For the use of a Registered Medical Practitioner

1.0 GENERIC NAME & BRAND NAME:
Sodium Alginate and Potassium Hydrogen Carbonate Oral Suspension
Digeraft® XT

2.0 QUALITATIVE & QUANTITATIVE COMPOSITION:
Each 10 ml contains:
Sodium Alginate IP……1000 mg
Potassium Hydrogen Carbonate Ph. Eur…200 mg
In a flavored base……..q.s.
Color: Erythrosine

(Raw Mango Flavour)

3.0 DOSAGE FORM & STRENGTH:
Oral Suspension

4.0 CLINICAL PARTICULARS:

4.1 THERAPEUTIC INDICATION
To treat the symptoms of gastro-esophageal reflux during concomitant treatment with or following withdrawal of acid suppressing therapy.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION
Adults and children 12 years and over: 5-10 ml after meals and at bedtime (one to two 5 ml measuring spoons).
Children under 12 years: Should be given only on medical advice.
Elderly: No dose modification is required for this age group.
Hepatic Impairment: No dose modification necessary.
Renal Insufficiency: Caution if highly restricted salt diet is necessary.

4.3 CONTRAINDICATIONS
This medicinal product is contraindicated in patients with known or suspected hypersensitivity to the active substances or to any of the excipients.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE
If symptoms do not improve after 7 days, the clinical situation should be reviewed.
This medicinal product contains 115.7 mg (5.0 mmol) sodium per 10 ml dose, equivalent to 5.8% of the WHO recommended maximum daily intake for sodium.
The maximum daily dose of this product is equivalent to 23.14% 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 some cases of congestive heart failure and renal impairment).
Potassium: This medicine contains 78.12 mg (2.0 mmol) potassium per 10 ml dose. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

4.5 DRUG INTERACTIONS
A time-interval of 2 hours should be considered between Digeraft XT intake and the administration of other medicinal products, especially tetracyclines, fluoroquinolones, iron salts, thyroid hormones, chloroquine, bisphosphonates, and estramustine.

4.6 USE IN SPECIAL POPULATIONS (SUCH AS PREGNANT WOMEN, LACTATING WOMEN, PAEDIATRIC PATIENTS, GERIATRIC PATIENTS ETC.)
Pregnancy:
Clinical studies in more than 500 pregnant women as well as a large amount of data from post-marketing experience indicate no malformative nor foeto/neonatal toxicity of the active substances. Digeraft XT can be used during pregnancy, if clinically needed.
Breast feeding:
No known effect on breast fed infants. Digeraft XT can be used during breast feeding.
Fertility:
No known effect on human fertility.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
This product 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), 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
Symptoms are likely to be minor; some abdominal discomfort may be experienced.
Management

In the event of overdose, symptomatic treatment should be given.

5.0 PHARMACOLOGIC PROPERTIES

5.1 Pharmacodynamic properties

On ingestion the suspension reacts with gastric acid to rapidly form a raft of alginic acid gel having a near-neutral pH which floats on the stomach contents quickly and 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 its structure, further protecting the oesophagus from these gastric components.

5.2 Pharmacokinetic properties

The mechanism of action of the medicinal product is physical and does not depend on absorption into the systemic circulation.

6.0 NONCLINICAL PROPERTIES

6.1 ANIMAL TOXICOLOGY OR PHARMACOLOGY

No pre-clinical findings of any relevance to the prescriber have been reported.

7.0 DESCRIPTION:

Digeraft XT is supplied for oral administration. Each 10 ml of Digeraft XT contains Sodium Alginate 1000 mg, Potassium Hydrogen Carbonate 200 mg.

8.0 PHARMACEUTICAL PARTICULARS

8.1 INCOMPATIBILITIES

Not applicable

8.2 SHELF-LIFE

Refer Pack

8.3 PACKAGING INFORMATION

Refer Pack

8.4 STORAGE/ HANDLING INFORMATION:

Refer Pack

9.0 PATIENT COUNSELLING 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.

10. DETAILS OF MANUFACTURER:
Refer Pack for manufacturer details.

MARKETED BY:
Abbott India Limited
Angel Space, Lifestyle Bldg. No D4, Gala No 7 to 10 & 17 to 20 Ground Floor, 107 to 110 & 117 to 120, First Floor, Pimplas Village, District Thane, Bhiwandi – 421 302, Maharashtra, 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 22/10/2024

For product complaints and queries please write to **webmasterindia@abbott.com**

Source: GAVISCON Advance Prescribing information
https://www.medicines.org.uk/emc/product/6715/smpc