For the use only of a Registered Medical Practitioners or a Hospital or a Laboratory

Anesthetic Antacid Gel

Mucaine® Gel

(Orange/Mint/American Ice cream soda/Pineapple flavour)

1. TRADENAME OF THE MEDICINAL PRODUCT

MUCAINE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Oxetacaine B.P.	10 mg
Aluminium hydroxide	0.291 gm
(Added as aluminium hydroxide paste equivalent to 0.380 g of Dried Aluminium Hydroxide Gel I.P.)	
Magnesium Hydroxide I.P.	98 mg
(Added as Magnesium Hydroxide paste)	

Colour: Sunset Yellow FCF (For Mucaine Gel Orange Flavour)
Colour: Erythrosine (For Mucaine Gel American Icecream Soda Flavour)
Colour: Brilliant Blue FCF and Quinoline Yellow (Mucaine Gel Pineapple Flavour)

All strengths/presentations mentioned in this document might not be available in the market.

3. PHARMACEUTICAL FORM

Oral Suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Mucaine is indicated for rapid and effective relief in gastritis, esophagitis, hiatus hernia, heartburn of pregnancy and peptic ulcer.

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Licensed User – Pfizer Limited, India

4.2 Posology and Method of Administration

1 to 2 teaspoonfuls 4 times a day, 15 minutes before each meal and at bed time. It is preferable to take it undiluted. However a sip of water may be taken if desired.

Route of administration: Oral

In Children

Dose requirements for young children have not been extensively evaluated. Since children are usually not able to describe their symptoms precisely, proper diagnosis should precede the use of an antacid.

4.3 Contraindications

Mucaine is contraindicated in patients with proven allergy to any ingredient (listed in Section 6.1 (List of Excipients).

4.4 Special Warnings and Special Precautions for Use

Aluminium salts are not, in general, well absorbed from the gastrointestinal tract, and systemic effects are therefore rare in patients with normal renal function. However, care is necessary in patients with chronic renal impairment since osteomalacia or adynamic bone disease, encephalopathy, dementia and microcytic anemia have been associated with aluminium accumulation in patients with chronic renal failure.

Magnesium hydroxide may be used cautiously in patients with impaired renal function.

4.5 Interaction with Other Medicaments and Other Forms of Interaction

Antacids have potentially important interactions with Beta-blocking agents, Cimetidine, Chloroquine, Digoxin, NSAIDs, Phenytoin, Tetracyclines, Iron preparations, Fluoroquinolones and Quinidine.

Concomitant use of these drugs with antacids should be avoided. When co-prescription of such drugs with antacid is indicated, sufficient temporal spacing should be maintained between the administration of these drugs and antacid.

Because of the ability of antacids to change gastric or urinary pH and adsorb or form complexes with other drugs, the rate and/or extent of absorption of other medications may be increased or reduced when such medications are used concurrently with antacids.

In general, patients should be advised not to take any other oral medication within 1 to 2 hours of consuming antacids.

4.6 Pregnancy and Lactation

There are no well-controlled studies to show safety in pregnant women, and use in pregnancy should be based on assessment of the risk/benefit ratio.

4.7 Effects on Ability to Drive and Use Machines

The data on patient's ability to drive or use machinery is not available.

4.8 Undesirable Effects

If held in the mouth for a long time, Mucaine owing to its Oxetacaine content may anesthetize the tongue and impair taste sensation. Glossitis of the hypersensitivity type, dizziness, faintness and drowsiness have occasionally occurred, especially when the recommended dose is exceeded. These effects disappear on stopping the treatment. Sometimes constipation may occur.

Aluminium hydroxide is astringent and may cause constipation. Large doses can cause intestinal obstruction.

Magnesium hydroxide may cause diarrhea. Chronic diarrhea due to long-term administration may result in electrolyte imbalance. Hypermagnesaemia may occur in patients with impaired renal function.

4.9 Overdosage

There are no reports of overdosage with antacids. Potential effects, based on the pharmacology of ingredients, include major electrolyte imbalances such as elevated serum magnesium and aluminium levels, hypophosphatemia, metabolic alkalosis, hyperosmolarity and dehydration. Glossitis of the hypersensitivity type, dizziness, faintness and drowsiness have occasionally occurred, especially when the recommended dose of Oxetacaine is exceeded.

