SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Eno

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 g of powder contains:

Sodium Bicarbonate Ph Eur	2.32 g
Citric Acid Ph Eur	2.18 g
Anhydrous Sodium Carbonate Ph Eur	0.50 g

Sodium content:
Each 5g of powder contains 0.85 g of sodium

3 PHARMACEUTICAL FORM

Powder.

4.0. CLINICAL PARTICULARS

4.1 Therapeutic Indications

The symptomatic relief of indigestion, flatulence and nausea.

4.2. Posology and Method of Administration

For oral administration.

Adults and children aged 12 years and over:
5 g (one 5 ml spoonful of powder) or one sachet dissolved in a glass of water. Drink as symptoms occur.

A second dose may be taken after 2-3 hours.

Minimum dosing interval: 2 hours.

Maximum daily dose (MDD): 2 x relevant dosage (5 g).

Maximum duration of antacid use at MDD: 14 days.

Children under 12 years: Do not use.

The elderly can take the adult dose.

4.3. Contra-indications

Persons on a restricted sodium diet e.g. those suffering from hypertension or congestive heart failure, should not use this product unless directed by a doctor.

Patients with impaired hepatic and renal function.

Sodium Carbonate + Sodium Bicarbonate + Citric Acid is contraindicated in patients with a prior hypersensitivity reaction to Sodium Carbonate + Sodium Bicarbonate + Citric Acid or any other ingredient of the preparation.

4.4. Special Warnings and Precautions for Use

Do not exceed the recommended dose as excess or prolonged use may lead to alkalosis.

Treatment should be discontinued if there is no improvement in condition.

Keep out of reach and sight of children.

4.5 Interaction with other medicinal products and other forms of interaction

The acid neutralising capacity of the product may alter the absorption profile of pH specific drugs given concomitantly.

4.6 Fertility, Pregnancy and lactation

For Eno no clinical data on exposed pregnancies are available.

Animal studies on each of the active ingredients do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.

Caution should be exercised when recommending to pregnant women.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Specific estimation of the frequency of adverse events for non-prescription products from post-marketing data is inherently difficult (particularly numerator data). On this basis, no estimate for MedDRA frequency categories is provided.

Gastrointestinal System SOC:

Minor gastrointestinal irritations, including belching, flatulence, and abdonminal distention.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellow card.

4.9 Overdose

It would be difficult to take an overdosage of the product either in the dry form or when mixed with water.

Moderate, acute overdosage may result in belching and gastro-intestinal disturbances. Treatment would be withdrawal of the product and symptomatic measures, as appropriate.

Severe acute overdosage may precipitate sodium overload (hypernatraemia or hyperosmolality) and possibly metabolic alkalosis. Symptoms may include restlessness, weakness, thirst, reduced salivation, dizziness, headache and possibly hypotension and tachycardia. Treatment would consist mainly of appropriate correction of fluid-electrolyte balance.

Acute ingestion of the neat powder may lead to gastric irritation, gas liberation and possibly stomach perforation. Treatment would be gastric lavage and general supportive and symptomatic measures.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

This product is an antacid.

Sodium bicarbonate Sodium carbonate Citric acid	)))	These react in the glass of water to produce sodium citrate, which has antacid buffering properties, and carbon dioxide which facilitates eructation. A slight excess of sodium bicarbonate remains with a small, direct acid neutralising contribution.

5.2 Pharmacokinetic properties

Since the antacid combination acts locally in the stomach and the components are all dissolved, a consideration of their systemic bioavailability and pharmacokinetic behaviour is not appropriate to safety and efficacy considerations.

Residual sodium and citrate ions available for absorption are safely handled by the body and excreted by normal metabolic routes.

5.3 Preclinical safety data

Preclinical safety data on these active ingredients in the literature, have not revealed any pertinent and conclusive findings which are of relevance to the recommended dosage and use of the product.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

None.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

None.

6.5 Nature and contents of container

Clear, flint glass jar (150 g) with polythene, tamper-evident, Jay-cap closure.

Sachet of laminate comprising 40 gsm paper/12 gsm low density polythene/0.012 mm aluminium foil/23 gsm low density polythene, containing 5 g of powder. The sachets (1 or 10) may be contained in a boxboard carton.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

GlaxoSmithKline Consumer Healthcare (UK) Trading Limited
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Brentford
Middlesex
TW8 9GS
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 44673/0056

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 June 1991 / 1 December 1998

10 DATE OF REVISION OF THE TEXT

28/02/2017