



Naturamore for Kids

Clinical Study Report



Clinical Trials

- Naturamore is **ONE OF THE VERY FEW BRANDS** in India to conduct DOUBLE BLIND rigorous, registered clinical trials of the products.
- Clinical trials provide us the **ASSURANCE** and **CONFIDENCE** that the product is **SAFE** and **EFFECTIVE**
- Studies are conducted following stringent guidelines by **WHO – GCP, ICMR AND OECD GUIDELINES**

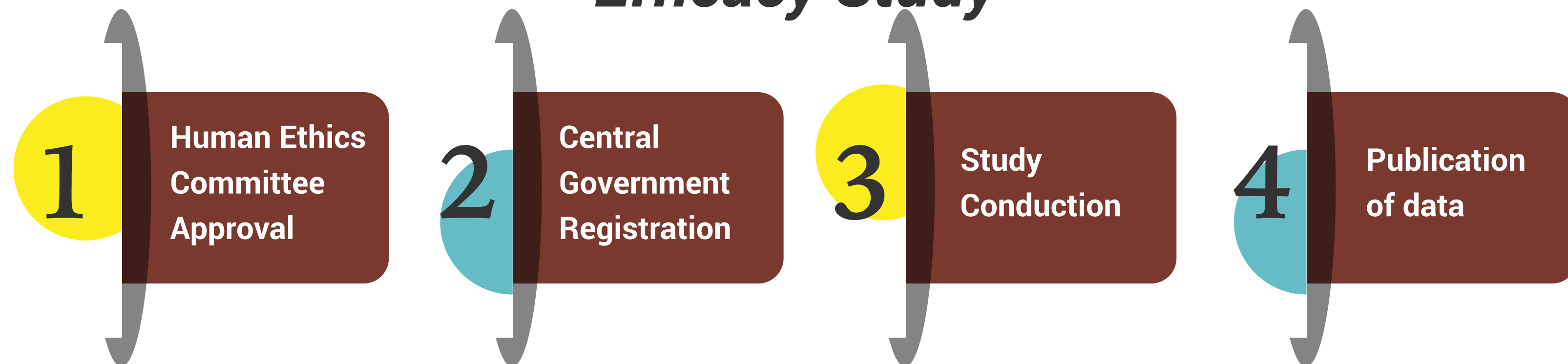


Steps in clinical study for Naturamore Products

Safety Study



Efficacy Study



Safety Study

Purpose

To assure total safety of the product for the consumption

Acute

To understand the highest safe dose of the product
(As per standard OECD 423 guidelines)

Sub – Acute

To understand safety of the product for long – term consumption
(As per standard OECD 423 guidelines)



Acute Toxicity Study

NO SAFETY CONCERNS observed even at
5000 mg / kg body weight dose.

It can be labelled as **SAFE FOR ORAL CONSUMPTION**
at recommended dosage



Sub – Acute Toxicity Study

Conducted as Repeated Dose 28-day
Oral Toxicity Study as per standard OECD guidelines

NO ADVERSE EFFECT on general health, growth, behavioural, neurological, Haematological, clinical chemistry and urinalysis parameters, organ weights and gross of the tissues / organs of the mice treated at the dose level of 1000 mg/kg body weight.

It can be labelled as
SAFE FOR LONG TERM CONSUMPTION
at recommended dosage



Efficacy Studies

Clinical trials in comparison with
Market Leader Product

Double Blind Study – Considered as
GOLD STANDARD in clinical trials

Central Registration Number:
CTRI/2019/11/021993 [Registered on: 13/11/2019]

Study Conducted for 90 days in 100 Subjects
(50 in each group)



Parameters Studied

- Growth and development of kids
- Serum iron and Serum calcium levels
- Mental activity, memory and intelligence
- Physical endurance - VO2 and Steppers test
- Overall Immunity
- Digestion profile
- Serum BDNF levels (brain promoting factor)
- Safety, tolerability and compliance testing



