National Agency for Food & Drug Administration & Control
(NAFDAC)

Registration & Regulatory Affairs

(R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
GASCOL SUSPENSION

(BANANA, STRAWBERRY, CLASSIC & SUGAR FREE)

1. NAME OF THE MEDICINAL PRODUCT

Gascol suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains

Magaldrate 540mg

Simethicone 100mg

3. PHARMACEUTICAL FORM

Suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Uses of Magaldrate and Simethicone:

- It is used to ease too much gas in the stomach.
- It is used to treat heartburn and upset stomach

4.2 Posology and method of administration

Use magaldrate and simethicone as ordered by your doctor. Read all the information given to you. Follow all instructions closely.

1-2 teaspoonful (5-10ml) to be taken between meals and at bed time or as directed by the medical practitioner.

- Take with or without food.
- Shake well before use.
- Measure liquid doses carefully. Use the measuring device that comes with magaldrate and simethicone. If there is none, ask the pharmacist for a device to measure magaldrate and simethicone.

4.3 Contraindications

Contraindicated in patients with kidney problems, and hypersensitivity.

4.4 Special warnings and precautions for use

- Caution should be exercised in patients with history of appendicitis, stomach pain, nausea, vomiting, diarrhea, blockage of the bowel, rectal bleeding of unknown cause, kidney problems, or have undergone recent bowel surgery, on a low-magnesium diet, who are taking other medications, any allergy, during pregnancy and breastfeeding.

4.5 Interaction with other medicinal products and other forms of interaction

Antacids may interact with a number of other drugs by altering their absorption and, sometimes, their elimination, thereby reducing their effectiveness. Antacids may also damage enteric coatings designed to prevent dissolution in the stomach. In order to minimise the risk of interactions, this product should not be taken within two to four hours of other medications (allow at least 4 hours before or 2 hours after erlotinib).

Examples of other medications which may be affected include, but are not limited to ACE inhibitors, salicylates e.g. aspirin, atazanavir, azithromycin, barbiturates, bile acids, bisphosphonates,

cephalosporin antibiotics, fluoroquinolone antibiotics, chloroquine and hydroxychloroquine, deflazacort, digoxin, dipyridamole, eltrombopag, erlotinib, fexofenadine, gabapentin, iron preparations, isoniazid, itraconazole, ketoconazole, lansoprazole, levothyroxine, lithium, methenamine, mycophenolate, nitrofurantoin, penicillamine, phenothiazines, phenytoin, proguanil, rifampicin, rosuvastatin, sulpiride, tetracyclines, tipranavir, ulipristal (avoid use with antacids).

There is a risk of metabolic alkalosis when oral magnesium salts are given with polystyrene sulphonate resins.

4.6 Fertility, Pregnancy and breast-feeding
Pregnancy

Animal studies are insufficient with respect to effects on pregnancy, embryonal/foetal development, parturition and postnatal development (see section 5.3). The potential risk for humans is unknown. As there is no specific data for this product, it is recommended that Gascol only be used in pregnancy on the advice of a doctor.

4.7 Effects on ability to drive and use machines
None

4.8 Undesirable effects

Constipation, diarrhea and intestinal pain.

4.9 Overdose
If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Magnesium trisilicate mixture is an antacid with slow neutralising action and mild laxative action.

5.2 Pharmacokinetic properties
Magnesium chloride and hydrated silica gel are formed during the neutralization. About 5% of magnesium is absorbed and traces of liberated silica may be absorbed and excreted in the urine.

Any sodium hydrogen carbonate not neutralized in the stomach is absorbed and excreted as bicarbonate and sodium ions in the urine in the absence of a plasma deficit.

5.3 Preclinical safety data
No further relevant information other than that which is included in other sections of the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

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6.2 Incompatibilities

Not applicable.

6.3 Shelf life

6.4 Special precautions for storage

Store in the original package.

Store below 30°C. Keep medicine away from direct sunlight

Keep all medicine out of the reach of children.

6.5 Nature and contents of container

150ml LDPE bottle, placed in an inner carton with insert

6.6 Special precautions for disposal

No special requirements.
Any unused product or waste material should be disposed of in accordance with local requirements.

7. SUPPLIER AND MANUFACTURER

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