Product Summary

1. Name of the medicinal product
Constipeg® sachets

2. Qualitative and quantitative composition
Each 13.7 g sachet contains
- PEG – polyethylene glycol (macrogol) USNF 13.125 g
- Potassium chloride IP 46.6 mg
- Sodium chloride IP 350.7 mg
- Sodium Hydrogen Carbonate IP 178.5 mg

3. Pharmaceutical form
Sachet for reconstitution with water.

4. Clinical particulars
4.1 Therapeutic indications
Symptomatic treatment of constipation in adults and children aged 8 years and above. An organic disorder should have been ruled out before initiation of treatment 10 g should remain a temporary adjuvant treatment to appropriate lifestyle and dietary management of constipation, with a maximum 3-months treatment course in children. If symptoms persist despite associated dietary measures, an underlying cause should be suspected and treated

4.2 Posology and method of administration
Oral use
1 to 2 sachets per day, preferably taken as a single dose in the morning. Each sachet should be dissolved in a glass of water just before use.
The effect of Constipeg® becomes apparent within 24 to 48 hours after its
administration.
In children, treatment should not exceed 3 months due to a lack of clinical data for treatment lasting longer than 3 months. Treatment-induced restoration of bowel movements will be maintained by lifestyle and dietary measures. The daily dose should be adapted according to the clinical effects and may range from one sachet every other day (especially in children) up to 2 sachets a day.

4.3 Contraindications
- Severe inflammatory bowel disease (such as ulcerative colitis, Crohn's disease) or toxic megacolon, associated with symptomatic stenosis
- Digestive perforation or risk of digestive perforation
- Ileus or suspicion of intestinal obstruction
- Painful abdominal syndromes of indeterminate cause
- Hypersensitivity to macrogol (polyethylene glycol)

4.4 Special warnings and precautions for use
Warnings
The treatment of constipation with any medicinal product is only an adjuvant to a healthy lifestyle and diet, for example:
- Increased intake of liquids and dietary fibre,
- Appropriate physical activity and rehabilitation of the bowel reflex.
Patients with hereditary problems of fructose intolerance should not take this medicinal product.
In case of diarrhoea, caution should be exercised in patients who are prone to a disturbance of water electrolyte balance (e.g. the elderly, patients with impaired hepatic or renal function or patients taking diuretics) and electrolyte control should be considered.
Precautions for use
Hypersensitivity reactions (rash, urticaria, and oedema) have been reported with drugs containing macrogol (polyethylene glycol) Exceptional cases of anaphylactic shock have been reported.
Constipeg® does not contain a significant quantity of sugar or polyol and can be prescribed to diabetic patients or patients on a galactose-free diet.
4.5 Interaction with other medicinal products and other forms of interaction
Not applicable

4.6 Fertility, pregnancy and lactation
Pregnancy
Macrogol was not teratogenic in rats or rabbits.
No effects during pregnancy are anticipated, since systemic exposure to Constipeg® is negligible. Constipeg® can be used during pregnancy.

Breastfeeding
No effects on the breast feeding newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to macrogol is negligible; Constipeg® can be used during breast feeding.

4.7 Effects on ability to drive and use machines
Not applicable.

4.8 Undesirable effects
Undesirable effects are listed under headings of frequency using the following categories:
Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); unknown (cannot be estimated from the available data).
Adult population:
The undesirable effects listed in the table below have been reported during clinical trials (including 600 adult patients) and post-marketing use. Generally, adverse reactions have been minor and transitory and have mainly concerned the gastrointestinal system:

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Adverse reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal disorders</td>
<td></td>
</tr>
<tr>
<td>Common</td>
<td>Abdominal pain and/ or distension</td>
</tr>
<tr>
<td></td>
<td>Diarrhoea</td>
</tr>
<tr>
<td></td>
<td>Nausea</td>
</tr>
</tbody>
</table>
Uncommon
Vomiting
Urgency to defecate
Fecal incontinence

Metabolism and Nutrition Disorders
Unknown
Electrolytes disorders (Hyponatremia, Hypokalaemia) and or dehydration, especially in elderly patients

Immune system disorders
Very rare
Hypersensitivity reactions (Pruritus, Rash, Face oedema, Quincke oedema, Urticaria, Anaphylactic shock)

Paediatric population:
The undesirable effects listed in the table below have been reported during clinical trials including 147 children aged from 6 months to 15 years and post-marketing use. As in adult population, adverse reactions have generally been minor and transitory and have mainly concerned the gastrointestinal system:

<table>
<thead>
<tr>
<th>System Organ Class</th>
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<tbody>
<tr>
<td>Gastrointestinal disorders</td>
<td></td>
</tr>
<tr>
<td>Common</td>
<td>Abdominal pain</td>
</tr>
<tr>
<td></td>
<td>Diarrhoea*</td>
</tr>
<tr>
<td>Uncommon</td>
<td>Vomiting</td>
</tr>
<tr>
<td></td>
<td>Bloating</td>
</tr>
<tr>
<td></td>
<td>Nausea</td>
</tr>
<tr>
<td>Immune system disorders</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>Hypersensitivity reactions (Pruritus, Rash, Face oedema,</td>
</tr>
<tr>
<td></td>
<td>Quincke oedema, Urticaria, Anaphylactic shock)</td>
</tr>
</tbody>
</table>

*Diarrhoea may cause perianal soreness

4.9 Overdose
Overdose could lead to diarrhoea which disappears when treatment is temporarily interrupted or the dosage is reduced.
Excessive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances
Cases of aspiration have been reported when extensive volumes of macrogol (polyethylene glycol) and electrolytes were administered with nasogastric tube.
Neurologically impaired children who have oromotor dysfunction are particularly at risk of aspiration.

5. Pharmacological properties
5.1 Pharmacodynamic properties
Osmotically acting laxatives
High molecular weight macrogols are long linear polymers which retain water molecules by means of hydrogen bonds. When administered by the oral route, they lead to an increase in volume of intestinal fluids. The volume of unabsorbed intestinal fluid accounts for the laxative properties of the solution.

5.2 Pharmacokinetic properties
The pharmacokinetic data confirm that macrogol undergoes neither gastrointestinal resorption nor biotransformation following oral ingestion.

5.3 Preclinical safety data
Toxicological studies conducted in different animal species did not reveal any sign of systemic or local gastrointestinal toxicity. Macrogol had no teratogenic, mutagenic, or carcinogenic effect. Potential drug interaction studies performed in rats on some NSAIDs, anticoagulants, gastric antisecretory agents, or on a hypoglycaemic sulfamide showed that PEG did not interfere with gastrointestinal absorption of these compounds.

6. Pharmaceutical particulars
6.1 Incompatibilities
None supplied.

6.2 Shelf life
As mentioned on the package material.

6.3 Special precautions for storage
As mentioned on the package material.
Administrative data

7. Marketing authorisation holder
Strides Shasun Limited
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Bannerghatta Road,
Bengaluru – 560 076, India

8. Toll free number for reporting
1800 4190601

9. Date of text
22nd December 2016