

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, 200mg aluminium hydroxide, 100mg light magnesium oxide, 20mg simethicone per 5ml.

3 PHARMACEUTICAL FORM

Suspension for oral administration.

4 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 Contraindications

- Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.
- Prostatic enlargement
- Glaucoma
- Obstructive uropathy
- Obstructive disease of the gastro-intestinal tract, paralytic ileus and intestinal atony
- Severe ulcerative colitis
- Myasthenia gravis
- Renal failure.

4.4 Special warnings and precautions for use

Use with caution in patients with renal impairment due to the risks of aluminium accumulation and hypermagnesaemia.

In the presence of renal insufficiency magnesium salts may cause hypermagnesaemia, important signs of which are respiratory depression and loss of deep tendon reflexes, both due to neuromuscular blockade.

Osteomalacia or adynamic bone disease, encephalopathy, dementia, and microcytic hypochromic anaemia have been associated with aluminium accumulation in patients with chronic renal impairment given large doses of aluminium hydroxide.

Excessive doses of aluminium hydroxide, or normal doses in patients with low phosphate diets, may lead to phosphate deficiency, accompanied by increased bone resorption and hypercalciuria with the risk of osteomalacia.

Oral citrate salts increase the absorption of aluminium from the gastrointestinal tract and patients with renal failure taking aluminium compounds should avoid citrate-containing preparations.

Ascorbic acid has also been reported to enhance aluminium absorption.

Aluminium hydroxide may be unsafe in patients with porphyria undergoing haemodialysis.

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 Interaction with other medicinal products 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.

Absorption of levothyroxine may be delayed or reduced due to binding to simeticone.

Absorption of aluminium from the gastrointestinal tract may be enhanced if aluminium compounds are taken with citrates or ascorbic acid (see section 4.4).

Because of the large number of possible interactions Kolanticon should not be taken at the same time as any other drugs. Kolanticon gel should preferably not be taken at the same time as other medicines since the absorption may be impaired (refer to the product information of each medicine being administered for specific advice on concomitant use with this type of medicinal product).

4.6 Fertility, Pregnancy and lactation

Pregnancy

Epidemiological studies in pregnant women with products containing dicycloverine hydrochloride (at doses up to 40 mg/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 60 mg 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.

Magnesium crosses the placenta.

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.

Breast-feeding

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.

Small amounts of magnesium are distributed into breast milk, however any increase in magnesium load to a breast-fed infant is considered unlikely to significantly alter magnesium clearance from the neonate.

4.7 Effects on ability to drive and use machines

None Known.

4.8 Undesirable effects

Summary of the safety profile

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

Tabulated list of adverse reactions

The following convention has been utilised for the classification of frequency: Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1000$ to $< 1/100$); rare ($\geq 1/10000$, $< 1/1000$), very rare ($< 1/10000$), not known (cannot be estimated from the available data)

System organ class	Undesirable effects	Frequency
Metabolism and Nutrition Disorders	Hypermagnesaemia Phosphate depletion accompanied by hypercalciuria	Not known
Eye disorders	Blurred vision	Not known
Gastrointestinal disorders	Dry mouth Constipation	Not known
Musculoskeletal and connective tissue disorders	Increased bone resorption Risk of osteomalacia	Not known
Renal and urinary disorders	Urinary retention	Not known

Other special populations

Hypermagnesaemia may occur, particularly in patients with renal impairment (see section 4.4)

Excessive doses or normal doses in patients on low phosphate diets, may lead to phosphate depletion accompanied by increased bone resorption and hypercalciuria with the risk of osteomalacia (see section 4.4).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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.

Large doses of aluminium hydroxide may cause intestinal obstruction.

5 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.

6 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 monohydrate, 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

18 months

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Amber glass bottles of 200 and 500 ml.

6.6 Special precautions for disposal

Shake well before use.

7 MARKETING AUTHORISATION HOLDER

Dendron Brands Limited
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Watford
Hertfordshire
WD18 7JJ
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 52731/0010

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29/07/1982 / 03/12/2002

10 DATE OF REVISION OF THE TEXT

14/04/2022