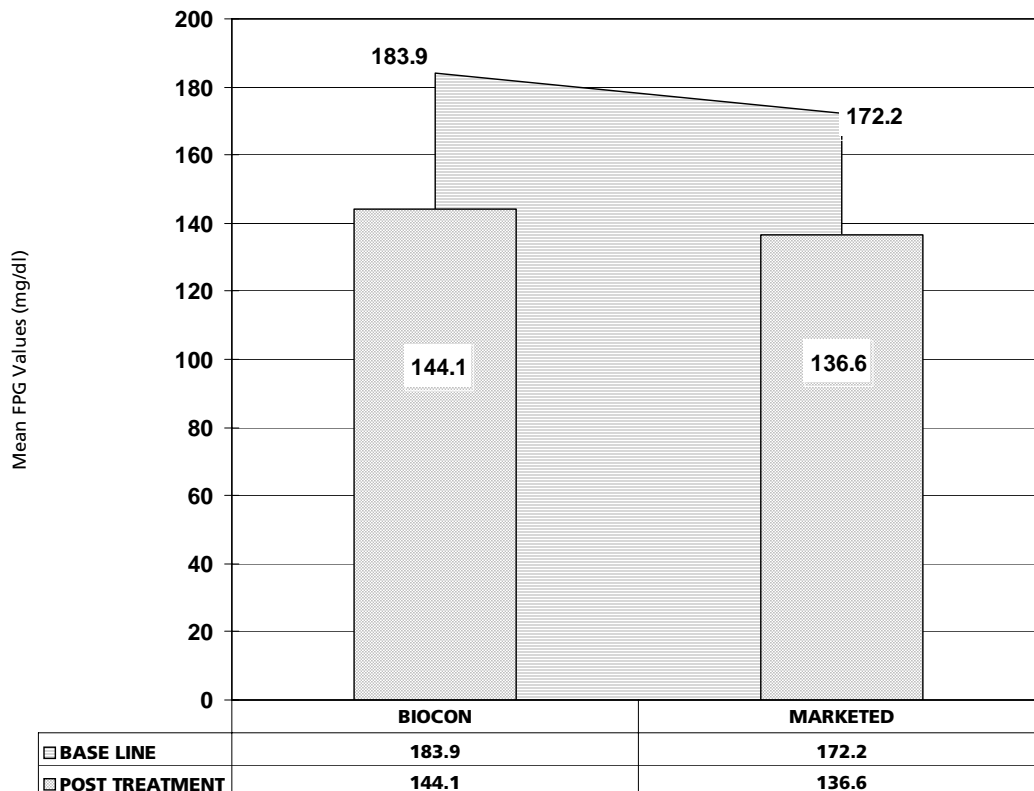
11. CONCLUSION :

The results of this study shows that INISUGEN – N Insulin Injection Isophane Ph. Eur., (containing Human Insulin of rDNA origin) 40 IU/ml, manufactured by Biocon is non-inferior when compared to an equivalent Marketed formulation in terms of efficacy and safety.

HbA1c values Baseline v/s Post Treatment
Human Isophane Insulin Injection



FPG values Baseline v/s Post Treatment
Human Isophane Insulin Injection



**PPPG Values Baseline v/s Post Treatment
Human Isophane Insulin Injection**

