SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT:

VISCO TABLETS.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION :

Each uncoated chewable tablet contains:

Alginic Acid	BP 100 mg
Magnesium Hydroxide	USP 400 mg
Dried Aluminium Hydroxide Gel	USP 200 mg
Simethicone	USP 50 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:

TABLETS.

Pink coloured, may contain white specks , round, flat faced with bevelled edges, uncoated chewable tablets having breakline on one side & plain on other side.

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications:

This combination acts as an antacid, anti-reflux agent & as an anti-flatulent for the temporary relief and treatment of duodenal and stomach ulcers, gastritis, hiatus hernia, esophagitis, heartburn and any similar gastrointestinal disorders in which control of gastric hyperacidity is desirable.

Rationale for the combination:

Magnesium Hydroxide and Dried Aluminium Hydroxide are used to provide relief from heartburn, indigestion, dyspepsia associated with excess hyperacidity.

Alginic Acid is used for the relief of heartburn due to gastro esophageal reflux as it forms a coating on the gastric contents. Simethicone, acts as an antiflatulent and relieves gas due to heartburn & indigestion.

This combination is therefore a rationale combination for providing relief of heartburn & in cases with increased hyperacidity.

4.2 Posology and method of administration:

1 to 2 tablets 3 to 4 times a day after meals or as directed by the physician.

4.3 Contraindications:

This combination should not be given to patients who are severely debilitated or suffering from kidney failure, alkalosis or hypermagnesemia.

4.4 Special warnings and special precautions for use:

Antacids can interfere with the absorption of iron preparations and/or tetracyclines. These should not be taken for more than 2 weeks, or if symptoms recur, unless otherwise directed by a physician. Antacids should not be taken within 2 hours of another medication, because the effectiveness of other medications may be altered.

Magnesium salts, in the presence of renal insufficiency, may cause CNS depression. Aluminium Hydroxide, in the presence of low phosphorus diets, may cause phosphorus deficiency. Aluminium salts tend to cause constipation.

Extensive use of aluminium-containing antacids may cause hypophosphatemia (low phosphate levels in the blood), which in severe cases could lead to muscle weakness, anorexia, and osteomalacia (softening of the bones due to defective bone mineralization).

Antacids containing Aluminium Hydroxide should be used with caution in patients who have recently suffered massive upper GI hemorrhage.

4.5 Interaction with other FPPs and other forms of interaction:

Not applicable.

4.6 Pregnancy and lactation:

If Aluminium-containing antacids are used in usual doses in pregnant females with normal renal function, the risk of adverse effects in the fetus are likely low. It has been suggested that Aluminium absorbed from antacid use may lead to functional abnormalities in potentially sensitive fetal organs, including the central nervous system and kidneys.

4.6 Pregnancy and lactation (contd):

However, there is no clinical data to support teratogenic effects or other developmental toxicities. The bioavailability of Aluminium Hydroxide is believed to be low, thus limiting potential fetal exposure; however, concurrent administration of citric or lactic acids may increase bioavailability. Simethicone has not been studied extensively with regard to reproductive effects. The intestinal absorption of

Simethicone is limited, which reduces the potential exposure to the fetus. It is not known whether Simethicone is excreted into human breast milk and the potential for adverse effects in the nursing infant from exposure to the drug are unknown.

No reports describing the use of Simethicone during human lactation or measuring the amount, if any, of the drug excreted into milk have been located.

4.7 Effects on Ability to drive & Use Machines:

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

4.8 ADVERSE REACTIONS:

This combination is normally well tolerated. The occasional constipating effect from Aluminium Hydroxide is balanced by the mild laxative effect of Magnesium Hydroxide.

4.9 OVERDOSAGE AND TREATMENT OF OVERDOSAGE:

Massive doses are unlikely to produce more than a mild gastrointestinal upset.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

Antacids are a class of drugs used to treat conditions caused by the acid that is produced by the stomach. The stomach secretes an acid called hydrochloric acid that helps to break down proteins. This acid causes the contents of the stomach to be acidic in nature, with a pH level of 2 or 3 (pH levels are a measure of acidity in the stomach: the lower the number, the greater the acidity). The stomach, duodenum and esophagus are protected from acid by several protective mechanisms. When there is too much acid or protective mechanisms are inadequate, the lining of the stomach, duodenum or esophagus may become damaged by the acid, giving rise to various gastrointestinal symptoms such as abdominal pain, heartburn (due to gastroesophageal reflux disease or GERD) and other gastro-esophageal symptoms. Antacids reduce acidity by neutralizing (counteracting) acid, reducing the acidity in the stomach and reducing the amount of acid that is refluxed into the esophagus or emptied into the duodenum. Antacids also work by inhibiting the activity of pepsin, a digestive

enzyme produced in the stomach that is active only in an acid environment and, like acid, is believed to be
injurious to the lining of the stomach, duodenum and esophagus.

