

Egyptian Herbal Monograph

Volume 1

Wild Medicinal Plants

Egyptian Drug Authority (EDA)

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***Plantago ovata* Forssk.**

لقمة النعجة - جنينة

1. Names & Synonyms (1- 6)

***Plantago ovata* Forssk.**

Syns.: *Plantago decumbens* Forssk., *P. ispaghul* Roxb

Family: Plantaginaceae

Arabic: Loqmet El-na'aga لقمة النعجة, Gneima جنينة

English name: Spogel plantain, Ispaghula, Blond Psyllium, Indian Plantago, Ispagol, Ispaghul, Pale Psyllium, Spogel .

*It is different species of Psyllium << See monograph of *Plantago afra* -Volume 2>>.

Psyllium and/or Ispaghula are the common names used for several members of the plant genus *Plantago*. Refer to the monograph of *Plantago afra* in Volume 2 of the Egyptian Herbal Monograph for more information.

2. Geographical distribution (3)

- The Nile region, Mediterranean coastal strip as well as all the deserts of the country including that of Sinai.

3. Parts used for medicinal purpose (3)

- Dried ripe seeds (7) and husk (Episperm and collapsed adjacent layers removed from the seeds (5, 8-10).

4. Major chemical constituents

Seeds:

- Polysaccharides: arabinoxylan mucilage, cellulose, hemicellulose and lignin (11).
- **Others:** Aucubin (iridoid glucoside) (5), crude fibers, proteins and fats (13).

Husk:

- **Polysaccharides:** arabinoxylan mucilage, cellulose, hemicellulose and lignin Insoluble (cellulose, hemicellulose and lignin) and soluble polysaccharaides and hemicellulose arabinoxylans (xylan backbone coupled with arabinose, rhamnose and galacturonic acid portions) (14).

- **Others:** Fatty acids, amino acids, minerals, sugars (14); alkaloids, tannins, saponins, flavonoids and phenols (16).

5. Traditional Medicinal Uses

- Treatment of habitual constipation (7, 8).
- Bulk laxative (9) in conditions where easy defecation with soft stool is desirable, e.g. in cases of painful defecation after rectal or anal surgery, anal fissures and haemorrhoids (7, 8, 10).

P. ovata is a traditional medicinal plant for use in the specified indications based upon long-standing use. In addition, the well established usage is verified and supported by scientific evidence.

6. Herbal preparations correlated to medicinal use (7-9)

- Herbal substance as dried ripe seeds
- Powdered drug
- Husk

Herbal preparations are in solid dosage forms. The pharmaceutical form should be described by the pharmacopoeia full standard term.

7. Posology and method of administration correlated to medicinal use (7, 8)

Preparation 1, 2

Indications A and B

Adolescents, adults and elderly

- 8 - 40 g daily, in 2 - 3 divided doses (7), with a maximum single dose of 13 g (9).

Children from 6 to 12 years of age

- 4 - 25 g daily, in 2 - 3 divided dose (7), with a maximum single dose of 8 g (9).

Preparation 3

Indications A and B

Adolescents, adults and elderly

- 2.5-30 g daily in 2-3 divided doses, with a maximum single dose of 8 g (8-10).

Children from 6 to 12 years of age

- 1.25-15 g daily, in 2-3 divided doses, with a maximum single dose of 4 g (8-10).

Duration of use

- Effects observed 12-24 hours after first dose, and may take 2-3 days (7, 9).
- If the constipation does not resolve within 3 days, a doctor or a pharmacist should be consulted (7).

Method of administration: Oral use (7-10)

- A sufficient amount of liquid (water, milk, fruit juice or similar aqueous liquid) should always be taken, e.g. 30 ml of water per one g of herbal substance (7- 9).
- The medicinal product can be mixed with the liquids and then swallowed or taken and then swallowed with sufficient quantity of liquid. Adequate fluid intake has to be maintained (7- 10).
- The product should be taken during the day at least half to one hour before or after intake of other medicines, not immediately prior to bed-time (7-10).

