SUMMARY OF PRODUCT CHARACTERSTICS

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1. Name of the medicinal product

Eno Lemon

2. Qualitative and quantitative composition

Each 4.5 g of powder contains:

Sodium Bicarbonate Ph Eur 2.0592 g

Citric Acid Ph Eur 1.9413 g

Anhydrous Sodium Carbonate Ph Eur 0.45 g

3. Pharmaceutical form

A pale green, free flowing powder with a definite crystalline sparkle.

4. Clinical particulars

4.1 Therapeutic indications

For the symptomatic relief of heartburn (pyrosis), sour stomach, acid indigestion and upset stomach due to these symptoms.

4.2 Posology and method of administration

Oral administration only.

Adults and children ages 12 and over: One 4.5g sachet dissolved in a minimum of 1 cup of water. Drink as symptoms occur.

Do not take more than two times a day.

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

Minimum dosing interval: 2 hours.

Maximum duration of antacid use at maximum daily dose: 14 days.

Do not use in children under 12 years.

4.3 Contraindications

Do not use in patients with:

- Liver, heart or kidney problems.
- High blood pressure
- Allergic reactions to sodium bicarbonate, sodium carbonate, ascorbic acid or any other ingredient in this product.
- In a low sodium diet.

4.4 Special warnings and precautions for use

Do not take more than the recommended dose.

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

Should not be taken for more than 14 days. The product may interfere with how other medications are absorbed.

The second dose should not be taken 2 hours after the first dose.

If symptoms persist for more than 2 weeks, or if symptoms worsen, medical advise should be sought.

Keep out of sight and reach 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

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 or lactating women.

4.7 Effects on ability to drive and use machines None.

This product is unlikely to affect the ability to drive or use machines.

4.8 Undesirable effects

None

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 EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

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 general supportive and symptomatic measures.

5. Pharmacological properties

5.1 Pharmacodynamic properties

This product is an antacid which contains Sodium bicarbonate, citric acid and sodium carbonate. These react in 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 neutralization 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 behavior 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

Sodium saccharin
Lime Flavour
Lemon Flavour
Speckfree green

6.2 Incompatibilities

None known

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store in below 30ºC. Protect from humidity.

6.5 Nature and contents of container

Paper/polyethylene/aluminium/polythene
laminate sachets

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

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