

# Laxido Module 4

## Laxido Paediatric

For internal illustrative purposes only.  
This module is for the UK market.

# Laxido<sup>®</sup>

Paediatric Plain

Macrogol 3350, sodium chloride,  
sodium hydrogen carbonate, potassium chloride



# Laxido<sup>®</sup> Paediatric Plain

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- Laxido<sup>®</sup> Paediatric Plain is an osmotic laxative
- Laxido<sup>®</sup> Paediatric Plain contains macrogol 3350 + electrolytes
- Laxido<sup>®</sup> Paediatric Plain is a Prescription-Only Medicine (POM)

## Therapeutic indications:

Laxido Paediatric Plain is indicated for the treatment of chronic constipation in children aged 1 to 11 years.

Laxido Paediatric Plain is indicated for the treatment of faecal impaction in children from the age of 5 years, defined as refractory constipation with faecal loading of the rectum and/or colon.



# Dosage & Treatment Duration<sup>1</sup>

## Chronic constipation:

- Usual starting dose is 1 sachet daily for children aged 1 – 6 years and 2 sachets daily for children aged 7 – 11 years.
- Treatment of children with chronic constipation 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.

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.


**Faecal Impaction:** Children aged from 5 to 11 years. Not recommended for children under 5 years of age. The dosage regimen should be stopped once disimpaction has occurred.

### Number of Laxido® Paediatric Plain sachets for treatment of faecal impaction

Age (years)	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
5 to 11	4	6	8	10	12	12	12

# How does Laxido<sup>®</sup> Paediatric Plain Work?<sup>1</sup>

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- Macrogol 3350 induces a laxative effect by virtue of its osmotic action in the gut, which makes faeces softer and easier to pass.
  - This product also contains electrolytes to ensure that there is no overall gain or loss of water, potassium or sodium.
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# Composition of Laxido<sup>®</sup> Paediatric Plain<sup>1</sup>

Active Ingredient	Amount per sachet
Macrogol 3350	6.563 g
Sodium chloride	175.4 mg
Sodium hydrogen carbonate (Bicarbonate)	89.3 mg
Potassium chloride	25.1 mg

Electrolyte	Content following reconstitution*
Sodium	65mmol/l
Chloride	53mmol/l
Hydrogen carbonate (Bicarbonate)	17mmol/l
Potassium	5.4mmol/l

\* In 62.5 ml of water

# Macrogol 3350<sup>2</sup>

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n = 3350

n= measure of molecular mass;  
larger number indicates higher molecular mass

Higher molecular weight macrogols e.g. macrogol 3350  
undergo negligible absorption and metabolism

Reduced risk of adverse events and toxicity

# Dosage and Administration<sup>1</sup>

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1.

Pour the contents of one sachet of Laxido<sup>®</sup> Paediatric Plain into a glass

2.

Add about a quarter of a glass of water (62.5 ml)

3.

Stir the mixture until the powder has dissolved to make a clear or slightly hazy solution

4.

Drink the solution

The correct number of sachets may be reconstituted in advance; just allow 62.5 ml of water for each sachet of Laxido<sup>®</sup> Paediatric Plain. The resulting solution must be kept covered & refrigerated for up to 24 hours.




# Undesirable Effects<sup>1</sup>

System Organ Class	Frequency	Adverse Event
Immune system disorders	Rare	Allergic reactions including anaphylactic reaction
	Not known	Dyspnoea and skin reaction (see below).
Skin and subcutaneous tissue disorders	Not known	Allergic skin reactions including angioedema, urticaria, pruritus, rash, erythema
Metabolism and nutrition disorders	Not known	Electrolyte disturbances, particularly hyperkalaemia and hypokalaemia.
Nervous system disorders	Not known	Headache
Gastro-intestinal disorders	Very common	Abdominal pain, borborygmi
	Common	Diarrhoea, vomiting, nausea and anorectal discomfort.
	Uncommon	Abdominal distension, flatulence
	Not known	Dyspepsia and peri-anal inflammation
General disorders and administration site conditions	Not known	Peripheral oedema



# Contraindications<sup>1</sup>

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- Patients with hypersensitivity to the active substances
  - Intestinal obstruction or perforation caused by a functional or structural disorder of the gut wall, or ileus
  - Patients with severe inflammatory conditions of the intestinal tract e.g. ulcerative colitis, Crohn's disease and toxic megacolon
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# Drug Interactions<sup>1</sup>

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- Medicinal products in solid dose form taken within one hour of administration of large volumes of macrogol preparations (as used when treating faecal impaction) may be flushed from the gastro-intestinal 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 (see section 4.4). 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.

# References

1. Laxido Paediatric Plain, 6.9g powder for oral solution. UK Summary of Product Characteristics. November 2021
2. Brayfield A, editor. Martindale The Complete Drug Reference 39<sup>th</sup> edition. London: The Pharmaceutical Press. 2017.