

SUMMARY OF PRODUCT CHARACTERISTICS

Product Summary

1. Trade Name of the Medicinal Product

Kolanticon Gel

2. Qualitative and Quantitative Composition

Kolanticon Gel is a white viscous suspension containing 2.5mg dicycloverine hydrochloride, 200mg aluminium hydroxide, 100mg light magnesium oxide, 20mg simethicone per 5ml.

3. Pharmaceutical Form

Suspension for oral administration.

Clinical Particulars

4.1 Therapeutic Indications

Treatment and prophylaxis of symptoms of peptic ulcer and functional dyspepsia especially in patients in whom gastric distress results from hyperacidity, smooth muscle spasm, including irritable bowel syndrome (IBS), and flatulence. Also indicated for symptomatic relief in oesophagitis, hiatus hernia, gastritis and iatrogenic gastritis.

4.2 Posology and Method of Administration

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

4.3 Contra-indications

Known idiosyncrasy to any of the ingredients. Should not be used in patients with prostatic enlargement, glaucoma, obstructive uropathy, obstructive disease of the gastro-intestinal tract, paralytic ileus and intestinal atony, severe ulcerative colitis, and myasthenia gravis.

4.4 Special Warnings and Precautions for Use

In the presence of renal insufficiency magnesium salts may cause central nervous system depression. Aluminium hydroxide in the presence of low phosphorous diets may cause phosphorous deficiency. Aluminium hydroxide may reduce absorption of tetracyclines when given concomitantly. Use with care in patients with hiatus hernia associated with reflux oesophagitis because anticholinergic drugs may aggravate this condition.

4.5 Interactions with other Medicaments and other forms of Interaction

Antacids may interfere with the absorption of tetracyclines, ACE inhibitors, digoxin, rifampicin, ketoconazole, penicillamine, ciprofloxacin (and other quinolones), anticoagulants and biphosphonates, if given concurrently. Because of the large number of possible interactions they should not be given at the same time as any other drugs.

4.6 Pregnancy and Lactation

Epidemiological studies in pregnant women with products containing dicycloverine hydrochloride (at doses up to 40mg/day) have not shown that dicycloverine 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 dicycloverine.

For aluminium hydroxide, magnesium oxide and simethicone no clinical data on exposed pregnancies are available.

Caution should be exercised when prescribing to pregnant women.

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 dicycloverine is secreted into human milk. Because many drugs are excreted in human milk, caution should be exercised when dicycloverine is administered to a nursing woman.

4.7 Effects on Ability to Drive and Use Machines.

None known

4.8 Undesirable Effects

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

4.9 Overdose

Signs and symptoms of dicycloverine 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.

Pharmacological Properties

5.1 Pharmacodynamic Properties

Dicycloverine hydrochloride: anticholinergic agent used as an antispasmodic; also has direct antispasmodic activity.

Aluminium hydroxide dried gel, magnesium hydroxide are antacids.

Simethicone: antiflatulent

5.2 Pharmacokinetic Properties

Dicycloverine hydrochloride:

Dicycloverine 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 dicycloverine 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.

Pharmaceutical Particulars

6.1 List of Excipients

Kolanticon Gel contains magnesium sulphate, methylcellulose 450, benzyl alcohol, sodium lauryl sulphate, saccharin sodium, alcohol 95%, methylparaben, propylparaben, butylparaben, citric acid, oil of cinnamon, oil of peppermint, oil of spearmint, oil of cedar leaf, oil of nutmeg, menthol and eucalyptol.

6.2 Incompatibilities

None known

6.3 Shelf Life

36 Months

6.4 Special Precautions for Storage

Store below 25°C

6.5 Nature and Contents of Container

Amber glass bottles of 200 and 500ml

6.6 Instruction for Use/Handling

Shake well before use.

Administrative Data

7. Marketing Authorisation Holder

Peckforton Pharmaceuticals Ltd,
Crewe Hall,
Crewe,
Cheshire,
CW1 6UL.
United Kingdom

8. Marketing Authorisation Number

PL 15760/0004

9. Date of First Authorisation/Renewal of Authorisation

15 October 1999

10. Date of (Partial) Revision of the Text

June 2007

11. Legal Category

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