Reference No. :- 01/2017

CLINICAL STUDY OF PRESERVA BOOSTHEALTH TABLET

Manufactured by:-

Planet Herbs Lifesciences (Pvt.) Ltd, B-4, Sara Industrial Estate, Selaqui, Dehradun-248197, INDIA

Formulated & Marketed / Funding By:-

Trigya Health Products Private Limited, E-375, Ist Floor, Greater Kailash –II, Delhi-110048

Place of study: - Prankamiya Ayurveda, Dr. Sharma's Hospital, 95/1 Rajpura Gurmandi , Delhi -110007

Packing Details: - Packed 60 Tablets in a Bottle

Best Before: - 36 Months from the date of Mfg.

Formulation: - Approved By Directorate of Ayurveda Dehradun (Uttarakhand)

Mfg. Lic. No.:- UK AY- 218 / 2010

Composition: -
Each Tablet Contains

S.N.	Common Name	Botanical Name	Part used	Shastriya Prayoga	Qty.in mg	Ref. Book
1	Shatavari	*Asparagus racemosus extract*	Root	Balya,Pushtidayak	300mg	Bhavapraksh Nighantu Page No. 378
2	Turmeric	*Curcuma longa*	Rhizome	Shothhar,Immunobooster	230mg	Page No.111
3	Ashwagandha	*Withania somnifera extract*	Root	Balya,Rasayan,Katishool, Sweta,Pradarhar,	100mg	Page No.379
4	Turmeric (95%Curcumin)	*Curcuma longa extract*	Rhizome	Shothhar,Immunobooster	70mg	Page No.111

Dosages form: - Oral (Tablet)

Dosage: - 1-2 Tablet twice a day before meal or as directed by the physician.

Vehicle / Anupan: - With Luke warm water

Indication:-

1. Female hormonal balance
2. Pre &/Menopause symptoms
3. Hot flashes
4. Rejuvenates reproductive system
5. Supports healthy system
6. Regulates ovulation
7. Breast Feeding issues
8. Pain in bones
9. Frequently abortions / miscarriages

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Date of Starting:- 11/11/2016

Date of Completion:- 12/01/2017

Trial Done By - 1. Dr. Shivani Kapil
B.A.M.S, M.S (Ayu.)
2. Dr. Harsh Gupta
B.A.M.S, M.D (Ayu.)

Number of Patient: - 32

Directions for Use: - 1 –2 tablet twice a day before meal or as directed by physician.

INTRODUCTION:-

Study design:-

This study was a prospective, open, clinical trial, conducted at the clinic from 11/11/2016 to 12/01/2017.

Inclusion criteria:- A total of 32 patient of reproductive issues of females with aged from 40 to 60 years with **problems of Hormonal Balance, Regulates ovulation , Pre & Post Menopause issues, During Breast Feeding** etc. and who were willing to give informed consent were included in the study

Exclusion criteria:-
Persons with known hypersensitivity to any of the ingredients of the formulation, any facial wound or abrasion, and who were not willing to give informed consent were excluded from the study.

Study procedure:-
A baseline history was obtained in order to determine the patient's eligibility for enrolment in the trial. The baseline assessment included personal data, a description of symptoms and details of past medical history (family history, history of possible exacerbating factor/s, etc.).

All the patients were advised to take the **"PRESERVA BOOSTHEALTH TABLET"** 1-2 twice a day before meal for a period of 12 weeks.

The subjective improvement evaluation was done by a predefined global grading system, which included following gradations:

1. "No improvement" 2. "Fair improvement" 3. "Remarkable improvement"

4. "Very good improvement" 5. "Excellent improvement".

Follow-up and Monitoring:-

All the patients were followed up for a period of 12 weeks, and at each weekly follow-up visit, the safety, and the improvement in female reproductive related disorder was evaluated.
At the end of the 12 week, the overall performance of the **"PRESERVA BOOSTHEALTH TABLET"** product was evaluated.

