IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0329/002/001
Case No: 2061404

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

Pierre Fabre Medicament

45 Place Abel Gance, **92100 Boulogne**, **Cedex**, **France**

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

Topaal Chewable Tablets

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 **10/03/2009**.

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

Topaal Chewable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Dried aluminium hydroxide	30	mg
Magnesium carbonate, light	40	mg
Alginic acid	200	mg
Silica, colloidal hydrated	130	mg

Excipients: Each chewable tablet contains 11mg sodium, 220mg lactose monohydrate and 880mg sucrose.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablets
Round, off-white or light cream coloured, 18mm diameter, flat faced bevel-edged chewable tablet, with a score-line on one face.
The score-line is only to facilitate breaking, for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the control of the symptoms of gastro-oesophageal reflux and oesophagitis associated with hiatus hernia and similar conditions.

4.2 Posology and method of administration

Adults and children over 12 years:
Oral route

The usual dose is 6 tablets daily in 3 doses preferably after meals. The tablets should be chewed.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings and precautions for use

Due to the presence of lactose, and sucrose patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
Care should be taken if used by patients with diabetes mellitus or low sugar diet because of the sugar content: sucrose 880 mg, lactose 220 mg.

This product contains 11 mg sodium per tablet: take into account for patients with strict low sodium diet.

Aluminium hydroxide may:
- cause constipation due to its astringent action; this effect may be balanced by the cathartic effect of the magnesium salts,
- may lead to phosphate depletion, particularly in patients on a low phosphate diet, e.g. malnutrition.
- cause delayed or decrease the absorption of certain drugs used in combination; see section 4.5.

Use with caution in chronic dialysed patients because of risk of encephalopathy due to aluminium.

In the presence of renal insufficiency magnesium salts may cause central nervous depression.

4.5 Interaction with other medicinal products and other forms of interaction

Aluminium hydroxide may form complexes with certain drugs e.g. tetracyclines, digoxin and vitamins, resulting in decreased absorption.
It is recommended that antacids are not administered at the same time as these medicines but taken at least 2 hours later.

4.6 Pregnancy and lactation

There is no adequate data from the use of Topaal tablets in pregnant women. Animal studies are insufficient with respect to effects on pregnancy, embryonal and foetal development, parturition and post-natal development.
The potential risk for humans is unknown. Topaal tablets should not be used during pregnancy unless clearly necessary.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Body System	**Adverse reactions (frequency not known)**
Metabolism and nutrition disorders	Phosphate decreased in case of prolonged treatment or overdose
Gastrointestinal disorders	Constipation Diarrhoea.

4.9 Overdose

Treatment should be symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD). Alginic acid ATC code: A02BX13.

Formation of a supernatant gel on the surface of the gastric fluid (lighter than water). This coats the cardio-tuberosity zone (shown by fibre optic endoscopy) and rises up into the oesophagus if reflux occurs.

Able to coat the mucosa.

5.2 Pharmacokinetic properties

Rapid (within 6 to 14 minutes) and persistent (lasting 2 to 4 hours) action confirmed by a double-blind, crossover placebo-controlled study.

5.3 Preclinical safety data

No preclinical findings of relevance to the prescriber have been reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Lactose monohydrate
Povidone
Citric acid monohydrate
Sodium hydrogen carbonate
Caramel flavour
Vanillin
Strawberry flavour
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25^{o}C.
Keep the blisters in the outer carton in order to protect from moisture.

6.5 Nature and contents of container

PVC/aluminium blisters as cards containing 14 tablets, in pack of 3 cards per cardboard box (42 tablets).

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

Pierre Fabre Médicament
45 Place Abel Gance
92100 Boulogne Cedex
France

8 MARKETING AUTHORISATION NUMBER

PA 329/2/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24 January 1983

Date of last renewal: 24 January 2008

10 DATE OF REVISION OF THE TEXT

March 2009