

IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0583/006/002

Case No: 2058085

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Ipsen Limited

190 Bath Road, Slough, Berkshire SL1 3XE, United Kingdom

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Idrolax 4g Junior, powder for oral solution

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **21/07/2009** until **04/05/2010**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Idrolax ® 4g Junior, powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains 4g of macrogol 4000.

For 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 children from 6 months to 8 years.

An organic disorder should have been ruled out by physician, especially in the age group under 2 years, before initiation of treatment. IDROLAX 4 g should remain temporary adjuvant treatment to appropriate lifestyle and dietary management of constipation, with a maximum 3-month treatment course. If symptoms persist despite associated dietary measures, an underlying cause should be suspected and treated.

4.2 Posology and method of administration

Oral use.

From 6 months to 1 year: 1 sachet per day.

From 1 to 4 years: 1 to 2 sachets per day.

From 4 to 8 years: 2 to 4 sachets per day.

The content of each sachet should be dissolved in about 50 ml of water just before use and taken on the morning in case of 1 sachet per day, or split among morning and evening in case of more than one sachet per day.

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

In children, treatment should not exceed 3 months in the lack of clinical data more than 3 months. Treatment-induced restoration of bowel movements will be maintained by lifestyle and dietary measures.

The daily dose should be adapted according to the clinical effects.

4.3 Contraindications

- severe inflammatory bowel disease (such as ulcerative colitis, Crohn's disease) or toxic megacolon, associated with symptomatic stenosis,
- digestive perforation or risk of digestive perforation,
- ileus or suspicion of intestinal obstruction,
- painful abdominal syndromes of indeterminate cause,
- hypersensitivity to macrogol (polyethylene glycol) or to any of the excipients.

4.4 Special warnings and precautions for use

Special Warning

Data on the efficacy in children under the age of 2 years are limited.

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 ruled out before initiation of treatment.

After a 3-month treatment course, a complete clinical supervision of constipation should be performed.

Patients with hereditary problems of fructose intolerance should not take this medicinal product.

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

Precaution for use

Very rare cases of hypersensitivity reactions (rash, urticaria, oedema) have been reported with drugs containing macrogol (polyethylene glycol). Exceptional cases of anaphylactic shock have been reported.

IDROLAX 4 g does not contain a significant quantity of sugar or polyol and can be prescribed to diabetic children or children on a galactose-free diet.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable.

4.6 Pregnancy and lactation

Pregnancy

This medicinal product is indicated for the symptomatic treatment of constipation in children aged from 6 months to 8 years.

However information about the use of macrogol 4000 during pregnancy or lactation is still of interest.

Macrogol 4000 was not teratogenic in rats or rabbits.

There are no adequate data from use of IDROLAX in pregnant women. Therefore, caution should be exercised when prescribing IDROLAX to pregnant women.

Lactation

There are no data on the excretion of macrogol 4000 in breast milk. As macrogol 4000 is not significantly absorbed, IDROLAX may be administered during lactation.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Undesirable effects have been reported during clinical trials involving 147 children aged from 6 months to 15 years with the following frequencies. These effects have always been minor and transitory and have concerned the gastrointestinal system.

Gastrointestinal disorders:

- common ($\geq 1/100$, $< 1/10$): diarrhoea and abdominal pain,
- uncommon ($\geq 1/1000$, $< 1/100$): bloating, vomiting and nausea.

There is no additional information from post-marketing surveillance: hypersensitivity reactions have not been reported in children so far. Nevertheless, such reactions may occur as reported in adults.

Excessive doses may cause diarrhoea, which generally disappears when the dosage is reduced or treatment temporarily interrupted. Diarrhoea may cause perianal soreness.

4.9 Overdose

Overdose leads to diarrhoea which disappears when treatment is temporarily interrupted or the dosage is reduced.

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

Cases of aspiration have been reported when extensive volumes of polyethylene glycol and electrolytes were administered with nasogastric tube. Neurologically impaired children who have oromotor dysfunction are particularly at risk of aspiration.

Cases of perianal inflammation and soreness have been reported when extensive volumes of macrogol solutions (4 to 11 litres) have been administered for colonic lavage either for preparation before colonoscopy or faecal desimpaction in case of encopresis.

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 gastrointestinal toxicity of macrogol 4000. Macrogol 4000 had no teratogenic, mutagenic, nor carcinogenic 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saccharin sodium (E954), orange-grapefruit flavour**

** Composition of the orange-grapefruit flavour:

Orange and grapefruit oils, concentrated orange juice, citral, acetaldehyde, linalol, ethyl butyrate, alpha terpineol, octanal, beta gamma hexenol, maltodextrine, gum arabic, sorbitol.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

(Paper/Aluminium/PE) sachet.

Single dose sachets presented in pack sizes of 10, 20, 30 and 50 sachets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Ipsen Limited
190 Bath Road
Slough
Berkshire SL1 3XE
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 583/6/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29 October 2004.

Date of last renewal: 5 May 2005.

10 DATE OF REVISION OF THE TEXT

July 2009