NEUTRAGEL®

ANTACID/ANTIFLATULENT SUSPENSION

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml contains:
Dried Aluminium Hydroxide gel USP..... 400 mg
Magnesium Hydroxide USP .....318.4 mg
Simethicone USP.....50 mg
Preservatives
Methylhydroxylbenzoate BP ……...20 mg
Propylhydoxybenzoate BP ……2 mg

PHARMACEUTICAL FORM: Pleasant tasting, pink, mint-flavoured oral suspension

CLINICAL PARTICULARS

Therapeutic indications: The symptomatic relief of gas, acid Indigestion, heartburn, hyperacidity, peptic ulceration and acid reflux (nyon'o)

Posology and method of administration

Take or give 20 minutes to 1 hour after meals and at bed time, or alternatively take as directed by your doctor
Adults; Two to six 5 ml teaspoonfuls (10 ml – 30 ml) every three to four times daily as required.
Adolescents; One to four 5 ml teaspoonfuls (5 ml – 20 ml) every three to four times daily as required.
Children under 12 yrs; Maximum of one 5 ml teaspoonful three to four times a day.

Contraindications:

Should not be used in patients who are hypersensitive to any of the active substances or excipients, are severely debilitated or suffering from kidney failure, or hypophosphataemia

Special warnings and special precautions for use:

In patients with renal impairment, plasma levels of both aluminium and magnesium increase. In these patients, a long-term exposure to high doses of aluminium and magnesium salts may lead to dementia and microcytic anaemia. Aluminium hydroxide may be unsafe in patients with porphyria undergoing haemodialysis. This product contains methyl paraben and propyl paraben which may cause allergic reactions (possibly delayed).

Interaction with other FPPs and other forms of interaction: NEUTRAGEL ® should not be taken simultaneously with other medicines as they may interfere with their absorption if taken within 1 hour. Aluminium-containing antacids may prevent the proper absorption of oral cephalosporins. Aluminium hydroxide and citrates may result in increased aluminium levels, especially in patients with renal impairment.

Pregnancy and lactation: The safety of NEUTRAGEL ® suspension in pregnancy has not been established. Magnesium is considered as compatible with lactation

Effects on ability to drive and use machines: No studies on the effects on the ability to drive and use machines have been performed.

Undesirable effects: Aluminum hydroxide mixture in common with other aluminium compounds is astringent and may cause nausea, vomiting and constipation. Large doses can cause intestinal obstruction. In large doses it may cause hypophosphataemia. Magnesium hydroxide may cause diarrhoea, mucosal irritation and absorption of magnesium may occur if there is gastro-intestinal atony or obstruction – hypermagnesaemia may occur. Concurrent use of aluminium-containing antacids with citrate salts can increase aluminium absorption i.e. citrate-containing solutions

Overdose: Serious symptoms are unlikely following overdosage. Treatment of magnesium overdose: consider administration of IV Calcium Gluconate, rehydration and forced diuresis. In case of renal deficiency, haemodialysis or peritoneal dialysis is necessary.

PHARMACOLOGICAL PROPERTIES

Mechanism of action: NEUTRAGEL ® is a balanced mixture of two antacids and an antiflatulent/antifoaming agent simethicone. The two antacids are magnesium hydroxide which is fast acting and aluminium hydroxide which is a slow acting antacid. The combination produces a fast onset of action and an increase in total buffering time.

PHARMACEUTICAL PARTICULARS

Incompatibilities: Not applicable.
Shelf life: 2 years
Storage: Do not store above 30 °C or freeze. Keep out of reach of children
Nature and contents of container; Natural HDPE plastic bottles and LDPE waded PP closure: 200 ml, or amber glass bottles and polypropylene screw-cap: 200 ml
Instructions for use and handling; No special requirements.

REGISTRATION NUMBER: TBA

PHARMACOLOGICAL CLASSIFICATION: Antacids with antiflatulents, ATC Code: A02AF02

CATEGORY OF DISTRIBUTION: General Sales

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