SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

NEOSANMAG FAST Chewable Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:
Famotidine.....10 mg
Calcium Carbonate .....800 mg
Magnesium Hydroxide …… 165 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORMS

Chewable Tablet
Round flat tablet and plain-plain sign.
Color: Uneven Pink
Odor: Mint

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

NEOSANMAG FAST is indicated for the relief of symptoms associated with hyperacidity such as nausea, stomach pain, heartburn, flatulence, and full sensation of the stomach which can not be treated with antacids alone.

4.2 Posology and Method of Administration

Posology
Adults and children above 12 years of age: 1 tablet, to be chewed first before swallowed. Maximum 2 tablets within 24 hours.

Paediatric Population
Children under 12 years of age: as directed by the physician.

Method of Administration
For oral use.

4.3 Contraindications

- Allergic condition to Famotidine and other acid reducers.
- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1

4.4 Special Warnings and Precautions for Use

- It should not be used with other Famotidine products or acid reducers.
- It should not be used if you have trouble swallowing.
- Consult with a physician or pharmacist before use if you are presently taking any prescription drug.

- Discontinue immediately and consult with a physician if stomach pain continues or when you have taken this product for more than 14 days.
- If you are pregnant or breast-feeding, consult with a physician before use.

4.5 Interaction with other medicinal products and other forms of interaction

NEOSANMAG FAST interacts with the following drugs:
Clarithromycin, tetracycline, ketoconazole, propantheline bromide, coumarine, anticoagulants, theophyline, benzodiazepine, adrenergic blockers, nifedipine, acetaminophen, phenytoin, and aspirin.

4.6 Fertility, pregnancy, and lactation

If you are pregnant or breast-feeding, consult with a physician before use.

4.7 Effects on ability to drive and use machines

There is no information of the effects of **NEOSANMAG FAST** on the ability to operate a vehicle or other heavy machinery. However, undesirable effects may occur (e.g. Headache, dizziness), which may influence the ability to drive and use machines (see section 4.8).

4.8 Undersirable effects

The frequency are provided according to the following convention:
Very common ≥ 1/10
Common ≥ 1/100 and ≤ 1/10
Uncommon ≥ 1/1,000 and ≤ 1/100
Rare ≥ 1/10,000 and ≤ 1/1,000
Very rare < 1/10,000
Not known (cannot be estimated from the available data).

Adverse Reactions by Body System (reported with famotidine / antacid combination)

SOC	Frequency	Adverse Event Preferred Term
Immune System Disorders	Not known	Hypersensitivity Anaphylactic reaction
Nervous System Disorders	Common	Headache
	Uncommon	Nervousness Paresthesia Dizziness
	Not known	Somnolence
Gastrointestinal Disorders	Uncommon	Abdominal discomfort and pain
		Abdominal distension
		Nause
		Diarrhoea
		Flatulence
		Dyspepsia
		Eructation
		Dysgeusia
		Oropharyngeal discomfort and pain
		Dry muth, thirst
		Vomiting
	Not known	Abdominal pain upper

Skin and subcutaneous tissue disorders	Not known	Pruritus
		Rash
		Urticaria
		Angiodema
General disorders and administration site conditions	Not known	Asthenia, fatigue

There have been very rare reports of:
- Cutaneous : as with other H2 antagonists, severe skin reactions (toxic epidermal necrolysis).
- Hypersensitivity reactions: bronchospasm .
- Hepatic disorders including hepatic cholestasis and such as raised laboratory values for transaminases, gamma-GT, alkaline phosphatase and bilirubin.
- Neurological disorders such as halluconations: disorientation, confusion and insomnia, epileptic seizures, drowsiness and agitation and depression related states. These have been reported to be reversible on stopping medication.
- Blood disorders such as thrombocytopenia, leucopenia, agranulocytosis and pancytopenia.
- Musculoskeletal disorders, such as muscle cramps.
- Others such as impotence, reduced libido, brast tension
- Alopecia
- Malaise.

The following side effects are generally attributed to antacids containing calcium and magnesium salts: change in stool frequency and consistence, bloating and fullness.

Reporting of suspected adverse reactions
Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via the Pharmacy and Poisons Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Patients have tolerated doses up to 800 mg/day of famotidine for more than a year without development of significant adverse effects.
No specific symptoms of overdose have been identified with this particular combination of substances.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Peptic Ulcer and Gastro Oesophageal Reflux Disease (GORD); H_2-Receptor Antagonist/Antacid
ATC code: A02BA53, famotidine, combinations

Famotidine reduces the acid and pepsin production, as well as the volume of basal, nocturnal and stimulated gastric secretion. Magnesium hydroxide and calcium carbonate have antacid properties by neutralization mechanism.

