Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Laxido, powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains the following quantitative composition of active ingredients:
Macrogol 3350 13.125g
Sodium Chloride 350.7mg
Sodium Hydrogen Carbonate 178.5mg
Potassium Chloride 46.6mg

The content of electrolyte ions per sachet following reconstitution in 125ml of water is equivalent to:
Sodium 65mmol/l
Chloride 53mmol/l
Hydrogen Carbonate (Bicarbonate) 17mmol/l
Potassium 5.4mmol/l

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution. Single-dose sachet containing a free flowing white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of chronic constipation. Laxido is also effective in resolving faecal impaction, defined as refractory constipation with faecal loading of the rectum and/or colon.
Laxido is indicated in adults, adolescents and the elderly.

4.2 Posology and method of administration

Laxido is for oral use.

Posology

Chronic Constipation:
A course of treatment for chronic constipation with Laxido does not normally exceed 2 weeks, although this can be repeated if required. As for all laxatives, prolonged use is not usually recommended. Extended use may be necessary in the care of patients with severe chronic or resistant constipation, secondary to multiple sclerosis or Parkinson's Disease, or induced by regular constipating medication in particular opioids and antimuscarinics.

Adults, adolescents and the elderly: 1-3 sachets daily in divided doses, according to individual response. For extended use, the dose can be adjusted down to 1 or 2 sachets daily.
Children below 12 years old: Not recommended.

Faecal Impaction:
A course of treatment for faecal impaction with Laxido does not normally exceed 3 days.

Adults, adolescents and the elderly: 8 sachets daily, all of which should be consumed within a 6 hour period.

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 2 sachets are taken in any one hour.

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

Method of administration:
Each sachet should be dissolved in 125 ml water. For use in faecal impaction, 8 sachets may be dissolved in 1 litre of water.

4.3 Contraindications

Laxido 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 to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

The fluid content of Laxido when re-constituted with water does not replace regular fluid intake and adequate fluid intake must be maintained.

The faecal impaction diagnosis should be confirmed by appropriate physical or radiological examination of the rectum and abdomen.

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) Laxido should be stopped immediately and electrolytes measured and any abnormality should be treated appropriately.

The absorption of other medicinal products could transiently be reduced due to an increase in gastro-intestinal transit rate induced by Laxido (see section 4.5).

This medicinal product contains 187mg of sodium per sachet, equivalent to approximately 9% of the WHO recommended maximum daily intake of 2g sodium for an adult.

When used to treat chronic constipation the maximum daily dose of this product is equivalent to approximately 28% of the WHO recommended maximum daily intake for sodium.

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

In patients with swallowing problems, who need the addition of a thickener to solutions to enhance an appropriate intake, interactions should be considered, see section 4.5.

4.5 Interaction with other medicinal products and other forms of interactions

Macrogol 3350 raises the solubility of medicinal products that are soluble in alcohol and mainly insoluble in water. It is a theoretical possibility that absorption of other medicinal products could be reduced transiently during use with Laxido (see section 4.4). There have been isolated reports of decreased efficacy with some concomitantly administered medicinal products, e.g. anti-epileptics. Therefore, other medicines should not be taken orally for one hour before and for one hour after taking Laxido.

Laxido may result in a potential interactive effect if used with starch-based food thickeners. The macrogol ingredient counteracts the thickening effect of starch, effectively liquefying preparations that need to remain thick for people with swallowing problems.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are limited amount of data from the use of Laxido in pregnant women. Studies in animals have shown indirect reproductive toxicity (see section 5.3). Clinically, no effects during pregnancy are anticipated, since systemic exposure to macrogol 3350 is negligible.

Laxido can be used during pregnancy.

Breast-feeding
No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to macrogol 3350 is negligible.

Laxido can be used during breast-feeding.

Fertility
There are no data on the effects of Laxido on fertility in humans. There were no effects on fertility in studies in male and female rats (see section 5.3).

4.7 Effects on ability to drive and use machines

Laxido has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Reactions related to the gastrointestinal tract occur most commonly.

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 Laxido. Mild diarrhoea usually responds to dose reduction.

The frequency of the adverse effects is not known as it cannot be estimated from the available data.

System Organ Class	**Adverse Event**
Immune system disorders	Allergic reactions, including anaphylaxis, angioedema, dyspnoea, rash, urticaria and pruritus.
Skin and subcutaneous tissue disorders	Erythema
Metabolism and nutrition disorders	Electrolyte disturbances, particularly hyperkalaemia and hypokalaemia.
Nervous system disorders	Headache
Gastrointestinal disorders	Abdominal pain, diarrhoea, vomiting, nausea, dyspepsia, abdominal distension, borborygmi, flatulence, anorectal discomfort.
General disorders and administration site conditions	Peripheral oedema

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. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, website: www.hpra.ie

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. This product also contains electrolytes to ensure that there is no overall gain or loss of water, potassium or sodium.

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. For most patients, the maintenance dose will be one to two sachets per day (adjusted according to individual response).

Comparative studies in faecal impaction using active controls (e.g. enemas) have not been performed. However, results from a non-comparative study have shown that, from a population of 27 adult patients, the listed combination of active substances cleared faecal impaction in 12/27 (44%) patients after one day's treatment, increasing to 23/27 (85%) following two days' treatment and 24/27 (89%) recovered at the end of three days.

5.2 Pharmacokinetic properties

Macrogol 3350 is virtually unabsorbed from the gastro-intestinal tract and is excreted, unaltered, in faeces. Any macrogol 3350 that enters the systemic circulation is excreted in urine.

5.3 Preclinical safety data

Preclinical studies provide evidence that macrogol 3350 has no significant systemic toxicity potential, based on conventional studies of pharmacology, repeated dose toxicity and genotoxicity.

There were no direct embryotoxic or teratogenic effects in rats even at maternally toxic levels that are a multiple of 66 x the maximum recommended dose in humans for chronic constipation and 25 x for faecal impaction. Indirect embryofetal effects, including reduction in fetal and placental weights, reduced fetal viability, increased limb and paw hyperflexion and abortions, were noted in the rabbit at a maternally toxic dose that was 3.3 x the maximum recommended dose in humans for treatment of chronic constipation and 1.3 x for faecal impaction. Rabbits are a sensitive animal test species to the effects of GI-acting substances and the studies were conducted under exaggerated conditions with high dose volumes administered, which are not clinically relevant. The findings may have been a consequence of an indirect effect of macrogol 3350 related to poor maternal condition as the result of an exaggerated pharmacodynamic response in the rabbit. There was no indication of a teratogenic effect.

There are long-term animal toxicity and carcinogenicity studies involving macrogol 3350. Results from these and other toxicity studies using high levels of orally administered high molecular weight macrogols provide evidence of safety at the recommended therapeutic dose.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acesulfame Potassium (E950)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Sachet: Two years.
Reconstituted solution: Six hours.

6.4 Special precautions for storage

Sachet: Store below 25°C.
Reconstituted solution: Store covered in a refrigerator (2°C to 8°C).

6.5 Nature and contents of container

The sachet is composed of paper, low density polyethylene and aluminium.
Sachets are packed in cartons of 2, 8, 10, 20, 30, 50 and 100.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Galen Pharma Ireland Limited
Finnabair Industrial Estate
Dundalk
Louth
A91P9KD
Ireland

8 MARKETING AUTHORISATION NUMBER

PA22680/001/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st July 2008
Date of last renewal: 30th April 2013

10 DATE OF REVISION OF THE TEXT

November 2021