In the event of overdosage, symptomatic treatment, with supportive measures and gastric lavage, if necessary, is recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Mucaine is a potent gastric mucosal anesthetic in antacid (aluminium and magnesium hydroxide) gel vehicle.

Aluminium hydroxide is used as an antacid. Given by mouth most of it remains in the gastrointestinal tract forming insoluble, poorly absorbable aluminum salts such as hydroxides, carbonates, and phosphates which are excreted in the feces.

Magnesium hydroxide is a quick acting antacid and its action is prolonged. In the stomach, magnesium hydroxide combines with gastric acid to form magnesium chloride. In the small intestine, magnesium hydroxide is regenerated and excreted in feces.

Oxetacaine is a local anesthetic. Oxetacaine relieves pain, bloating, discomfort, and fullness. Normally Oxetacaine when administered alone is absorbed into the blood, metabolized in the liver and excreted in the urine. But when given with aluminium and magnesium hydroxide, its absorption is retarded and hence, it remains in contact with gastric mucosa for a longer time. In course of time, it mixes with the food and passes into the intestines. However, the concentration obtained there is probably so low that no effect is produced on the intestinal mucosa. Since the anesthetic effect is due to the non-ionized molecules, which are lipid soluble and can penetrate nerve membranes, Oxetacaine maintains its activity even at a low pH

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In contrast to almost all other local anesthetics, Oxetacaine ionizes only to a very small extent at a low pH such as that of gastric acid. Since the anesthetic effect is due to the non-ionized molecules, which are lipid soluble and can penetrate nerve membranes, Oxetacaine maintains its activity even at a low pH. Normally Oxetacaine when administered alone is absorbed into the blood, metabolized in the liver and excreted in the urine. But when given with aluminium and magnesium hydroxide, its absorption is retarded and hence, it remains in contact with gastric mucosa for a longer time. In course of time, it mixes with the food and passes into the intestines. However, the concentration obtained there is probably so low that no effect is produced on the intestinal mucosa.

5.3 Preclinical Safety Data

Carcinogenesis

Carcinogenesis studies have not been done in animals. Extensive clinical experience over many decades suggests no evidence of carcinogenic potential of antacids.

Mutagenesis

Mutagenesis studies have not been done in animals. Extensive clinical experience over many decades suggests no evidence of mutagenic potential of antacids.

Impairment of Fertility

Extensive clinical experience over several decades suggests that antacids have no effect on fertility.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Mucaine Gel Orange Flavour: Sorbitol solution IP, Guar gum IP, Citric Acid Monohydrate IP, Glycerine IP, Benzoic Acid IP, Sodium Benzoate IP, Saccharine Sodium IP, Sodium Hypochlorite solution, Strong Ammonia solution, Butyl Paraben IP, Propyl Paraben IP, Bronopol BP, Colour FDC Yellow No. 6, Orange oil sweet, Orange Booster.

Mucaine Gel Mint Flavour: Sorbitol solution IP, Benzoic Acid IP, Sodium Benzoate IP, Saccharine Sodium IP, Peppermint oil IP, Menthol IP, Sodium Hypochlorite solution, Strong Ammonia solution.

Mucaine Gel American Icecream soda Flavour: Sorbitol solution IP, Benzoic Acid IP, Sodium Benzoate IP, Saccharine Sodium IP, American Ice cream soda flavour, Erythrosine, Sodium Hypochlorite solution, Strong Ammonia solution.

Mucaine Gel Pineapple Flavour: Sorbitol Solution IP, Benzoic Acid IP Sodium Benzoate IP, saccharine Sodium IP, Brilliant Blue FCF, Quinoline Yellow, Pineapple flavour, Sodium Hypochlorite solution, Strong Ammonia Solution.

6.2 Incompatibilities

None

6.3 Shelf Life

Mucaine Gel Orange Flavour/Mint Flavour/American Ice cream soda Flavour:
36 months

6.4 Special Precautions for Storage

Store in tightly closed container and avoid freezing.

6.5 Nature and Contents of Container

Mucaine Gel Orange Flavour/Mint Flavour: 200 ml/350 ml PET Amber Color Bottle

Mucaine Gel American Ice cream soda Flavour: 120 ml PET Amber Color Bottle

Mucaine Gel Pineapple Flavour : 120 ml PET amber color Bottle

6.6. Instruction for Use/Handling

Do not exceed recommended dosage.
Shake well before use.
Keep out of reach of children.