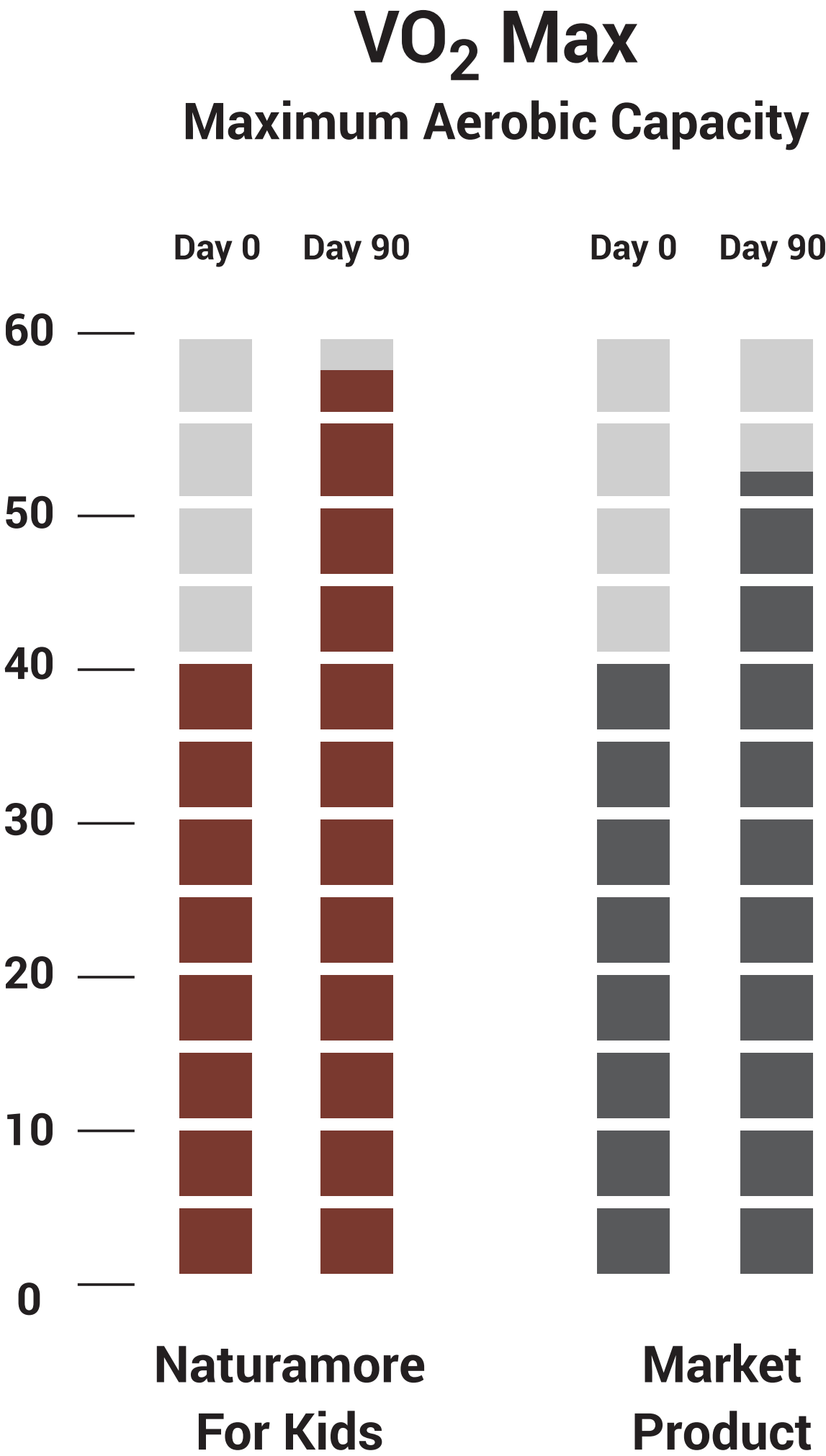
Results & Interpretation



Endurance testing

Maximum Aerobic Capacity (VO2 Max)
(It is the maximum amount of oxygen you can utilize during exercise. It's commonly use to test the aerobic endurance or cardiovascular fitness.)

