Laxido Paediatric Plain, 6.9g sachet, powder for oral solution: Please refer to the Summary of Product Characteristics (SPC) before prescribing.

Abbreviated Prescribing Information.

Presentation: Single-dose sachet, each containing a white powder composed of: Macrogol 3350 6.563g, sodium chloride 175.4mg, sodium hydrogen carbonate 89.3mg, and potassium chloride 25.1mg.

Indications: Treatment of chronic constipation in children aged 1 to 11 years and treatment of faecal impaction in children from the age of 5 years.

Dosage: Chronic constipation: The usual starting dose is 1 sachet daily for children aged 1 to 6 years, and 2 sachets daily for children aged 7 to 11 years. The dose should be adjusted up or down as required to produce regular soft stools. If the dose needs increasing this is best done every second day. For children below 2 years of age, the maximum recommended dose should not exceed 2 sachets a day. For children aged 2 to 11 years, the maximum recommended dose needed does not normally exceed 4 sachets a day. Treatment needs to be for a prolonged period (at least 6 to 12 months); however, safety and efficacy have only been proven for a period of up to 3 months. Treatment should be stopped gradually and resumed if constipation recurs. **Faecal impaction:** A course of treatment for faecal impaction is for up to 7 days as follows in children aged 5 to 11 years**: Day 1**: 4 sachets, **Day 2**: 6 sachets, **Day 3**: 8 sachets, **Day 4**: 10 sachets, **Days 5 to 7**: 12 sachets daily. The daily number of sachets should be taken in divided doses within a 12 hour period. Treatment should be stopped once disimpaction has occurred. After disimpaction, the recommended dosing for children with chronic constipation should be followed to prevent re-impaction. Not recommended for children below 5 years of age for the treatment of faecal impaction, or in children below 1 year of age for the treatment of chronic constipation. For patients 12 years and older, it is recommended to use Laxido Orange. **Patients with impaired cardiovascular or renal function:** There are no clinical data for these groups of patients. Therefore Laxido Paediatric Plain is not recommended for treating faecal impaction in children with impaired cardiovascular function or impaired renal function.

Administration: Each sachet should be dissolved in 62.5ml (quarter of a glass) of water. The correct number of sachets may be reconstituted in advance and kept covered and refrigerated for up to 24 hours. For example, for use in faecal impaction, 12 sachets can be made up into 750ml of water.

Contraindications: 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.

Warnings and Precautions: The fluid content of Laxido Paediatric Plain when re-constituted with water does not replace regular fluid intake. Adequate fluid intake must be maintained. The faecal impaction diagnosis should be confirmed by appropriate physical or radiological examination of the rectum and abdomen. If patients develop any symptoms indicating shifts of fluids/electrolytes, Laxido Paediatric Plain should be stopped immediately. High doses used to treat faecal impaction should be administered with caution to patients with impaired gag reflex, reflux oesophagitis or diminished levels of consciousness. The absorption of other medicinal products could transiently be reduced due to an increase in gastrointestinal transit rate induced by Laxido Paediatric Plain. This medicinal product contains 93 mg of sodium per sachet, equivalent to approximately 4.6% of the WHO recommended maximum daily intake of 2 g sodium for an adult. In patients with swallowing problems, who need the addition of a thickener to solutions to enhance an appropriate intake, interactions should be considered.

Interactions: Medicinal products in solid dose form taken within one hour of large volumes of macrogol preparations (as used when treating faecal impaction) may be flushed from the gastrointestinal tract and not absorbed. Macrogol raises the solubility of medicinal products that are soluble in alcohol and relatively insoluble in water. There is a possibility that the absorption of other medicinal products could be transiently reduced during use with Laxido Paediatric Plain. There have been isolated reports of decreased efficacy with some concomitantly administered medicinal products e.g. anti-epileptics. Laxido Paediatric Plain 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.

Fertility, pregnancy and lactation: Studies in animals have shown indirect reproductive toxicity. There are limited data from the use of the Laxido formulation in pregnant women. Clinically, no effects during pregnancy or on the breast-fed newborn/infant are anticipated, since systemic exposure to macrogol 3350 is negligible. Laxido Paediatric Plain can be used during pregnancy and breast-feeding. There are no data on the effects of the Laxido formulation on fertility in humans.

Effects on ability to drive and use machines: Laxido Paediatric Plain has no influence on the ability to drive and use machines.

Undesirable effects: Reactions related to the gastrointestinal tract occur most commonly; in the treatment of chronic constipation, diarrhoea or loose stools normally respond to a reduction in dose.

Diarrhoea, abdominal distension, anorectal discomfort and mild vomiting are more often observed during treatment for faecal impaction. Vomiting may be resolved if the dose is reduced or delayed**. Very common (≥1/10):** abdominal pain, borborygmi; **Common (≥1/100, <1/10):** diarrhoea, vomiting, nausea, anorectal discomfort; **Uncommon (≥1/1,000, <1/100):** abdominal distension, flatulence; **Rare (≥1/10,000, <1/1,000):** allergic reactions including anaphylactic reaction; **Frequency not known (cannot be estimated from the available data):** allergic skin reactions including angioedema, dyspnoea, rash, erythema, urticaria, pruritus, electrolyte disturbances, particularly hyperkalaemia and hypokalaemia, headache, dyspepsia, peri-anal inflammation, peripheral oedema.
Overdose: Refer to SPC.
Legal Category: This product is subject to medical prescription.
List Price: Cartons of 30 sachets: €6.17.
MA Number: PA 22680/1/3.
Full prescribing information available from the MA Holder: Galen Pharma Ireland Limited, Finnabair Industrial Estate, Dundalk, Co Louth, Ireland.
Date of Preparation: November 2021.

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie.
Adverse events should also be reported to Galen Limited on 048 3833 4974 and select the customer services option, or e-mail customer.services@galen-pharma.com.
Medical information enquiries should also be directed to Galen Limited.

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