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Nugel-O

Anaesthetic Antacid Suspension

Composition:

Each 15 mL Contains

Alginic Acid	BP	200 mg
Dried Aluminium Hydroxide	BP	250 mg
Magnesium Hydroxide	BP	250 mg
Magnesium Trisilicate	BP	250 mg
Dimethicone (Activated)	BP	125 mg
Oxetacaine	BP	30 mg

EXCIPIENTS

Nugel-O Suspension : Sorbitol Solution 70%, Propylene Glycol, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, EDTA Disodium, Saccharin Sodium, Sodium Citrate, Xanthan Gum, Flavour, Colour

ACTIONS AND PHARMACOLOGY : NUGEL-O is a balanced mixture of two antacids; aluminium hydroxide is a slow-acting antacid and magnesium hydroxide is a quick-acting one. The two are frequently combined in antacid mixtures. Aluminium hydroxide on its own is an astringent and may cause constipation. This effect is balanced by the effect of magnesium hydroxide, which, in common with other magnesium salts, may cause diarrhoea. Gastro-intestinal side effects are thus rare with NUGEL-O and this makes it especially suitable when long term therapy is necessary.

Dimethicone either alone or with antacid mixture acts as an antifoaming agent to reduce flatulence. It is a silicon polymer that lowers surface tension and allows the small bubbles of froth to coalesce into large bubbles that can be more easily passed up from the stomach or down from the colon. Antacid Dimethicone combination may also be useful for the relief of hiccup in palliative care.

Alginic Acid is combined with antacids to encourage adherence of the mixture to the mucosa. Alginate as mucosal protectant is useful in reflux oesophagitis. As the ingredients used in this drug are well established, tolerated and accepted all over the world and hence test confirming its physiological availability pharmacological effects studies are not conducted.

Oxetacaine is added to the formulation to act as a local anaesthetic. This will further assist in the relief of symptoms associated with Ulcer, Gastritis, Reflux Oesophagitis, etc.

PHARMACOKINETICS : The absorption of aluminium and magnesium from antacids is small. Aluminium hydroxide is slowly converted to aluminium chloride in the stomach. Some absorption of soluble aluminium salts occurs in the gastro-intestinal tract with urinary excretion. Any absorbed magnesium is likewise excreted in the urine.

INDICATIONS : NUGEL-O acts as an antacid in non-ulcer dyspepsia and is used for the symptomatic relief of gastritis, hyperacidity associated with peptic ulceration, relief from ulcer, reflux oesophagitis, heartburn and flatulence.

DOSAGE & ADMINISTRATION : 15 mL (One tablespoonful) twice daily for adults or as directed by the Physician. Not to be used in Children.

CONTRAINDICATIONS: Do not use this product if you are presently taking a prescription antibiotic drug containing any form of tetracycline. This medicine should not be given to any patient who has demonstrated a sensitivity to it. The use of aluminium- or magnesium-containing antacids is contra-indicated in patients with symptoms of appendicitis, since these medicines may increase the danger of perforation or rupture due to their constipating or laxative effects. The use of aluminium-containing antacids (except those containing aluminium phosphate) is contra-indicated in patients with hypophosphataemia due to the phosphate binding properties of aluminium salts. The use of magnesium-containing antacids is contra-indicated in patients with severe renal function impairment due to increased danger of occurrence of hypermagnesaemia. Pregnant and lactating women can take it after consulting the Physician

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DRUG INTERACTIONS : The rate and/or extent of absorption of many medicines may be increased or decreased. Therefore, medication should not be taken within one to two hours of NUGEL-O. An incomplete list of substances for which the above statement has been shown to apply includes: tetracycline, iron salts, isoniazid, ethambutol, some anti-muscarinic drugs, benzodiazepines, phenothiazines, ranitidine, indomethacin, phenytoin, nitrofurantoin, Vitamin A, fluoride and phosphate. An increase in the plasma level of quinidine and possible toxicity may result if alkalinisation of the urine occurs following antacid therapy.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Antacids may interfere with drugs by increasing the gastric pH altering disintegration, dissolution, solubility, ionization and gastric emptying time.

Absorbing or binding drugs to their surface resulting in decreased bio-availability such as tetracycline

Increasing urinary pH affecting the rate of drug elimination.

Urinary excretion of certain drugs may also be affected.

Antacids reduce the absorption of ACE Inhibitors Beta-blockers

Antacids containing Magnesium salt may increase absorption of Sulphonylureas and thereby increases the hypoglycemic effect

OVERDOSE : Treatment is symptomatic and supportive.

STORAGE CONDITION : Store below 30°C. Protect from light.

SIDE EFFECTS: Some patients may experience dizziness, faintness or drowsiness. Sensitivity reactions including skin eruptions (dermatitis, urticaria), pruritus, glossitis, have been reported. Magnesium-containing antacids may cause diarrhoea. Aluminium-containing antacids may cause constipation.

WARNING & PRECAUTIONS : No clinical data on exposed pregnancies are available. Use of antacids should be avoided in the first trimester of pregnancy. Caution should be exercised when prescribing to pregnant and lactating women. Adequate diagnostic studies are recommended. The possibility of gastrointestinal carcinoma should be considered in patients with protracted or recurrent indigestion.

SHELF LIFE: Nugel-O Suspension should be administered within 30 months from the date of manufacture.

PRESENTATION : NUGEL-O Suspension - Bottle pack of 100 & 200 mL

Manufactured in India by :
Sai Mirra Innopharm Pvt. Ltd.
288 & 299, SIDCO Estate, Ambattur, Chennai - 600 098.

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