More value is considered better

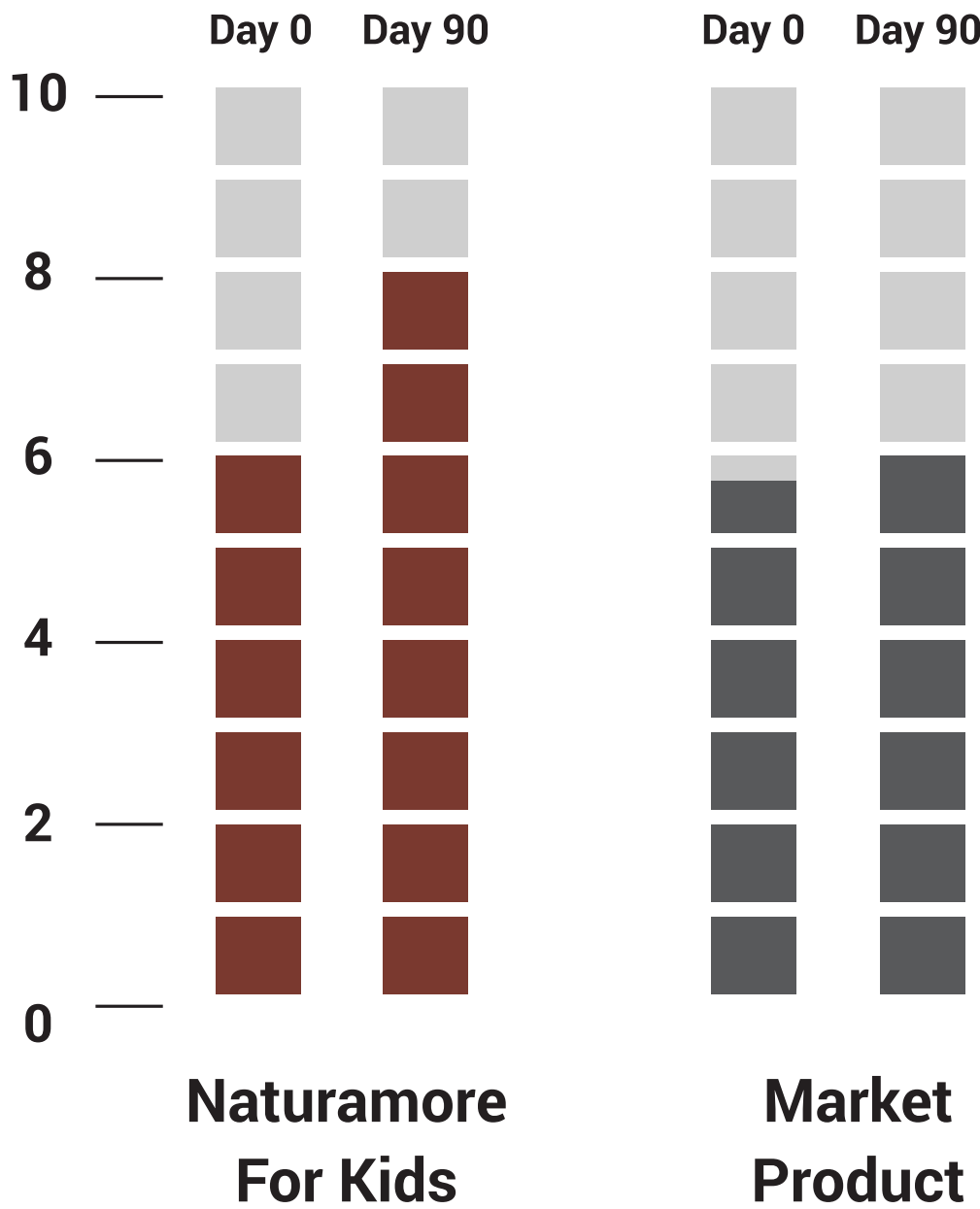


Intelligence & Mental Development

