1.8 Summary of product characteristics

1. Name of the medicinal product

Indogol sachet Orange Flavour powder for oral solution

2. Qualitative and quantitative composition

Each sachet contains:

Macrogol 3350.....13.125g
Sodium Chloride.....350.7mg
Sodium Bicarbonate 178.5mg
Potassium Chloride 46.6mg

3. Pharmaceutical form

Powder for oral solution

A white to off white granules powder with orange flavour filled in printed sachet.

4. Clinical particulars

4.1 Therapeutic indications
For the treatment of chronic constipation.

For resolving faecal impaction. Faecal impaction is defined as refractory constipation with faecal loading in the rectum and/or colon confirmed by physical or radiological examination of the abdomen and rectum.

4.2 Posology and method of administration
Indogol Orange Flavour powder for oral solution is for oral use.

Chronic constipation

A course of treatment for chronic constipation with Indogol Orange Flavour powder for oral solution does not normally exceed 2 weeks, although this can be repeated if required. As for all laxatives, prolonged use is not usually recommended.

Adults, adolescents and the elderly: 1-3 sachets daily in divided doses, according to individual response.

Children below 12 years old: Not recommended.

Patients with renal insufficiency: No dosage change is necessary.

Faecal impaction

Adults, adolescents and the elderly: A course of treatment for faecal impaction does not normally exceed 3 days.

Dosage is 8 sachets daily, all of which should be consumed within a 6-hour period.

The above dosage regimen should be stopped once disimpaction has occurred. An indicator of disimpaction is the passage of a large volume of stools. After disimpaction, it is recommended that the patient follows an appropriate bowel management programme to prevent reimpaction.

Children below 12 years old: Not recommended.

Patients with impaired cardiovascular function: For the treatment of faecal impaction, the dose should be divided so that no more than four sachets are taken in any one hour.

Patients with renal insufficiency: No dosage change is necessary for the treatment of either constipation or faecal impaction.

Administration:

Each sachet should be dissolved in 125 ml water.

4.3 Contraindications

Indogol Orange Flavour powder for oral solution is contraindicated in intestinal obstruction or perforation caused by functional or structural disorder of the gut wall, ileus and in patients with severe inflammatory conditions of the intestinal tract (e.g. ulcerative colitis, Crohn's disease and toxic megacolon).

Hypersensitivity to the active substances or any of the excipients.

4.4 Special warnings and precautions for use

Confirm diagnosis of faecal impaction / faecal loading of the rectum by physical or radiological examination of the abdomen and rectum.

Mild adverse drug reactions are possible as indicated in Section 4.8. If patients develop any symptoms indicating shifts of fluids/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure) Indogol Orange Flavour powder for oral solution should be stopped immediately and electrolytes measured and any abnormality should be treated appropriately.

When using high doses of this medicine to treat faecal impaction, use caution in patients with impaired gag reflex, reflux oesophagitis or reduced levels of consciousness.

This medicine contains 0.63 mmol (25 mg) potassium per sachet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

This medicinal product contains 187 mg sodium per sachet, equivalent to 9.35% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

When used to treat chronic constipation, the maximum daily dose of this product is equivalent to 28.05% of the WHO recommended maximum daily intake for sodium.

Indogol Plain is considered high in sodium. This should be particularly taken into account for those on a low salt diet.

4.5 Interaction with other medicinal products and other forms of interaction

Macrogol 3350 raises the solubility of medicinal products that are soluble in alcohol and relatively insoluble in water. It is a theoretical possibility that absorption of these drugs could be reduced transiently.

There have been isolated reports of decreased efficacy with some concomitantly administered medicinal products, e.g. anti-epileptics.

4.6 Pregnancy and lactation
There is no experience with the use of Indogol Orange Flavour powder for oral solution during pregnancy and lactation and it should only be used if considered essential by the physician.

4.7 Effects on ability to drive and use machines
Indogol Orange Flavour powder for oral solution has no influence on the ability to drive and use machines.

4.8 Undesirable effects
Reactions related to the gastrointestinal tract are the most common to occur.

Immune System Disorders:

Allergic reactions, including anaphylactic reaction. Other symptoms of allergic reactions include dyspnoea, urticaria and pruritus.

Gastro-intestinal Disorders:

Potential gastro-intestinal effects that may occur include abdominal distension and pain, anal discomfort, flatulence, vomiting, borborygmi and nausea.

These reactions may occur as a consequence of expansion of the contents of the gastrointestinal tract, and an increase in motility due to the pharmacologic effects of Indogol Orange Flavour powder for oral solution.

In the treatment of chronic constipation, diarrhoea or loose stools normally respond to a reduction in dose.

Diarrhoea, abdominal distension, anal discomfort and mild vomiting are more often observed during the treatment for faecal impaction. Vomiting may be resolved if the dose is reduced or delayed.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose
Severe distension or pain can be treated using nasogastric aspiration. Vomiting or diarrhoea may induce extensive fluid loss, possibly leading to electrolyte disturbances that should be treated appropriately.

5. Pharmacological properties

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Osmotically acting laxatives.

ATC code: A06A D65

Macrogol 3350 induces a laxative effect through its osmotic action in the gut. It increases the stool volume, which triggers colon motility via neuromuscular pathways. The physiological consequence is an improved propulsive colonic transportation of the softened stools and a facilitation of the defaecation. Electrolytes combined with macrogol 3350 are exchanged across the intestinal barrier (mucosa) with serum electrolytes and excreted in faecal water without net gain or loss of sodium, potassium and water.

Clinical studies using the listed active substances for the treatment of chronic constipation have shown that the dose required to produce normally formed stools tends to decrease over time. Many patients, respond to between one and two sachets a day, but this dose should be adjusted depending on individual response.

5.2 Pharmacokinetic properties
Macrogol 3350 is virtually unabsorbed from the gastro-intestinal tract and is excreted, unaltered, in faeces. Any macrogol 3350 that is absorbed is excreted via the urine.

5.3 Preclinical safety data
Preclinical studies provide evidence that macrogol 3350 has no significant systemic toxicity potential, although no tests of its effects on reproduction or genotoxicity have been conducted.

There are no long-term animal toxicity or carcinogenicity studies involving macrogol 3350, although there are toxicity studies using high levels of orally administered high-molecular weight macrogols that provide evidence of safety at the recommended therapeutic dose.

6. Pharmaceutical particulars

6.1 List of excipients
Acesulfame Potassium
Orange Flavour
(861994 TD-0991)
6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 months

Reconstituted solution: 24 hours

6.4 Special precautions for storage
Sachet: Do not store above 30 °C. protect from heat and light

Reconstituted solution: Store covered in a refrigerator (2 °C to 8 °C).

6.5 Nature and contents of container
10 paper foil printed sachet enclosed in a printed box with package insert (1 x 10’s)

6.6 Special precautions for disposal and other handling
After 24 hours, any unused solution should be discarded.

7. Marketing authorisation holder

Indus Pharma (Pvt.) Ltd.

Plots No. 26-27, 63-67, Sector-27, Korangi Industrial Area, Karachi-74900, PAKISTAN.

8. Marketing authorisation number(s)

092866

9. Date of first authorisation/renewal of the authorisation

3rd -December,2018

10. Date of revision of the text

N/A