5.2 Pharmacokinetic properties

The pharmacokinetic properties of famotidine are not significantly modified when administered with magnesium hydroxide 165 mg and calcium carbonate 800 mg.

Famotidine

Famotidine obeys linear kinetics.

Famotidine is rapidly absorbed with dose-related peak plasma concentration occuring at 1-3 hours after administration. The mean bioavailability of an oral dose is 40-45%. It is not modified when taken during meals. First-pass metabolism is minimal. Repeated doses do not lead to accumulation of the drug.

Protein binding in the plasma is relatively low (15-20%). The plasma half-life after a single oral dose or multiple repeated doses (for 5 days) is approximately 3 hours.

Metabolism occurs in the liver, with formation of an inactive metabolite, the sulfoxide.

Following oral administration, the mean urinary excretion of famotidine is 65-70% of the absorbed dose, 25 to 30% as unchanged compound. Renal clearance is 250 to 450 ml/min, indicating some tubular excretion. A small amount may be excreted as the sulfoxide.

The half-life is prolonged in patients with renal impairment.

Calcium carbonate and Magnesium hydroxide

Calcium carbonate and magnesium hydroxide are converted to soluble chloride salts by gastric acid. Approximately 10% of the calcium and 15-20% of the magnesium is absorbed, and the remaining soluble chlorides are reconverted to insoluble salts, and are eliminated in the faeces. In individuals with normal kidney function the small amounts of calcium and magnesium that are absorbed are rapidly excreted by the kidneys.

5.3 Preclinical safety data

Pre-clinical data for famotidine reveal no special hazard for humans based on conventional studies of safety, pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and toxicity to reproduction.

GENERAL TOXICOLOGY

Famotidine

Famotidine has low acute and repeated dose toxicity when administrated orally.

Magnesium hydroxide

Magnesium hydroxide low acute and repeated dose toxicity.

Calcium carbonate

Calcium Carbonate has low acute and repeated dose.

GENOTOXICITY

Famotidine

Famotidine was reported to be non-genotoxic in in-vitro and in-vivo assays.

Magnesium hydroxide

Magnesium hydroxide was reported to be non-genotoxic in in-vitro assays.

Calcium carbonate

Calcium Carbonate is reported to be non-genotoxic in in-vitro assays.

CARCINOGENICITY

Famotidine

Famotidine did not reveal carcinogenic potential in animal studies.

Magnesium hydroxide

No carcinogenic data on magnesium hydroxide was reported in published literature. However, mice fed magnesium chloride for 96 weeks showed no carcinogenic potential.

Calcium carbonate
There is no non-clinical data available. However, calcium carbonate is unlikely to have carcinogenic potential as both calcium and carbonate are natural constituents of cellular systems in humans.

Development and Reproductive Toxicity
Teratogenicity

Famotidine
Famotidine did not reveal any teratogenic effects in rat and rabbit studies.

Magnesium hydroxide
Magnesium hydroxide did not cause any teratogenic effects in combined repeated dose and reproductive/developmental
toxicity studies in rats.

Calcium carbonate
Calcium carbonate did not cause any developmental/teratogenicity in rats.

FERTILITY
Famotidine
Famotidine did not impair fertility in rat and rabbit reproductive toxicity studies.

Magnesium hydroxide
Magnesium hydroxide did not produce any effects on reproduction in combined repeated dose and reproductive/developmental toxicity studies in rats.

Calcium carbonate
Calcium carbonate did not impair fertility in combined repeated/ reproductive/ developmental toxicity studies in rats.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol
Crospovidone
Hydroxypropyl Cellulose LM
Edicol Ponceau 4R
Sucralose
Purified water
Ethyl alcohol
Peppermint oil
Mannitol DC
Skimmed milk powder
Beta cyclodextrin
Talc
Silicon dioxide colloidal
Magnesium stearate

6.2 Incompatibilites
Not applicable.

6.3 Shelf life
24 months.

6.4 Special Precaution for Storage
Store below 30°C, away from light.

6.5 Nature and Contents of Containers
Folding box containing 8 catch covers @ 1 strip @ 2 chewable tablets.

6.6 Special Precaution for Disposal and other Handling
No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

7.1 Marketing Authorization Holder
Name : PT SANBE FARMA
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7.2 Manufacturer
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8. MARKETING AUTHORIZATION NUMBER(S)
H2011/20998/153

9. DATE OF FIRST REGISTRATION / RENEWAL OF THE REGISTRATION
June 2026

10. DATE OF REVISION
June 2026.