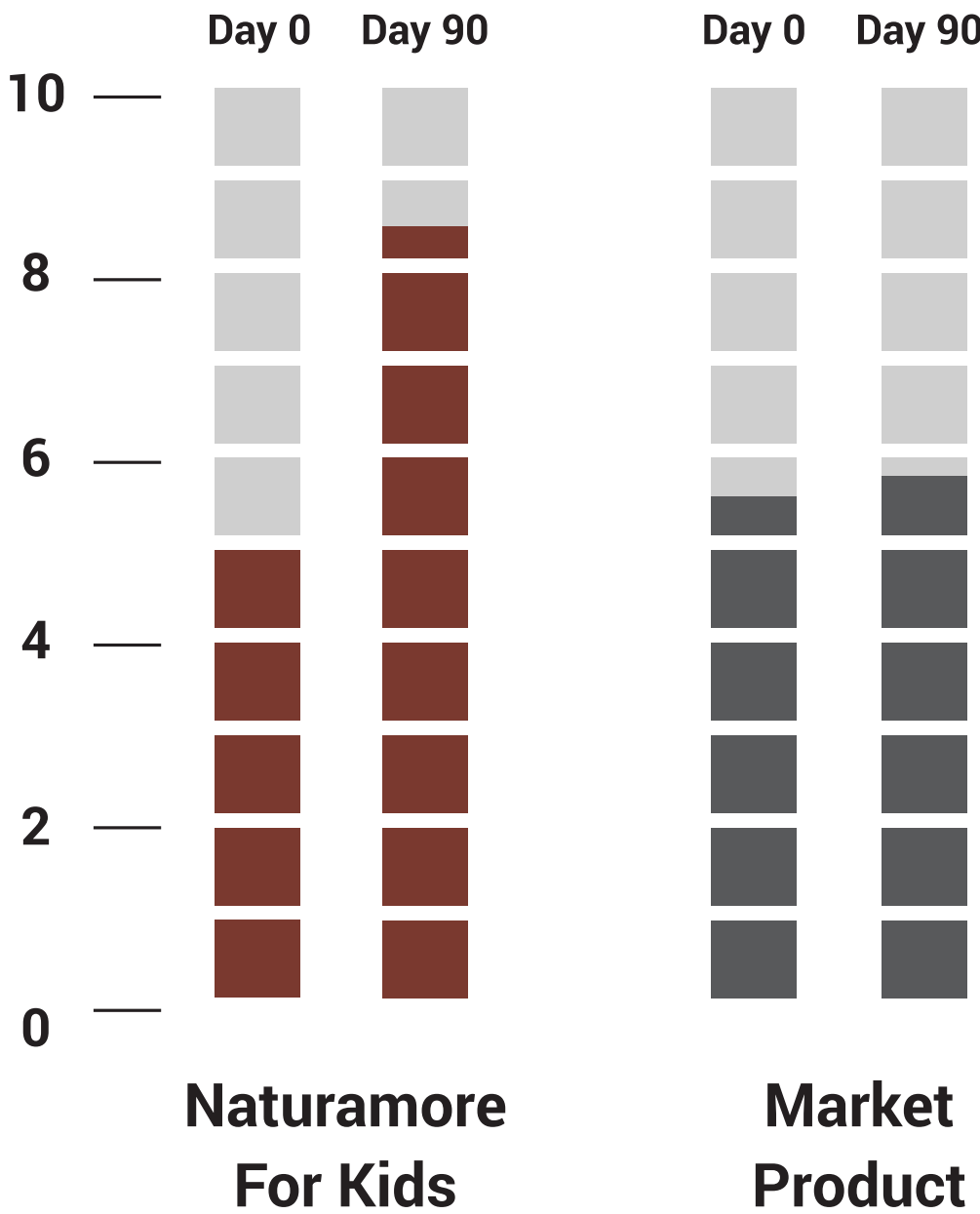
It is to check your overall intellectual development of kids.

