

ACIPEP TABLETS

Alginic Acid, Magnesium Hydroxide, Dried Aluminium Hydroxide & Sodium Bicarbonate Tablets

Summary of Product Characteristics

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1 NAME OF THE MEDICINAL PRODUCT

ACIPEP TABLETS

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each bilayer contains:

Alginic Acid BP.....	200 mg
Magnesium Hydroxide BP.....	150 mg
Dried Aluminium Hydroxide Gel BP.....	300 mg
Sodium Bicarbonate BP.....	70 mg
Excipients.....	q.s.

Colour: Erythrosine

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORMS

Oral Tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indication.

Indicated for Ulcer and non-ulcer dyspepsia Hyperacidity, reflux esophagitis and flatulence.

4.2 Posology and method of administration.

Adult:

Tablet: One tablet twice daily or as directed by the Physician

4.3 Contraindications

ACIPEP TABLETS should preferably not be taken at the same time as other drugs as they may impair their absorption.

Antacids may also damage the enteric coatings designed to prevent dissolution in the stomach.

Most drug interactions can be avoided by taking antacid 2 hrs before or after ingestion of other drugs.

4.4 Special warnings and precaution for use.

Children:

Antacids should not be given to young children (under 6 years of age) unless ordered by their doctor. In addition, aluminum- or magnesium-containing medicines should not be given to

premature or very young children because they may cause serious side effects, especially when given to children who have kidney disease or who are dehydrated.

Older adults:

Elderly persons with bone problems or with Alzheimer's disease should not use aluminum-containing antacids. The aluminum may cause their condition to get worse.

Teratogenicity/effects in Pregnancy:

We do not have clinical studies that support the safety of ACIPEP TABLETS for use during pregnancy; therefore, as with any medication being used during pregnancy, we advise that you consult your physician.

4.5 Interaction with other medicinal product and other forms of interaction.

Antacids may interfere with drugs by:

Increasing the gastric pH altering disintegration, dissolution, solubility, ionization and gastric emptying time. Adsorbing or binding drugs to their surfaces resulting in decreased bioavailability. Increasing urinary pH affecting the rate of drug elimination.

Antacids may also damage the enteric coatings designed to prevent dissolution in the stomach.

Antacids have been shown to interact with quinolone antibiotics, resulting in reduced absorption of the later drugs.

4.6 Pregnancy and Lactation.

We do not have clinical studies that support the safety of ACIPEP TABLETS for use during pregnancy; therefore, as with any medication being used during pregnancy, we advise that you consult your physician.

4.7 Effect on the ability to drive and use machine.

Not applicable.

4.8 Undesirable effect.

Magnesium containing antacids: laxative effect as saline cathartic may cause diarrhea; hypermagnesemia in renal failure patients.

Aluminium containing antacids: constipation; aluminium intoxication

Antacids: dose dependent rebound hyperacidity

Along with its needed effects, a medicine may cause some unwanted effects.

Although the following side effects occur very rarely when this medicine is taken as recommended, they may be more likely to occur if too much medicine is taken in large doses.

It is taken for a long time. It is taken by patients with kidney disease

4.9 Overdose.

For aluminum-containing antacids: Bone pain; constipation (severe and continuing); feeling of discomfort (continuing); loss of appetite (continuing); mood or mental changes; muscle weakness; swelling of wrists or ankles; weight loss (unusual)

For magnesium-containing antacids: Difficult or painful urination (with magnesium trisilicate); dizziness or lightheadedness; feeling of discomfort (continuing); irregular heartbeat; loss of appetite (continuing); mood or mental changes; muscle weakness; unusual tiredness or weakness; weight loss (unusual)

Treatment of overdose: Check with your doctor as soon as possible if any of the above side effects (which may be signs of overdose) occur.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties.

ACIPEP TABLETS is best given when symptoms occur or are expected, usually between mealtimes, and at bedtime, four or more times daily; additional doses may be required up to once an hour. Liquid preparations are usually more effective than solid preparations.

Alginic acid containing antacid mixtures such as alginic acid, aluminium hydroxide, magnesium trisilicate can be particularly useful in patients with reflux oesophagitis.

Aluminium & Magnesium in ACIPEP TABLETS:

ACIPEP TABLETS contains the right balance of aluminium & magnesium compounds so as not to significantly change bowel function.

Activated Dimethicone (Simethicone) in ACIPEP TABLETS:

Either alone or with antacid mixture acts as an antifoaming agent to reduce flatulence. It is a silicon polymer that lowers surface tension and allows the small bubbles of froth to coalesce into large bubbles that can be more easily passed up from the stomach or down from the colon. Antacid–Simethicone combination may also be useful for the relief of hiccup in palliative care.

Alginic acid in ACIPEP TABLETS:

It is combined with antacids to encourage adherence of the mixture to the mucosa. Alginate as mucosal protectant is useful in reflux oesophagitis.

As the ingredients used in this drug are well established, tolerated and accepted all over the world, tests confirming ACIPEP TABLETS physiological availability and pharmacological effects studies are not conducted.

5.2 Pharmacokinetic properties.

Mixtures of alginic acid and antacid, when given orally, react with gastric acid to form a viscous barrier (raft) which floats on the surface of the gastric contents. In vivo, raft formation was significantly better in normal subjects who ingested dilute acid with the labeled alginate/antacid than in subjects who ingested the labeled alginate/antacid with plain water.

Gastric emptying of the labeled alginate was also slowed by the presence of acidified gastric contents. These results suggest that the formation of an effective alginic acid antireflux barrier requires acidic gastric contents.

5.3 Preclinical safety data.

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate **	BP
Colour Erythrosine	In House
Methyl Hydroxy Benzoate	BP
Propyl Hydroxy Benzoate	BP
Sodium Saccharine	BP
Maize Starch	BP
Purified Talc	BP
Magnesium Sterate	BP
Peppermint flavor	In House

6.2 Incompatibilities

unknown

6.3 Shelf-life

36 months

6.4 Special precautions for storage

Do not store above 30°C. Store in a dry place.

6.5 Nature and composition of immediate packaging

Pink and white colour circular flat bilayer tablets packed in a blister. Such one blister is packed in a carton along with a leaflet.

7 MARKETING AUTHORISATION HOLDER

SAM PHARMACEUTICALS LIMITED.
8/9, OYADIRAN ESTATE,
SABO, YABA
LAGOS, NIGERIA

DUPEN LABORATORIES PVT. LTD.
C 1 – 49/36, DEGAM ROAD,
INDUSTRIAL TOWNSHIP
VAPI 396195, GUJRAT. INDIA

8 MARKETING AUTHORISATION NUMBER(S)

C4-1196

9 AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

20th Feb 2026