SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

"Carbellon" Tablets.

2. Qualitative and Quantitative Composition

Active Constituents:

	Quantity per tablet
Activated Charcoal Ph.Eur.	100 mg
Magnesium Hydroxide Ph.Eur.	100 mg

3. Pharmaceutical Form

Black, circular, biconvex uncoated tablet.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

"Carbellon" Tablets are recommended for the treatment of indigestion, flatulence, dyspepsia and hyperacidity.

4.2. Posology and method of administration

"Carbellon" Tablets are for oral administration.

Adults and the Elderly: 2—4 tablets to be taken three times a day.

Children (6— 12 years of age): 2 tables to be taken three times a day.

Children under 6 years of age: Not recommended

4.3. Contraindications

Because of potential toxicity, high doses of magnesium containing antacids are contraindicated in patients with impaired renal function. Magnesium hydroxide is also contraindicated in patients with intestinal obstruction.

4.4. Special warnings and precautions for use

There are no known special warnings or special precautions for use.

4.5. Interactions with other medicinal products and other forms of interaction

As the activated charcoal constituent has a highly adsorptive capacity for many drugs used in medicine, care should be taken when administering 'Carbellon' Tablets concomitantly with drugs which are absorbed by the charcoal and where the dose has been adjusted for each patient to achieve a suitable control of symptoms. Such drugs include digoxin, phenytoin, phenobarbitone and chlorpromazine and related phenothiazines. Activated charcoal also has a highly adsorptive capacity for such antibiotics as the penicillins and tetracyclines. The efficacy of the treatment of patients with these antibiotics depends on the maintenance of optimum drug/blood levels, so care should be taken when administering 'Carbellon' Tablets in conjunction with these drugs.

Magnesium hydroxide may interfere with the absorption of tetracyclines when these are taken concomitantly.

4.6. Pregnancy and lactation

Data on a limited number of exposed pregnancies indicate no adverse effects of activated charcoal or magnesium hydroxide on pregnancy or on the health of the foetus / newborn child. To date no other relevant epidemiological data are available.
Animal studies are insufficient to assess the direct or indirect harmful effects with respect to pregnancy, embryonal / foetal development, parturition or postnatal development.

Activated charcoal is considered pharmacologically inert and is not absorbed from the gastrointestinal tract. Some magnesium maybe secreted in breast milk but not in quantities thought to be harmful to the child. No detrimental effects are therefore anticipated with its use during pregnancy or lactation.

Caution should be exercised when taken by pregnant women or during lactation.

4.7. Effects on ability to drive and use machines

None known.

4.8. Undesirable effects

Administration of "Carbellon" Tablets may cause diarrhoea due to the magnesium hydroxide content of the formulation. Mucosal irritation and absorption of magnesium may occur if there is gastro-intestinal atony or obstruction.

4.9. Overdose

No cases of overdosage with "Carbellon" Tablets have been reported. Activated charcoal is, in any case, often used in the treatment of emergency poisoning due to its ability to bind many poisons in the stomach. However, the ingestion of large quantities of magnesium salts particularly in renal insufficiency may result in hypermagnesaemia. Symptoms of hypermagnesaemia include flushing of the skin, thirst, hypotension, drowsiness, respiratory depression, cardiac arrhythmias and arrest and coma. Treatment of hypermagnesaemia involves the intravenous injection of calcium gluconate and dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Activated charcoal is commonly recommended for treatment of chemical indigestion and has been shown to produce a decrease in intestinal gas due to its adsorptive properties. It is not absorbed from the gastro-intestinal tract and there are no known side effects due to its administration.

The management of indigestion, dyspepsia and peptic and duodenal ulceration aims to either decrease the hydrogen ion production and peptic activity in the gut or to increase the ability of the gut to deal with and resist the effects of these agents. By interaction of magnesium hydroxide with the hydrochloric acid content of the gastric juice and subsequent conversion to magnesium chloride, a decrease in the gut hydrogen ion concentration can be achieved. In addition, by reducing the total amount of available hydrogen ions, magnesium hydroxide can irreversibly inactivate pepsin by reducing the quantity of acid

reaching the duodenum thereby allowing the inactivation of pepsin by duodenal bicarbonate to occur more readily, a desirable effect in patients with duodenal ulcers.

5.2. Pharmacokinetic properties

Activated charcoal is an inert substance which is unabsorbed from the gastro-intestinal tract.

Approximately 15-30% of the magnesium chloride produced by the reaction of magnesium hydroxide with hydrochloric acid is available for absorption. The magnesium ions are rapidly excreted by the kidney. In the intestine the remaining magnesium chloride is converted to the relatively insoluble carbonate form via sodium bicarbonate in pancreatic and intestinal secretions. The insoluble carbonate salts are excreted in the stools.

5.3. Preclinical safety data

No remarks.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Carmellose Sodium Ph.Eur
Sucrose Ph. Eur
Icing Sugar
Colloidal Hydrated Silica Ph.Eur
Magnesium Stearate Ph.Eur
Alginic Acid Ph.Eur
Sodium Lauryl Sulphate Ph.Eur
Sodium Starch Glycollate BP
Industrial Methylated Spirit BP
Peppermint Oil Ph.Eur

6.2. Incompatibilities

None known.

6.3. Shelf life

Five years from date of manufacture.

6.4. Special precautions for storage

Store below 25°C in a dry place. Protect from light.

6.5. Nature and contents of container

The product containers are polypropylene tablet containers with a polyethylene cap ("Securitainer") containing 50 or 250 tablets.

6.6. Instruction for use, handling and disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

PL 00287/0008

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16/11/2005

10 DATE OF REVISION OF THE TEXT

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