More value is considered better

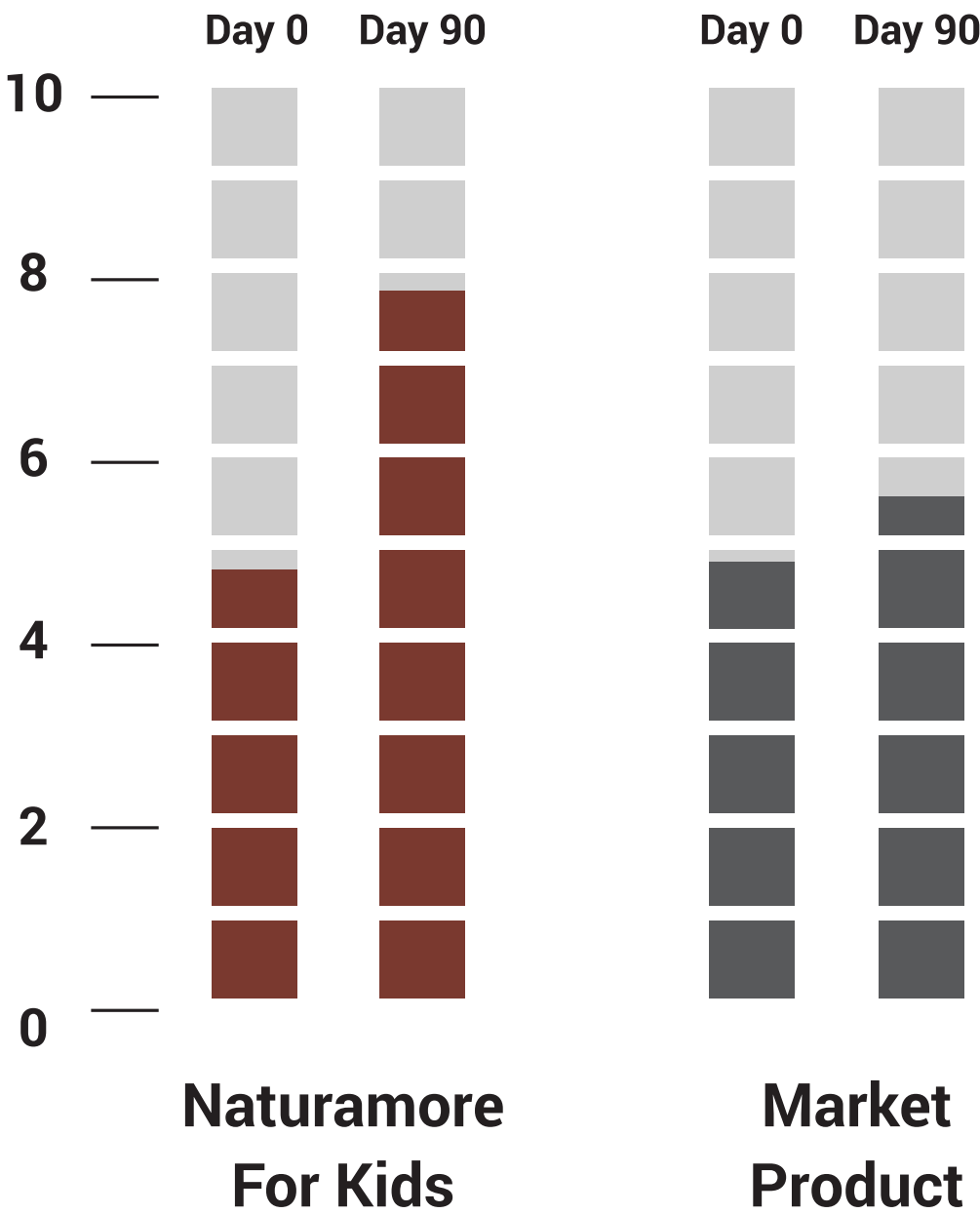
Social Skills



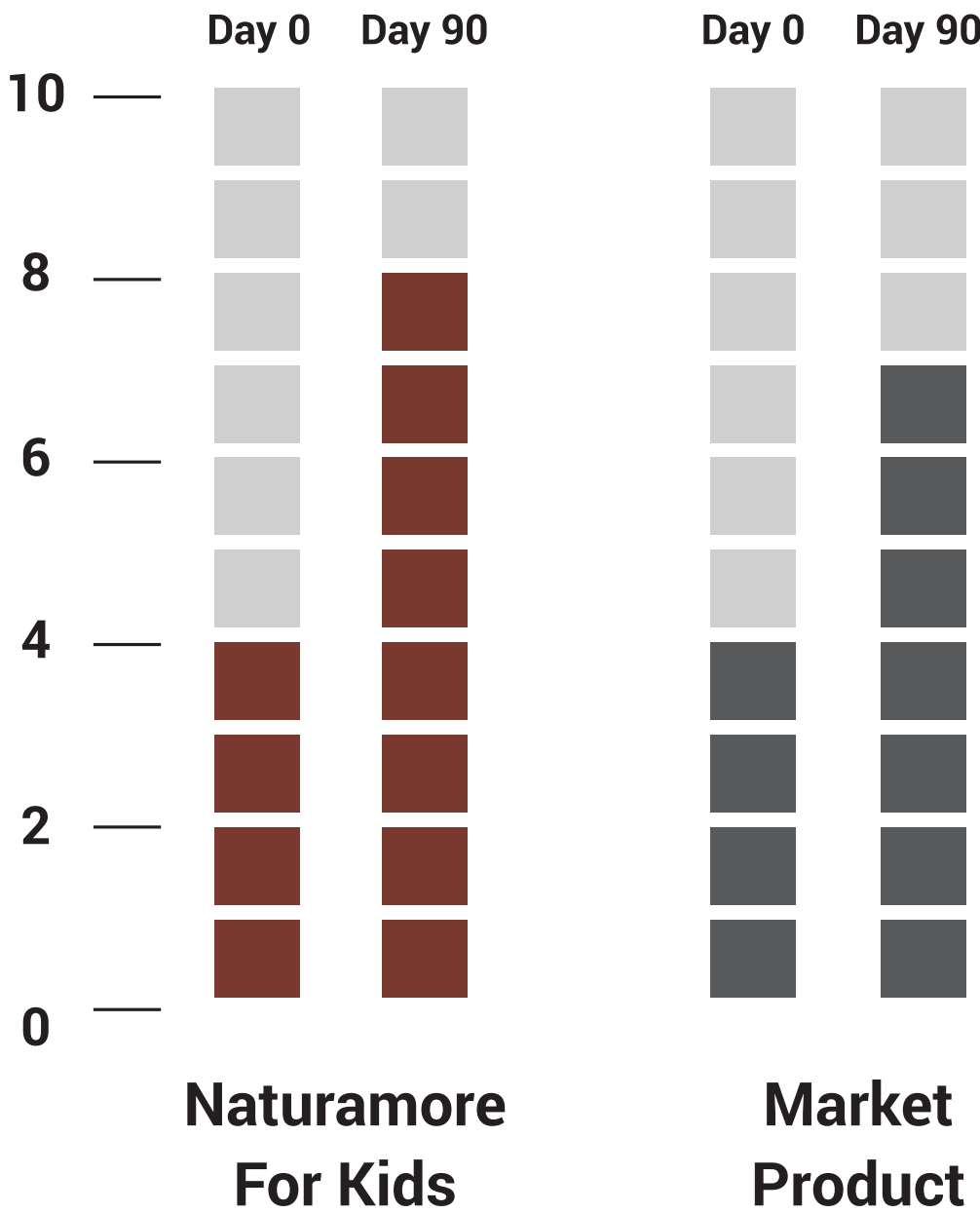
Motivation



Self Regulation



Empathy



Development & Behaviour

It is to check your overall intellectual development of kids.

More value is considered better

*It can be observed from the table that Naturamore for kids **OUTPERFORMED** the market product on all the parameters of development and beheaviour of kids.*

Parameter	Naturamore For Kids		Market Product	
	Baseline	Day 90	Baseline	Day 90
Gross Motor Skills	8.91	18.20	9.05	14.31
Attention & Concentration	11.79	20.67	11.62	13.62
Over Activity & Impulsivity	14.05	22.31	13.70	14.78
Inactivity	6.48	12.20	6.64	8.44
Planning / Organisation	5.49	10.73	5.58	7.73
Perception of Space & Directions	6.52	12.58	6.66	7.91
Perception of visual forms	5.66	11.00	5.62	7.82
Memory	13.45	24.04	13.23	15.98
Spoken Language	6.79	12.60	7.16	9.07
Verbal Communication	4.64	8.24	4.77	6.00
Academic Skills	12.66	25.53	12.20	15.30
Social Skills	13.93	27.53	14.02	15.82
Emotional Issues	17.79	36.98	17.80	19.20
Obsessive Actions	8.57	5.27	8.70	9.62

Other Parameters

- There was **SIGNIFICANT IMPROVEMENT** in certain domains in eating behaviour like Food responsiveness, Emotional over eating, Enjoyment of food, Desire to drink, satiety responsiveness, sluggish eating, emotional under eating
- There was **SIGNIFICANT IMPROVEMENT** in all domains of Development and Behaviour Score in Test product than Marketed product treated group.
- Test product and marketed product treated group showed **SIGNIFICANT IMPROVEMENT** in anthropometric parameters with height, weight and BMI.
- There was **SIGNIFICANT IMPROVEMENT** in Overall immunity, Serum Iron, Serum Calcium and Serum BDNF levels



Conclusion

- Naturamore for Kids may help **COMPLETE OVERALL NUTRITIONAL REQUIREMENTS** of kids in growing age
- Naturamore for Kids may help **INTELLIGENCE, COGNITION AND MEMORY** performance of kids
- Naturamore for Kids may help **OVERALL DEVELOPMENT OF KIDS**
- Naturamore for Kids is **SAFE TO CONSUME FOR A LONG TERM** in recommended dosage without any adverse events