Powder formulations:

When preparing the product for administration, it is important to try to avoid inhaling any of the powder in order to minimise the risk of sensitisation to the active ingredient (7,8).

8. Contraindications (7-10)

- Hypersensitivity to the active substances and to other plants of the same family.
- Patients with a sudden change in bowel habit that persists for more than 2 weeks.
- Undiagnosed rectal bleeding and failure to defecate following the use of a laxative.
- Patients suffering from abnormal constrictions in the gastro-intestinal tract, with diseases of the oesophagus and cardia, potential or existing intestinal blockage (ileus), paralysis of the intestine or megacolon.
- Patients who have difficulty in swallowing or any throat problems.

9. Special warnings and precautions for use (7-10)

- If the symptoms worsen during the use of the medicinal product, a doctor or a pharmacist should be consulted.
- The use is not recommended in children below 6 years of age.
- If abdominal pain occurs or in cases of any irregularity of faeces, the use of Ispaghula should be discontinued and medical advice must be sought.
- Ispaghula or other bulk-forming laxatives should be used before using other purgatives if change of nutrition is not successful.
- Ispaghula should not be used by patients with faecal impaction and symptoms such as abdominal pain, nausea and vomiting unless advised by a doctor because these symptoms can be signs of potential or existing intestinal blockage (ileus).
- The treatment of debilitated patients and/or elderly patients requires medical supervision.
- In order to decrease the risk of gastrointestinal obstruction (ileus), Ispaghula should be used together with medicinal products known to inhibit peristaltic movement (e.g. opioids) and only under medical supervision.
- When taken with inadequate fluid amounts, bulk forming agents can cause obstruction of the throat and oesophagus with choking and intestinal obstruction. Symptoms can be chest pain, vomiting, or difficulty in swallowing or breathing.

10. Interactions with other medicinal products and other forms of interaction (7-10)

- Enteral absorption of concomitantly administered medicines such as minerals, vitamins (B12), cardiac glycosides, coumarin derivatives, carbamazepine and lithium may be delayed. For this reason, the product should not be taken ½ to 1 hour before or after intake of other medicinal products.
- Diabetic patients should take Ispaghula only under medical supervision because adjustment of anti-diabetic therapy may be necessary.
- Concomitant use with thyroid hormones requires medical supervision because the dose of the thyroid hormones may have to be adjusted.

11. Fertility, pregnancy and lactation (7-10)

- The use may be considered during pregnancy and lactation, if necessary and if change of nutrition is not successful. Bulk laxatives should be used before using other purgatives.
- No fertility data available.

12. Effects on ability to drive and use machines

- No studies on the effect on the ability to drive and use machines have been performed.

13. Undesirable effects (7-10)

- If adverse reactions occur, a doctor or a pharmacist should be consulted.
- Flatulence may occur with the use of the product, which generally disappears in the course of the treatment.
- Abdominal distension and risk of intestinal or oesophageal obstruction and faecal impaction may occur, particularly if swallowed with insufficient fluid.
- Ispaghula contains potent allergens. The exposure to these allergens is possible through oral administration, contact with the skin and, in the case of powder formulations, also by inhalation. Consequently, to this allergic potential, individuals exposed to the product can develop hypersensitivity reactions such as rhinitis, conjunctivitis, bronchospasm and in some cases, anaphylaxis. Cutaneous symptoms such as exanthema and/or pruritus have also been reported. Special attention should be given to individuals manipulating the powder formulations routinely.

14. Overdose (7-10)

- Abdominal discomfort, flatulence and intestinal obstruction.
- Adequate fluid intake should be maintained and management should be symptomatic.

