CLINICAL STUDY OF PRESERVA ARTHROGOLD 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 of Dehradun (Uttarakhand)

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

Composition: -

Each Tablet Contains

S.NO.	Common Name	Botanical Name	Part used	ShastriyaPrayoga	Qty.in	Ref. Book
1	Salai Guggul (Boswellic acid60%)	Bosewellia serrata extract	Resin	Vata vikarhar	mg 300mg	BhavaPrakash PageNo. 203/509
2	Turmeric	Curcuma longa	Rhizome	Shothhar,Shoolhar, Rakatshodhak,Vathar	150mg	PageNo.111
3	Rasana	Pluchea lanceolata extract	Leaves	Aamvathar,Vatvikarhar	150mg	PageNo.77
4	Ashwagandha	Withania somnifera extract	Root	Sandhivathar, Shothhar	100mg	PageNo.379
5	Turmeric	Curcuma longa extract	Rhizome	Shothhar, Shoolhar,Rakatshodhak,Vathar	50mg	PageNo.111
6	Black pepper	Piper nigrum extract	Fruit	Amvatahar	10mg	PageNo.17

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. Arthritis and it complications
- 2. Back pain
- 3. Morning stiffness
- 4. Muscular Sprain
- 5. Sciatica
- 6. Grip strength
- 7. Swelling
- 8. Indigestion
- Slight fever

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Rajpura-Guilliandi, Do.

Date of Starting:- 07/11/2016 Date of Completion: - 09/01/2017

Number of Patient: - 38

Trial Done by :-

1. Dr. Shivani Kapil

B.A.M.S, M.S(Avu.)

2. Dr. Harsh Gupta

B.A.M.S, M.D(Ayu.)

Directions for Use: - 1-2 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 07/11/2016 to 09/01/2017.

Inclusion criteria:- A total of 38 patient of Arthritis male & females with aged from 40 to 75 years with morning stiffness, pain in joints, inflammation, Back pain, Indigestion, slight fever 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 ARTHROGOLD 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 Arthritis related disorder was evaluated.

At the end of the 12 week, the overall performance of the "PRESERVA ARTHROGOLD TABLET" product was evaluated.

Primary and Secondary end points:-

The predefined end point was improved pain in joints, morning stiffness, back pain 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 "PRESERVA ARTHROGOLD TABLET"

"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 38 patients were enrolled in the study. There was significant improvement in the "PRESERVA ARTHROGOLD TABLET" after 12 weeks application, and the improvement trend continued, till the end of the study period.

Out of 40 subjects

38 had "Remarkable" improvement back pain, slightly fever,

22 had "Very good" improvement morning stiffness, pain in joints, inflammation

18 had "Excellent" improvement in the Arthritis and it's complications

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

The principle constituents of Salai Guggul, Turmeric, Rasna in Anti Arthritis

Ashwagandha have become Balaya (Tonic)

Black pepper has become the chief Pramaathi (Cleaning agent of blocked channels)

The results of some new studies are promising, indicating that Salai Guggul, Turmeric, Rasna, Ashwagandha, Black pepper can decrease the Arthritis related disorders.

Were included the excellent effects of "PRESERVA ARTHROGOLD TABLET" might have been due to the and properties of the ingredients, which also have excellent safety profile.

45% improvement in controlling, digestion, Slight fever, Muscular Sprain, Morning stiffness 66% decreases Pain in joints, inflammation, Arthritis, Back pain, Grip strength Swelling 70% increase Grip strength

CONCLUSION:-

This study observed a significant improvement in which also have excellent safety profile. Therefore, it may be concluded that "PRESERVA ARTHROGOLD TABLET" is effective and safe for usage, in the management of back pain, morning stiffness, swelling & indigestion a common cause of in the general population in often poorly understood and managed.

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PRE-DISPOSING FACTORS:-

- 1. Arthritis and it complications
- 2. Back pain
- 3. Morning stiffness
- 4. Muscular Sprain
- 5. Sciatica
- 6. Grip strength
- 7. Swelling
- 8. Indigestion
- 9. Slightly fever

JUSTIFICATION OF HERBAL THERAPY:-

A total of 38 patients, of both sexes, aged from 30 to 70 years, Arthritis 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	Male	12
2	Female	26

STATICAL DATA: (According to Age)

S. No.	Age	No. of Patient	
1-	Between 30 to 40	03	
2-	Between 40 to 50	16	
3-	Between 55 to 60	10	
4-	Between 65 to 70	09	

STATICAL DATA: (According to Diet)

S. No.	Diet Habit	No. of Patient	
1-	Vegetarian	06	
2-	Non-Vegetarian	32	

OBSESVATION & CRITERIA

Criteria of Arthritis, Back pain, Morning stiffness, Muscular Sprain, Grip strength Swelling Indigestion Slightly fever etc. were the following:

- 1. Arthritis↓
- 2. Back pain↓
- 3. Morning stiffness↓
- 4. Muscular Sprain ↓
- 5. Sciatica
- 6. Grip strength↑
- 7. Swelling ↓
- 8. Indigestion \downarrow
- 9. Slightly fever

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Researched by:-

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