For the use only of Registered Medical Practitioner

1. Generic Name and Brand Name

Sodium Alginate, Sodium Bicarbonate & Calcium Carbonate Chewable Tablets
Digeraft® Chewable Tablets

2. Qualitative and Quantitative Composition:

Each uncoated chewable tablet contains:
Sodium Alginate I.P…….250 mg
Sodium Bicarbonate I.P……106.5 mg
Calcium Carbonate I.P……..187.5 mg

3. Dosage Form & strength

Refer section 1 & 2

4. Clinical particulars

4.1 Therapeutic indication

Indicated for the treatment of heartburn and Indigestion.

4.2 Posology and method of administration

Posology
Adults and children 12 years and over: Two to four tablets after meals and at bedtime (up to four times per day).
Children under 12 years: Should be given only on medical advice.
Elderly: No dose modifications necessary for this age group.
Hepatic Impairment: No dose modification necessary.
Renal Insufficiency: Caution if highly restricted salt diet is necessary

Method of administration: For oral administration only
The tablet must be chewed thoroughly before swallowing

4.3 Contraindications

Hypersensitivity to the active substance or any of the excipients

4.4 Special warnings and precautions for use

If symptoms do not improve after seven days, the clinical situation should be reviewed. Sodium: This medicinal product contains 253 mg sodium (11 mmol) per 4 tablet dose, equivalent to 12.65% of the WHO recommended maximum daily intake for sodium. The maximum daily dose of this product is equivalent to 50.6% of the WHO recommended maximum daily intake for sodium. This product is considered high in sodium. This should be particularly taken into account for those on a low salt diet (e.g. in in some cases of congestive heart failure, hypertension, edema, and renal impairment).
Each four-tablet dose contains 320 mg (3.2 mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.

This medicinal product contains 3.75 mg aspartame in each tablet. Aspartame is hydrolysed in the gastrointestinal tract when orally ingested. One of the major hydrolysis products is phenylalaine. Due to its aspartame content this medicinal product should not be given to patients with phenylketonuria. Patients with rare hereditary problems of fructose intolerance, glucose-galactose, malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

CAUTION: For Sodium and Calcium content use in patients with hypertension, renal and cardiac failure, oedema states and in hypercalcemic states.

4.5 Drug Interactions

A time-interval of 2 hours should be considered between Sodium alginate, Sodium bicarbonate & Calcium carbonate intake and the administration of other medicinal products, especially tetracyclines, digoxine, fluoroquinolone, iron salt, ketoconazole, neuroleptics, thyroid hormones, penicilamine, beta-blockers (atenolol, metoprolol, propanolol), glucocorticoid, chloroquine, estramustine and bisphosphonates (diphosphonates).

4.6 Use in special populations (Pregnancy, Nursing woman, Pediatric use, Geriatric use)

Pregnancy:

Clinical studies in more than 500 pregnant women as well as a large number of data from postmarketing experience indicate no malformative nor feto/ neonatal toxicity of the active substances. Sodium Alginate, Sodium Bicarbonate & Calcium Carbonate can be used during pregnancy, if clinically needed.

Breastfeeding:

Pre-clinical investigations have revealed alginate has no negative effect on parental or offspring fertility or reproduction. No effects of the active substances have been shown in breastfed newborns/infants of treated mothers. Sodium Alginate, Sodium Bicarbonate & Calcium Carbonate can be used during breast-feeding.

Fertility:

Clinical data do not suggest that Sodium Alginate, Sodium Bicarbonate & Calcium Carbonate has an effect on human fertility.

Pediatric Use

Treatment of children younger than 12 years of age is not generally recommended, except on medical advice.