15. Relevant biological activities

Laxative effect:

- The effect of Ispaghula husk on colonic motility of the right and left side was examined in 10 patients with left sided diverticular disease. After treatment, five of the seven patients with abdominal pain and six of the nine patients with altered bowel habit responded to treatment (17).
- *P. ovata* seeds increased stool weight and water content owing to the water-bound fiber residue and an increased faecal bacterial mass. Clinical studies have demonstrated that ingestion of 18 g of *P. ovata* seeds significantly increases faecal fresh and dry weights as compared with weights obtained with placebo (18).
- In a short-term study, 42 adults with constipation (43 bowel movements per week) received either Ispaghula (7.2 g/day) or Ispaghula plus senna (6.5g+1.5g/day). Both treatments increased defecation frequency, and wet and dry stool weights, improved stool consistency, and gave subjective relief (19).
- A study investigating the use of Ispaghula after haemorrhoidectomy found that it reduced pain and tenesmus rate and shortened postoperative hospital stay (20).
- A Cochrane review assessing different strategies for managing faecal incontinence and constipation in patients with neurological disease showed that Ispaghula husk increased stool frequency in cases of Parkinson's disease, but did not alter colonic transit time (21).
- In cases of simple and chronic constipation and among the elderly, the use of Ispaghula husk is reported to be effective (22, 23).
- Ispaghula use as a bulking agent is well established, but many of the reported studies were only single blinded. A systematic review on the use comparing non-bulk-forming laxatives (lactulose, lactitol, docusate, magnesium salts and bisocodyl) with fiber (Ispaghula and bran) on chronic constipation in adults found that there was little evidence to establish which class of laxative was superior to another. Both improved the symptoms of constipation compared to placebo, with no severe side effects being reported (24).

Hypercholesterolaemia:

- In a double-blind, placebo controlled, parallel-group study, 26 men with mild-to-moderate hypercholesterolaemia (serum cholesterol concentration: 4.86– 8.12 mmol/L) received Ispaghula (Metamucil) 3.4 g, or cellulose placebo, three times daily at meal times for eight weeks. There were no significant changes in serum lipid concentrations with placebo treatment, compared with baseline values. Differences in serum cholesterol concentrations between the two groups were statistically significant after four weeks (25).

- A meta-analysis of eight published and four unpublished studies carried out in four countries reviewed the effect of consumption of Ispaghula-enriched cereal products on blood cholesterol, and LDL and HDL cholesterol concentrations. Overall, the trials included 404 adults with mild-to-moderate hypercholesterolaemia who consumed low-fat diets. The meta-analysis indicated that subjects who consumed Ispaghula cereal had lower total cholesterol and LDL cholesterol than subjects who ate control cereal concentrations (26).
- A meta-analysis included eight studies involving a total of 384 patients with hypercholesterolaemia who received Ispaghula and 272 subjects who received cellulose placebo. Compared with placebo, consumption of 10.2 g Ispaghula per day for 58 weeks lowered serum total cholesterol concentrations by 4% and LDL cholesterol by 7%, but did not affect serum HDL cholesterol or triacyl glycerol concentrations (27).
- In a 12-week study, 50 children (aged 2–11 years) with LDL cholesterol concentrations 5110 mg/dL received either cereal enriched with Ispaghula (3.2 g soluble fiber per day) or plain cereal whilst maintaining a low-fat diet. Total cholesterol decreased for the Ispaghula group in comparison with for the control group. LDL cholesterol also decreased for the treated group in comparison with the placebo group (28).

16. Additional Information

Ispaghula husk is a well-established herbal medicinal product used in patients to whom an increased daily fiber intake may be advisable e.g. as an adjuvant in constipation predominant irritable bowel syndrome. Also; it is used as an adjuvant to diet in the treatment of mild to moderate hypercholesterolaemia under medical supervision (5, 8, 10) in a daily dose of 7 – 20 g, 1-3 times daily for adolescents, adults and elderly (8).

17. 1. Date of compilation/last revision

13/11/2023

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