Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Laxaclear 5.9 g, powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains 5.9g of Macrogol 3350

Excipients with known effect:
Laxaclear 5.9g contains 12.5 mmol (287.36 mg) of sodium, 1 mmol (39.098 mg)of potassium and 5 mg of aspartame (E951) per sachet. The vanilla flavour contains trace amounts of sulphur dioxide (E220) (15 ppm) and less than 1mg benzyl alcohol (0.0066 mg).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.
White or almost white granular powder for oral solution which on reconstitution gives a clear colourless solution with a characteristic flavour of vanilla.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For use as a short term laxative in cases of constipation in adults, adolescents and the elderly.

4.2 Posology and method of administration

Posology

Paediatric population
The safety and efficacy of Laxaclear in children aged 0-12 years have not yet been established. No data are available.

Adults, Adolescents and Elderly
The usual dose is 1-2 sachets per day in one intake. The maximum dose is 4 sachets per day. No dosage adjustment is necessary in the elderly.

As with all laxatives, prolonged use is not recommended. A course of treatment for constipation with Laxaclear does not normally exceed 5 days, although this can be repeated if required.

No dosage adjustment is required in patients with renal impairment.

Method of administration
The sachets of powder are dissolved in 100ml of water, stirring to aid dissolution, prior to oral administration. The powder dissolves completely to give a clear or slightly hazy solution.

The effect of Laxaclear becomes apparent 24 to 48 hours after its administration.

4.3 Contraindications

1. Hypersensitivity to the active substance or to any of the excipients listed in section 6.1;
2. Severe inflammatory bowel conditions (such as ulcerative colitis, Crohn's disease) and toxic megacolon;
3. Perforation or risk of perforation;
4. Ileus or suspicion of intestinal obstruction, symptomatic stenosis;
5. Phenylketonuria, as Laxaclear contains a source of phenylalanine.

4.4 Special warnings and precautions for use

Warnings
For patients using this preparation for the first time, if there is no improvement after 5 days, medical advice should be sought.
The treatment of constipation is only an adjuvant to sensible diet on the part of the patient (increased intake of liquids and plant fibres) and advice concerning physical activity and rehabilitation of defecation.

Precautions
Laxaclear contains polyethylene glycol. Some rare allergy manifestations and very exceptional cases of anaphylactic reactions have been reported solely with high doses of polyethylene glycol used in preparation for colonic diagnostic procedures.

Laxaclear contains 290mg sodium per sachet, equivalent to 14.5% of the WHO recommended maximum daily intake of 2 g sodium for an adult. Patients on a sodium-restricted diet (e.g. heart failure or hypertensive patients) should take into account the product's sodium content (290 mg per sachet).

Laxaclear contains 1 mmol potassium per sachet. This should be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet. Laxaclear also contains aspartame, which is a source of phenylalanine.

It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.
Laxaclear contains benzyl alcohol, high volumes should be used with caution and only if necessary, especially in subjects with liver or kidney impairment becaue of the risk of accumulation and toxicity (metabolic acidosis).
Laxaclear also contains trace amounts of sulphur dioxide which may rarely cause severe hypersensitivity reactions and bronchospasm.

4.5 Interaction with other medicinal products and other forms of interactions

Medication in solid dose form taken within one hour of administration of large volumes of macrogol preparations may be flushed from the gastrointestinal tract and not absorbed.

Clinical interactions with other drugs have been reported extremely rarely. No specific reactions with individual drugs or classes of drugs have been observed.

Macrogol raises the solubility of medicinal products that are soluble in alcohol and relatively insoluble in water. There is therefore a theoretical possibility that the absorption of such medicinal products could be transiently reduced.

4.6 Fertility, pregnancy and lactation

Fertility
No information on the effects of macrogol 3350 on fertility is available.
No effects on fertility are anticipated, since systemic exposure to macrogol 3350 is negligible.

Pregnancy
No clinical data on exposed pregnancies are available.
No effects during pregnancy are anticipated, since systemic exposure to macrogol 3350 is negligible.

Lactation
There is no human data on the excretion of macrogol 3350 in milk.
No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to macrogol 3350 is negligible.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Reactions related to the gastrointestinal tract are the most commonly occurring.

Immune system disorders:
Very rare (<1/10,000): Allergic reactions, including anaphylaxis. Other symptoms of allergic reactions include dyspnoea, urticaria and pruritis.

Gastrointestinal disorders:
Very common (>1/10): Mild diarrhoea
Common (≥1/100 to <1/10): Abdominal pain, abdominal distension, flatulence, borborygmi
Rare (>1/10,000 to <1/1,000): Vomiting, nausea, anal discomfort

The gastrointestinal 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 Laxaclear. Mild diarrhoea usually responds to dose reduction.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Overdose leads to diarrhoea, which subsides when treatment is temporarily interrupted or the dosage is reduced.
Extensive fluid loss due to diarrhoea or vomiting may require correction of electrolyte disturbances.
Severe pain or distension can be treated by nasogastric aspiration.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Osmotically acting laxatives, ATC code: A06A D65.

Macrogol 3350 acts by virtue of its osmotic action in the gut, which induces a laxative effect. Macrogol 3350 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 defecation. 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.

5.2 Pharmacokinetic properties

Macrogol 3350 is unchanged along the gut. It is virtually unabsorbed from the gastro-intestinal tract. Any macrogol 3350 that is absorbed is excreted via the urine.

The electrolyte concentration of the reconstituted solution is such that it may be assumed that no electrolyte exchanges occur between the intestines and plasma.

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.
Indirect embryofoetal effects were noted in the rabbit at clinically relevant doses. Treatment caused an increased incidence of malrotated limbs, reduction in foetal and placental weights, reduced foetal viability and abortions at maternally toxic doses**.** The safety margin was 1.1 x the maximum recommended dose for faecal impaction in a 60 kg adult for malrotated limb and 2.9 x below the maximum recommended dose for the remaining findings.

Rabbits are sensitive animal test species to the effects of GI acting substances and the studies were conducted under exaggerated conditions with administered high dose volumes. The relevance of these findings to humans is unknown.
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

Sodium Sulphate Anhydrous
Sodium Chloride
Sodium Hydrogen Carbonate
Potassium Chloride
Aspartame (E951)
Vanilla Flavour (containing Caramel Color (E150)), Maltodextrin (maize), Gum Arabic/Acacia Gum (E414), Benzyl alcohol and Sulphur Dioxide (E220)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.
Reconstituted solution should be refrigerated (2-8°C) and used within 24 hours.
Reconstituted solution can be stored at room temperature (below 25ºC) for 2 hours.

6.4 Special precautions for storage

Do not store above 25ºC.
For storage conditions after reconstitution, see section 6.3.

6.5 Nature and contents of container

Sachet: laminate consisting of surlyn 1652, aluminum, paper and polyethylene.

Pack sizes: boxes of 10 or 20 sachets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Helsinn Birex Pharmaceuticals Limited
Damastown
Mulhuddart
Dublin 15
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0294/022/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th August 2013
Date of last renewal: 15th August 2018

10 DATE OF REVISION OF THE TEXT

November 2018