

Package leaflet: Information for the patient

KOLANTICON® GEL Oral Suspension

Dicycloverine Hydrochloride, Aluminium Hydroxide Gel, Light Magnesium Oxide, Simeticone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

1. What Kolanticon Gel is and what it is used for
2. What you need to know before you take Kolanticon Gel
3. How to take Kolanticon Gel
4. Possible side effects
5. How to store Kolanticon Gel
6. Contents of the pack and other information

1. WHAT KOLANTICON GEL IS AND WHAT IT IS USED FOR

- Kolanticon Gel contains an antispasmodic (relieves muscle spasm), an antifatulent (relieves wind) and antacids.
- Kolanticon Gel is used to treat stomach complaints, such as irritable bowel syndrome, where there are problems such as painful cramps, indigestion and flatulence (wind).
- It helps to relieve painful cramps by relaxing the muscles of the intestine. It helps to relieve indigestion by reducing acidity, and relieve flatulence by bringing together all the small bubbles of gas to form a large bubble which can be expelled.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE KOLANTICON GEL

Do not take Kolanticon Gel if:

- You are allergic to any of the active substances or any of the other ingredients of this medicine (listed in section 6)
- You have difficulty passing urine because of an enlarged prostate or other condition
- You have ulcerative colitis or other conditions affecting movement of food through the gastrointestinal tract
- You have myasthenia gravis (a very rare muscle disease)
- You have glaucoma (a condition involving increased pressure within the eye resulting in poor vision)
- You have kidney failure.

Warnings and precautions

Talk to your doctor or pharmacist before taking Kolanticon Gel if:

- You have or have had kidney problems
- You have a low phosphate diet
- You have existing or you have been advised that there is a risk of you developing bone problems (such as osteomalacia)
- You have a hiatus hernia (a condition with symptoms such as acid or food regurgitation)
- You have porphyria (an inherited condition causing skin blisters, abdominal pain and brain or nervous system disorders) and are undergoing haemodialysis.
- You are taking one of a group of antibiotics called tetracyclines

Other medicines and Kolanticon Gel:

Tell your doctor or pharmacist if you are taking, have recently taken or might take **any** other medicines, in particular antibiotics (e.g. tetracycline, ciprofloxacin, rifampicin), ACE inhibitors, anticoagulants, digoxin, levothyroxine, ketoconazole, penicillamine or bisphosphonates.

Kolanticon Gel should not be taken at the same time as other medicines. This is because Kolanticon Gel may affect the absorption of other medicines or the way they work; you may be advised to leave a gap between taking some medicines and Kolanticon. You may check the instructions for your other medicines and ask your doctor or pharmacist for advice before taking Kolanticon.

Avoid taking ascorbic acid (vitamin C) or any preparations containing a citrate salt, e.g. potassium citrate, at the same time as Kolanticon, as they may increase the amount of aluminium absorbed by your body and the chance of side-effects.

Pregnancy and breast-feeding:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Kolanticon Gel contains:

- small amounts of ethanol (alcohol), less than 100 mg per dose.
- methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), butyl parahydroxybenzoate, which may cause allergic reactions (possibly delayed).

3. HOW TO TAKE KOLANTICON GEL

Adults and Children over 12 years old:

- Take two to four 5 ml spoonfuls (10 – 20 ml) every four hours if needed.
- **Shake the bottle before use to mix the ingredients properly.** Then measure out the amount you need onto a 5 ml spoon and swallow the liquid.

If you take more than you should:

- If you accidentally take too much medicine you should talk to your doctor or go to your nearest hospital casualty department straight away. Signs of overdose include (i.e. the following list is not exhaustive): headache, dizziness, nausea, vomiting, abdominal pain and blurred vision.

If you forget to take Kolanticon Gel:

- If you forget to take your medicine at the correct time, do not worry. Do not take twice as much next time. Just take your medicine as soon as you remember and carry on as before.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Kolanticon Gel can cause side effects, although not everybody gets them.

Possible side effects include:

- dry mouth, blurred vision, constipation, difficulty passing urine
- in people taking excessive doses or following a low phosphate diet: low phosphate levels in the blood, high calcium levels in the urine, risk of bones becoming softer.
- hypermagnesaemia (a high level of magnesium in the blood). Signs and symptoms can include low blood pressure, slow heart rate, slow and shallow breathing, muscle weakness

The frequency of these side effects is not known (cannot be estimated from the available data).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE KOLANTICON GEL

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date on the label, or if the medicine has deteriorated in any way. Keep your medicine in the original bottle and store below 25°C. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Kolanticon Gel contains:

The active ingredients are: Each 5 ml spoonful of Kolanticon Gel contains: 2.5 mg dicycloverine hydrochloride, 200 mg aluminium hydroxide, 100 mg magnesium oxide and 20 mg simeticone.

The other ingredients are: Magnesium sulphate, methylcellulose 450, benzyl alcohol, sodium lauryl sulphate, saccharin sodium, alcohol 95%, methyl parahydroxybenzoate, propyl parahydroxybenzoate, butyl parahydroxybenzoate, citric acid, oil of cinnamon, peppermint oil, oil of spearmint, oil of cedar leaf, oil of nutmeg, eucalyptol, menthol and demineralised water.

What Kolanticon Gel looks like and contents of the pack:

Kolanticon Gel is a thick, white liquid in bottles of 200 ml and 500 ml.

Marketing Authorisation Holder and Manufacturer:

Dendron Brands Limited, 94 Rickmansworth Road, Watford, Hertfordshire, WD18 7JJ, United Kingdom.

This leaflet was last revised in March 2022.

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PRODUCT NAME:	KOLANTICON GEL
PIP CODE:	
CODE	
COMP PIL	PIL
SIZE	145 x 210 mm
MARKET	
SCALE	100%
COLOURS	BLACK CUTTER

DATE 21.03.22
VERSION NO. 1
AMENDED BY B.MCCOMBE



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