Pharmacotherapeutic group: Antacid
ATC code: **A02A**
Mechanism of action:
Alginic Acid forms a viscous layer which floats on the surface of gastric contents (gastric juice). When reflux occurs, this antacid containing Alginate layer enters the oesophagus first and protects the oesophageal mucosa from erosion and inflammation due to acid-reflux (Reflux-oesophagitis).
Magnesium Hydroxide:
It is a quick acting antacid and the action is prolonged. It is a mild laxative. The relative insolubility of Magnesium Hydroxide slows its emptying from the stomach, thus prolonging its neutralizing effect.

5. PHARMACOLOGICAL PROPERTIES (contd)

5.1 Pharmacodynamic properties: (contd)

Aluminium Hydroxide:
It has astringent and demulcent properties by which it forms a protective coat over the ulcer crater.
Simethicone:
Simethicone has anti-foaming and antibubbling properties. It acts in the stomach & intestines by altering the surface tension of gas and mucus bubbles enabling them to coalesce and alter their surface tension. This enables the passage of gas through the intestine either through belching, passing flatus or increased absorption of gas into the blood stream.

5.2 Pharmacokinetic properties:

Alginic Acid, is given, usually formulated with an antacid, in the management of gastro-oesophageal reflux disease . Alginic Acid reacts with gastric acid to form a viscous gel (often termed a raft) that floats on top of the gastric contents. This raft then acts as a mechanical barrier to reduce reflux.

Aluminium Hydroxide, given orally, slowly reacts with the hydrochloric acid in the stomach to form soluble aluminium chloride, some of which is absorbed. The presence of food or other factors that decrease gastric emptying prolongs the availability of Aluminium Hydroxide to react and may increase the amount of aluminium chloride formed. About 100 to 500 micrograms of the cation is reported to be absorbed from standard daily doses of an aluminium containing antacid, leading to about a doubling of usual aluminium concentrations in the plasma of patients with normal renal function.

Absorbed aluminium is eliminated in the urine, and patients with renal failure are therefore at particular risk of accumulation (especially in bone and the CNS).

The aluminium compounds remaining in the gastrointestinal tract, which account for most of a dose, form insoluble, poorly absorbed aluminium salts in the intestines including hydroxides, carbonates, phosphates and fatty acid derivatives, which are excreted in the faeces.

5. PHARMACOLOGICAL PROPERTIES (contd)

5.2 Pharmacokinetic properties: (contd)

Magnesium Hydroxide, given orally, reacts relatively rapidly with hydrochloric acid in the stomach to form magnesium chloride and water. About 30% of the magnesium ions are absorbed from the small intestine.

Simethicone is excreted unchanged in the feces .

5.3 Preclinical safety data:

Preclinical data reveal no special hazard for humans based on conventional studies of general pharmacology, genotoxicity and carcinogenic potential.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients: Sucrose, Mannitol, Maize Starch, Saccharin Sodium, Methyl Hydroxy benzoate, Propyl Hydroxybenzoate , Sodium Hydroxide, Menthol, Magnesium Stearate, Purified Talc, Flavour: American Mint (DC-213), Colour: Erythrosine (Supra), Peppermint Flavour & Purified Water.

6.2 Incompatibilities:

Not applicable.

6.3 Shelf life: 24 MONTHS.

6.4 Special precautions for storage:

Store at a temperature not exceeding 30°C

PROTECT FROM MOISTURE & LIGHT.

6.5 Nature and contents of container:

Registered packs: Tablets are packed in printed glassine poly foil at upper side & white plain glassine poly foil at bottom side. Strip pack of 10 tablets.25 such strips are packed along with an insert in a printed carton**.(25 x 10's) AND**

Al/PVC blister {Clear transparent PVC film coated with PVDC on inner side}. Printed 04 colour white back board NR with BOPP lamination and side open carton.

Blister of 10 's; 10 such blisters packed in a printed carton along with pack insert**.(10 x 10's).**

6.6 Instructions for use and handling:

No special requirements. Any unused product or waste material should be disposed off in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER:

ARISTO PHARMACEUTICALS PRIVATE LIMITED.

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8. MA number issued by Ethiopian FDA:

06198/07308/REN/2020

9. Date of first authorization/renewal of the authorization:

24-07-2021

10. DATE OF REVISION OF THE TEXT:

04-07-2023.