Primary and Secondary end points:-
The predefined end point was improved regulates ovulation, hormonal balance, and predefined secondary safety endpoints (for short and long term) were assessed by the incidence of adverse events and patient compliance to the therapy.

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Adverse events:-

All the adverse events either reported or observed by the patients were recorded with information about the severity, date of onset, duration and action taken regarding the study drug.

Relation of adverse events to the study medication were predefined as

"Unrelated" (a reaction that does not follow a reasonable temporal sequence from the time of administration of the drug),

"Possible" (follows a known response pattern to the suspected drug, but could have been produced by the patient's clinical state or other modes of therapy administered to the patient)

"Probable" (follows a known response pattern to the suspected drug that could not be reasonably explained by the known characteristics of the patient's clinical state).

RESULTS:-

A total of 32 patients were enrolled in the study. There was significant improvement in the **"PRESERVA BOOSTHEALTH TABLET"** after 12 weeks application, and the improvement trend continued, till the end of the study period.

Out of 32 subjects, 17 had "Remarkable" improvement hormonal balance

12 had "Very good" improvement regularization in ovulation

11 had "Excellent" improvement in the

There were no clinically significant adverse reactions, either reported or observed, during the entire study period and the overall compliance to **"PRESERVA BOOSTHEALTH TABLET"** was excellent.

The principle constituents of **SHATAVARI, TURMERIC and ASHWGANDHA**

SHATAVARI & ASHAWGANDHA have become the chief reliving contents.

The results of some new studies are promising, indicating that **SHATAVARI, TURMERIC & ASHWGANDHA** can decrease the female reproductive issues.

TURMERIC also reduces the infections, inflammations etc. were included the excellent effects of **"PRESERVA BOOSTHEALTH TABLET-"** might have been due to the and properties of the ingredients, which also have excellent safety profile.

CONCLUSION:-

60 % improvement level of **Hormonal Balance**
44 % improvement in controlling **Regulates ovulation, Pre & Post Menopause issues**
26% improvement in **Breast feeding issues**

This study observed a significant improvement in which also have excellent safety profile. Therefore, it may be concluded that **"PRESERVA BOOSTHEALTH TABLET"** is effective and safe for usage, in the management of **Hormonal Imbalance, Pre. & Post Menopause issues, Breast feeding issues etc.** a common cause of in the general population in often poorly understood and managed.

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PRE-DISPOSING FACTORS:-

1. Hormonal Balance
2. Regulates ovulation
3. Pre Menopause issues
4. Post Menopause issues
5. During Breast Feeding
6. Reproductive issues
7. Overweight
8. Breast feeding issues
9. Laziness

JUSTIFICATION OF HERBAL THERAPY

A total of 32 patients, of both sexes, aged from 30 to 60 years, hormones & reproductive issues and related disorder, and who were willing to give informed consent in the study.

STATICAL DATA: (According to Sex)

S. No.	Sex	No. of Patient
1	Female	32

STATICAL DATA: (According to Age)

S. No.	Age	No. of Patient
1-	Between 30 to 35	05
2-	Between 35 to 45	14
3-	Between 45 to 50	08
4-	Between 50 to 60	05

STATICAL DATA: (According to Diet)

S. No.	Diet Habit	No. of Patient
1-	Vegetarian	22
2-	Non-Vegetarian	10

OBSESVATION & CRITERIA:- Criteria of Hormonal Balance, Regulates ovulation, Pre. & Post Menopause issues, Breast Feeding issues, Reproductive issue, Overweight, Breast feeding issues, Laziness etc. were the following:

1. Hormonal Balance
2. Regulates ovulation
3. Reducing Pre Post Menopause issues
4. Reducing Post Menopause issues
5. Reducing Breast Feeding issues
6. Weight reducing
7. Feeling Happiness

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Patients were also interrogated for any side effects occurring during the period of the trial.

Researched by:-

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