Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Idrolax 10g, powder for oral solution in a sachet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Macrogol 4000 .....10.00g per sachet

Excipients with known effect:
Sorbitol (E420) .....1.7 mg per sachet.
Sulphur dioxide (E220) .....0.12* 10^{-2} mg per sachet

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution in sachet.
Almost white powder with an odour and taste of orange-grapefruit.

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. IDROLAX 10 g should remain a temporary adjuvant treatment to appropriate lifestyle and dietary management of constipation, with a maximum 3-month 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.

Posology
1 to 2 sachets (10-20 g) per day, preferably taken as a single dose in the morning.
The daily dose should be adjusted according to the clinical response and may range from one sachet every other day (especially in children) up to 2 sachets a day.

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

Paediatric population
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.

Method of administration
The content of each sachet should be dissolved in about 50 ml of water just before use and taken in the morning. The resultant solution will be clear and transparent like water.

4.3 Contraindications

- severe inflammatory bowel disease (such as ulcerative colitis, Crohn's disease) or toxic megacolon,
- digestive perforation or risk of digestive perforation,
- ileus or suspicion of intestinal obstruction or symptomatic stenosis,
- painful abdominal syndromes of indeterminate cause,

- hypersensitivity to the active substance or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

Special 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,
- advice on appropriate physical activity and rehabilitation of the bowel reflex.

An organic disorder should have been excluded before initiation of treatment.

This medicine contains macrogol (polyethylene glycol). Hypersensitivity (anaphylactic shock, angioedema, urticaria, rash, pruritus, erythema) to drugs containing macrogol (polyethylene glycol) have been reported, see section 4.8.

This medicine contains sulphur dioxide, which may rarely cause severe hypersensitivity reactions and bronchospasm.

This medicine contains 1.7 mg of sorbitol in each sachet.
This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially "sodium-free".

In case of diarrhoea, caution should be exercised in patients at risk of disturbances of water-electrolyte balance (e.g. the elderly or patients with impaired hepatic or renal function or patients taking diuretics) and electrolyte control considered.

Use with caution in patients with impaired gag reflex and patients prone to regurgitation or aspiration.
Cases of aspiration have been reported when extensive volumes of polyethylene glycol and electrolytes were administered with nasogastric tube. Neurologically impaired children who have oral-motor dysfunction are particularly at risk of aspiration.

In patients withswallowing problems, who need the addition of a thickener to solutions toenhance an appropriate intake, interactions should be considered, see section4.5.

Precautions for use
IDROLAX 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

There is a possibility that the absorption of other medicinal products could be transiently reduced during use with IDROLAX, particularly medicinal products with a narrow therapeutic index or short half-life such as digoxin, anti-epileptics, coumarins and immunosuppressive agents, leading to decreased efficacy.
IDROLAX may result in a potential interactive effect when used with starch-based food thickeners. The polyethylene glycol (PEG) 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
Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).
There are limited amount of data (less than 300 pregnancy outcomes) for the use of IDROLAX in pregnant women.
No adverse effects during pregnancy are anticipated, since systemic exposure to IDROLAX is negligible. IDROLAX can be used during pregnancy.

Lactation
There are no data on the excretion of IDROLAX in breast milk. No effects on the breast fed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to macrogol 4000 is negligible. IDROLAX can be used during breast feeding.

Fertility:
No fertility studies were conducted with IDROLAX however since macrogol 4000 is not significantly absorbed no effect on fertility is anticipated.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and /or use machines have been performed.

4.8 Undesirable effects

Adverse Drug Reactions 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); not known (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 mostly mild and transitory and have mainly concerned the gastrointestinal system:

System Organ Class	Adverse reactions
Gastrointestinal disorders	
Common	Abdominal pain Abdominal distension Diarrhoea* Nausea
Uncommon	Vomiting Defaecation urgency Fecal incontinence
Metabolism and Nutrition Disorders	
Not known	Electrolytes disorders (Hyponatremia, Hypokalaemia) and or dehydration, especially in elderly patients
Immune system disorders	
Not known	Hypersensitivity (Anaphylactic shock, Angioedema, Urticaria, Rash, Pruritus, Erythema

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 mostly mild and transitory and have mainly concerned the gastrointestinal system:

System Organ Class	Adverse reactions
Gastrointestinal disorders	
Common	Abdominal pain Diarrhoea*
Uncommon	Vomiting Abdominal distension Nausea
Immune system disorders	
Not known	Hypersensitivity (Anaphylactic shock, Angioedema, Urticaria, Rash, Pruritus)

* Diarrhoea may cause perianal soreness

Reporting of suspected adverse reactions
Reporting of 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

Diarrhoea, abdominal pain and vomiting have been reported. In cases of severe diarrhoea, weight loss and electrolytes imbalance may occur.
Diarrhoea due to excessive dosing disappears when treatment is temporarily interrupted or the dosage is reduced.

Excessive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Osmotically acting laxatives.
ATC code: A06AD15.
High molecular weight (4000) 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 4000 undergoes neither gastrointestinal resorption nor biotransformation following oral ingestion.

5.3 Preclinical safety data

Toxicological studies in different species of animals did not reveal any signs of systemic or local gastrointestinal toxicity of macrogol 4000. Macrogol 4000 had no teratogenic or , mutagenic effect. Potential drug interactions studies performed in rats on some NSAIDs, anticoagulants, gastric antisecretory agents, or on a hypoglycaemic sulfamide showed that IDROLAX did not interfere with gastrointestinal absorption of these compounds. No carcinogenicity studies have been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saccharin sodium (E954**)**
Orange-grapefruit flavour**

**Composition of the orange-grapefruit flavour
Orange and grapefruit essential oils, concentrated orange juice, citral, acetaldehyde, linalol, ethyl butyrate, alpha terpineol, octanal, beta gamma hexenol, maltodextrin, gum arabic, sorbitol (E420), Butylated hydroxyanisole BHA (E320) and sulphur dioxide (E220).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

(Paper / Aluminium / PE) sachet.
Single dose sachets presented in pack sizes of 10, 20, 50 and 100 sachets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

MAYOLY PHARMA FRANCE
3 Place Renault
92500
Rueil-Malmaison
France

8 MARKETING AUTHORISATION NUMBER

PA22808/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 February 2002.

Date of last renewal: 5 May 2010.

10 DATE OF REVISION OF THE TEXT

August 2025