Geriatric Use

No dose modification necessary in this group

4.7 Effects on ability to drive and use machines

Sodium Alginate, Sodium Bicarbonate & Calcium Carbonate has no or negligible influence on the ability to drive and use machines

4.8 Undesirable effects

Adverse reactions have been ranked under headings of frequency using the following convention: very common (1/10), common (1/100 and < 1/10,000) uncommon (1/1000 and 1/100), rare (1/10,000 and < 1/1000), very rare (<1/10,000) and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse Event
Immune System Disorders	Very rare	Anaphylactic and anaphylactoid reactions. Hypersensitivity reactions such as urticaria.
Respiratory, Thoracic and Mediastinal Disorders	Very rare	Respiratory effects such as bronchospasm

4.9 Overdose

Symptoms:

The patient may experience abdominal discomfort and may notice abdominal distension.

Management:

In the event of overdose symptomatic treatment should be given

5. Pharmacological properties

5.1 Mechanism of action

The medicinal product is a combination of two antacids (calcium carbonate and sodium bicarbonate) and an alginate.

On ingestion, the medicinal product reacts rapidly with gastric acid to form a raft of alginic acid gel having a near neutral pH and studies have shown that the raft interacts with and caps the acid pocket in the stomach, reducing oesophageal acid exposure. The raft floats on the stomach contents effectively impeding gastro-oesophageal reflux, for up to 4 hours, and protecting the oesophagus from acid, pepsin and bile. In severe cases the raft itself may be refluxed into the oesophagus, in preference to the stomach contents, and exert a demulcent effect. In addition in vitro evidence has shown that the raft has a secondary action and is able to entrap bile and pepsin within it structure, further protecting the oesophagus from these gastric components.^

Calcium carbonate neutralises gastric acid to provide fast relief from indigestion and heartburn. This effect is increased by the addition of sodium bicarbonate which also has a neutralising action.^

5.2 Pharmacodynamic Properties

Pharmacotherapeutic group: Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD); ATC Code: A02BX

On Ingestion Sodium Alginate, Sodium Bicarbonate & Calcium Carbonate reacts with gastric acid to form a raft of alginic acid gel having a near neutral pH and which floats on the stomach contents effectively impeding gastroesophageal reflux. In severe cases the raft itself may be refluxed into the oesophagus in preference to the stomach contents and exert a demulcent effect

5.3 Pharmacokinetic properties

The mode of action of Sodium Alginate, Sodium Bicarbonate & Calcium Carbonate is physical and does not depend on absorption into the systemic circulation.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

No preclinical findings relevant to the prescriber have been reported

7. Description

Digeraft Chewable tablets is supplied for oral administration as an uncoated chewable tablet of Sodium Alginate, Sodium Bicarbonate & Calcium Carbonate. Each uncoated chewable tablet of Digeraft Chewable tablet contains Sodium Alginate 250 mg, Sodium Bicarbonate 106.5 mg & Calcium Carbonate 187.5 mg.

8. Pharmaceutical particulars

8.1 Incompatibilities

NA

8.2 Shelf Life

Refer Pack

8.3 Packaging Information

Refer Pack

8.4 Storage condition & handling instructions

Refer pack.

9. Patient Counseling Information

- Inform patients of the potential for drug interactions. A time-interval of 2 hours should be considered between its administration of other medicinal products, especially tetracyclines, digoxine, fluoroquinolone, iron salt, ketoconazole, neuroleptics, thyroid hormones, penicillamine, beta-blockers (atenolol, metoprolol, propranolol), glucocorticoid, chloroquine and bisphosphonates (diphosphonates) and estramustine.
- Inform the patients about the necessary precautions when on a sodium restricted diet.
- Inform the patients to talk to their doctor, pharmacist or nurse, if they get any side effects. This includes any possible side effects not listed in this document.

10. Details of manufacturer

Manufactured by:

Refer pack for manufacturer details.

Marketed by:

Abbott India Limited

Angel Space, Lifestyle Bldg. No. D-4,
Gala No. 7 to 10 & 17 to 20 Ground Floor,
107 to 110 & 117 to 120 First Floor,

Pimplas Village, Dist. Thane,
Bhiwandi - 421 302, India.
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11. Details of permission or licence number with date
Refer pack for Permission/License details.

12. Date of revision
Version 1.0, dated 02/08/2024

For Product Complaints/Adverse events or Queries please write to **webmasterindia@abbott.com**