# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Regulan Lemon/Lime Flavour 3.4g per sachet Powder for Oral Solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lemon/Lime flavour Regulan sachet contains 3.4 g of Ispaghula Husk.

For excipients, see 6.1.

## 3 PHARMACEUTICAL FORM

Powder for Oral Solution
Pre-measured, single-dose sachets containing a lemon/lime flavoured beige, fine ground powder which when reconstituted with water is intended for administration as an oral solution.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

For the relief of constipation and for patients who need to increase their daily fibre intake.

### 4.2 Posology and method of administration

The measured dosage should be poured into a glass and 150ml (¼ pint) of cool water, milk, fruit juice or other liquid added, stirred, and taken immediately. Additional liquid may be taken if required. Adequate fluid intake should be maintained.

When preparing the product for administration, it is important to try to avoid inhaling any of the powder in order to minimize the risk of sensitization to the active ingredient.

**Adults and children over 12 years**
Usual dosage is the entire contents of one sachet taken one to three times daily.

**Elderly**
No alteration in dosage necessary.

**Children 6-12 years**
A reduced dosage based upon age of the child should be given. ½ - 1 level teaspoonful one to three times daily.

### 4.3 Contraindications

Not to be given to patients with intestinal obstruction, faecal impaction, colonic atony or hypersensitivity to ispaghula ***(see 4.4 Special warnings and precautions for use)*** or any of the excipients.

### 4.4 Special warnings and precautions for use

Lemon/Lime Flavour Regulan should always be taken as a liquid suspension and should be drunk immediately after mixing. The last dose should not be taken immediately before going to bed since impaired or reduced gastric motility may impair the intestinal passage and then cause sub-obstruction.

Warning on hypersensitivity reactions
In individuals with continued occupational contact to powder of Plantago ovata seeds (i.e. healthcare workers, caregiver allergic sensitization may occur due to inhalation, this is more frequent in atopic individuals. This sensitization usually leads to hypersensitivity reactions which could be serious (see 4.8 Undesirable effects). It is recommended to assess clinically the possible sensitization of individuals at risk and, if justified, to perform specific diagnostic tests. In case of proven sensitization leading to hypersensitivity reactions, exposure to the product should be stopped immediately and avoided in the future (see 4.3 Contraindications).

It may be advisable to supervise treatment in the elderly or debilitated and patients with intestinal narrowing or decreased motility, as rare instances of gastrointestinal obstruction have been reported with mucilloid preparations when taken, contrary to the administration instructions, with insufficient liquid.

Each sachet contains 26mg of phenylalanine and this should be considered in phenylketonuric patients.

The colouring agent, Sunset Yellow, can cause allergic type reactions including asthma. Allergy is more common in those people who are allergic to aspirin.

## 4.5 Interaction with other medicinal products and other forms of interaction

None known.

## 4.6 Fertility, pregnancy and lactation

Controlled studies in pregnant and lactating women are not available, but the product has been in wide use for many years without apparent ill consequence and animal studies have shown no hazard. Ispaghula is not thought to be absorbed nor is it thought to enter breast milk. Nevertheless the benefits of therapy should be weighed against the possible risks if used during pregnancy and lactation.

## 4.7 Effects on ability to drive and use machines

None known.

## 4.8 Undesirable effects

Gastrointestinal disorders: Regulan (Ispaghula), as with other bulk laxatives, may temporarily increase flatulence and abdominal distension when the product is first used. Other symptoms including nausea, diarrhoea and abdominal discomfort or pain have rarely been reported (<1 in 1000).

Intestinal obstruction and faecal impaction may occur very rarely (<1 in 10,000), especially if the product is taken with insufficient fluid.

Immune system disorders SOC: Ispaghula/psyllium husk 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. As a consequence to this allergic potential, individuals exposed to the product can develop hypersensitivity reactions such as rhinitis, conjunctivitis, bronchospasm and in some cases, anaphylaxia. Cutaneous symptoms as exanthema and/or pruritus have also been reported. Special attention should be given to individuals manipulating the powder formulations routinely (see 4.4 Special warnings and precautions for use).

## 4.9 Overdose

No instances of true overdosage have been reported. If overdosage should occur there is no specific treatment and symptomatic measures should be employed.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

The active constituent, ispaghula husk, is the epidermis and collapsed adjacent layers removed from the dried ripe seeds of *Plantago ovata*, containing mucilage and hemicelluloses.

The ispaghula husk is not absorbed and produces its effect as a bulking agent by physical means alone.

## 5.2 Pharmacokinetic properties

Not applicable.

## 5.3 Preclinical safety data

Not applicable.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Maltodextrin
Citric acid, anhydrous
Citrus flavour
Aspartame (E951)
Sunset yellow FCF (E110)

## 6.2 Incompatibilities

None known.

## 6.3 Shelf life

Three years.

## 6.4 Special precautions for storage

Do not store above 25°C.
Store in the original package.

## 6.5 Nature and contents of container

Paper/aluminium foil/polyethylene sachets. The product is available in packs of 30 sachets.

## 6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

A patient leaflet is provided with details of use and handling of the product. See 4.2.

## 7 MARKETING AUTHORISATION HOLDER

Procter & Gamble (Health & Beauty Care) Limited
The Heights, Brooklands
Weybridge
Surrey, KT13 0XP
United Kingdom

## 8 MARKETING AUTHORISATION NUMBER

PA 441/34/1

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15 November 1990

Date of last renewal: 15 November 2005

## 10 DATE OF REVISION OF THE TEXT

March 2012