**IRISH MEDICINES BOARD ACTS 1995 AND 2006**

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

**(S.I. No.540 of 2007)**

**PA1288/004/001**
Case No: 2042926

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

Transferred from PA0375/005/001.

**Madaus GmbH**

**51101 Cologne**, **Germany**

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

**Agiolax Pico 5mg Lozenges**

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 **30/11/2007** until **03/02/2010**.

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

Agiolax Pico 5mg Lozenges

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 lozenge contains:
Sodium picosulfate monohydrate equivalent to Sodium picosulfate, anhydrous 5 mg.

For excipients, see 6.1.

## 3 PHARMACEUTICAL FORM

Lozenges
A rectangular yellow lozenge with a break-line.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

For use in cases of constipation and illnesses requiring an easy defaecation.

### 4.2 Posology and method of administration

Adults, elderly people, children over 12 years: 1-2 lozenges once per day.

Children over 4 years: after consulting a physician ½ lozenge once per day.

The lozenges should preferably be taken in the evening. They can be sucked or chewed or be swallowed whole with some liquid.

As a rule, the laxative effect sets on 10-12 hours after administration.

The maximum use in three days. However, it may be repeated if necessary.

### 4.3 Contraindications

Agiolax® Pico must not be used in patients with existing or imminent ileus. It should not be used either in cases of acute inflammatory diseases of the gastrointestinal tract and children under the age of 4 years. In children of a more advanced age, the product should be used only after careful assessment of the benefit-risk ratio. Agiolax® Pico is contraindicated in pregnant women.

### 4.4 Special warnings and precautions for use

None.

## 4.5 Interaction with other medicinal products and other forms of interaction

The active ingredient sodium picosulfate can potentiate the loss of potassium caused by other drugs (e.g. diuretics, corticosteroids). The sensitivity to cardiac glycosides can be enhanced due to increased losses of potassium. Concurrently administered antibiotics may result in a loss of the laxative effect of sodium picosulfate.

## 4.6 Pregnancy and lactation

Agiolax® Pico is contraindicated in pregnant women.

No experience in women is available regarding the administration during lactation. Sodium picosulfate and its metabolites do not pass into breast milk.

## 4.7 Effects on ability to drive and use machines

None.

## 4.8 Undesirable effects

Adverse reactions are rare in short-term administration. Prolonged use of Agiolax® Pico may result in an aggravation of constipation. Furthermore, in high-dose administration abuse or misuse, severe diarrhoea with increased salt and water loss may occur, which can result in cardiac and muscular dysfunction. This may require intravenous fluid replacement.

## 4.9 Overdose

Overdosage produces diarrhoea. If required, compensatory measures should be considered.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Sodium picosulfate, the active ingredient of Agiolax® Pico, is a laxative of the triarylmethane group. After its metabolization in the colon, it inhibits the absorption of fluid and enhances the secretion of water and electrolytes. Hard stools are hence softened. The stool volume is increased and peristaltic activity stimulated.

## 5.2 Pharmacokinetic properties

Intestinal absorption of sodium picosulfate is low. After bacterial cleavage of sulfate ester in the colon, the resulting diphenolic laxative is partially absorbed (maximum plasma levels are approx.27ng/ml after 14 hours) and after conjugation excreted in bile. Elimination occurs to a small extent as glucuronide via the urine. Most of it is excreted in faeces in the form of free diphenol and also as picosulfate. No chemical knowledge on plasma-protein binding is available.

## 5.3 Preclinical safety data

(a) *Acute toxicity*

Acute toxicity of sodium picosulfate in a variety of animals ranges from 5 to 15 g/kg (also see para 4.9 Signs and Symptoms of Overdosage, Compensatory Measures and Antidotes).

(b) *Chronic toxicity*

In chronic toxicity tests in a variety of animal species, daily doses of up to 50 mg./kg/body weight did not show any evidence of toxic effects.

(c) *Mutagenic and tumorigenic potential*

No experience investigations on the mutagenic and tumorigenic potential have been reported.

(d) *Reproductive toxicology*

Embryonal toxicity tests carried out in rats and rabbits have not shown any evidence of teratogenic potential in doses of up to 100mg/kg/day. At this dose embryotoxic effects appeared in both species. Daily doses of more than 10 mg/kg, administered during fetal development and lactation, inhibited the increase in weight of the offspring and produced a higher mortality rate in the young animals. The fertility of male and female rats remained undisturbed up to a dose of 100 mg/kg/day. No experience in women is available regarding the administration during pregnancy and lactation.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Acesulfame Potassium
Gelatin
Glycerol 85%
Guar gum
Lecithin
Maize Starch
Aromatic (natural plum flavour)
-contains Ethanol

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf Life

3 years.

### 6.4 Special precautions for storage

Do not store above 25°C.

### 6.5 Nature and contents of container

Blister packs (PVC / aluminium).

Contents: 10, 20 and 40 lozenges.

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

Madaus GmbH
51101 Cologne
Germany

## 8 MARKETING AUTHORISATION NUMBER

PA 1288/4/1

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 February 2000

Date of last renewal: 04 February 2005

## 10 DATE OF REVISION OF THE TEXT

November 2007