Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Kolanticon Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Kolanticon gel is a white viscous suspension containing 2.5mg Dicycloverine Hydrochloride (Dicyclomine Hydrochloride), 200mg Aluminium Hydroxide Gel, 100mg Light Magnesium Oxide, 20mg Simethicone per 5ml.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Oral suspension

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the symptomatic relief of gastritis, hyperacidity and flatulence.

4.2 Posology and method of administration

Two to four 5ml spoonfuls every four hours as required.

4.3 Contraindications

Contra-indications: Known idiosyncrasy to any of the ingredients. Should not be used in patients with prostatic enlargement, paralytic ileus or patients with closed angle glaucoma or those with a shallow anterior chamber. It should not be used in patients with pyrexia where the ambient temperature is high.

4.4 Special warnings and precautions for use

Precautions: Use with caution in conditions characterised by tachycardia such as thyrotoxicosis, cardiac insufficiency or failure and in cardiac surgery.
In the presence of renal insufficiency magnesium salts may cause central nervous system depression.

Prolonged use of aluminium in patients with renal failure can cause aluminium intoxication. Aluminium hydroxide absorbs phosphate and excessive dose or low phosphate diet may lead to rickets. Aluminium hydroxide may reduce absorption of tetracyclines when given concomitantly.

If symptoms do not improve, the physician should be consulted.

Use with care in patients with hiatus hernia associated with reflux oesophagitis because anticholinergic drugs may aggravate this condition.

4.5 Interaction with other medicinal products and other forms of interaction

Aluminium hydroxide may reduce absorption of certain medications, including tetracycline antibiotics, digoxin ACE

inhibitors, rifampicin, ketoconazole, penicillamine, ciprofloxacin (and other quinolones), anticoagulants and biphosphonates, if given concomitantly. Because of the large number of possible interactions they should not be given at the same time as any other drugs.

The effects of this product may be enhanced by the concomitant administration of other drugs with anticholinergic properties such as amantidine, some antihistamines, butyrophenones, phenothiazines and tricyclic antidepressants.

4.6 Pregnancy and lactation

Use in Pregnancy and Lactation: Epidemiological studies in pregnant women with products containing dicyclomine hydrochloride (at doses up to 40mg/day) have not shown that dicyclomine increases the risk of foetal abnormalities if administered during the first trimester of pregnancy. Reproduction studies have been performed in rats and rabbits at doses of up to 100 times the maximum recommended dose (based on 60mg per day for an adult person) and have revealed no evidence of impaired fertility or harm to the foetus due to dicyclomine.

Since the risk of teratogenicity cannot be excluded with absolute certainty for any product, the drug should be used during pregnancy only if clearly needed.

It is not known whether dicyclomine is secreted into human milk. Because many drugs are excreted in human milk, caution should be exercised when dicyclomine is administered to a nursing woman.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Side-Effects: In particularly sensitive patients dicyclomine hydrochloride may cause atropine-like side-effects such as dry mouth, blurred vision, urinary retention or constipation.

4.9 Overdose

Overdosage: Signs and symptoms of dicyclomine hydrochloride overdose include: headache, nausea and vomiting, blurred vision, dilated pupils, hot dry skin, dizziness, vertigo, dryness of mouth, difficulty in swallowing and CNS stimulation. Treatment may include emetics, gastric lavage and symptomatic therapy if indicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Dicyclomine hydrochloride: anticholinergic agent used as an antispasmodic;

Also has direct antidepressants activity.

Aluminium hydroxide gel:	antacids
Magnesium hydroxide:	antacids
Simethicone:	antiflatulent

5.2 Pharmacokinetic properties

Dicyclomine hydrochloride:

Dicyclomine hydrochloride when given orally was rapidly and completely absorbed and the drug and/or its metabolites

were found in the urine (dominant route of elimination) within 1 hour after drug ingestion. Plasma half-life of 4-6 hours was found for dicyclomine and/or its metabolites.

Antacids:

Act by local action in the stomach by neutralising stomach acid and are largely unabsorbed.

5.3 Preclinical safety data

None applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Sulphate
Methylcellulose
Benzyl Alcohol
Sodium Lauryl Sulphate
Saccharin Sodium
Alcohol 95%
Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Butyl Parahydroxybenzoate
Citric Acid Monohydrate
Oil of Cinnamon
Peppermint Oil
Oil of Spearmint
Oil of Cedar Leaf
Oil of Nutmeg
Menthol
Eucalyptol
Demineralised water

6.2 Incompatibilities

None known.

6.3 Shelf Life

36 months.

6.4 Special precautions for storage

Store below 25ºC.

6.5 Nature and contents of container

Amber glass bottles of 150, 200 and 500ml.

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

Shake well before use.

7 MARKETING AUTHORISATION HOLDER

Peckforton Pharmaceuticals Limited
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8 MARKETING AUTHORISATION NUMBER

PA 946/1/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08 February 2002

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