

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sterwin Antacid Tablets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Calcium carbonate 600 mg
Heavy Magnesium Carbonate 125 mg

For excipients see 6.1.

3 PHARMACEUTICAL FORM

Chewable tablets.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Antacid neutralises excess acid in order to provide relief from heartburn, acid indigestion and trapped wind.

4.2. Posology and method of administration

Adults: Suck or chew 1-2 tablets as required.
Do not exceed 12 tablets per day.

Children: Antacid tablets are not recommended for children.

4.3 Contraindications

There are no specific contraindications.

4.4. Special warnings and precautions for use

Keep out of reach of children.

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

There have been no interactions reported with Antacid Tablets. Although large doses of antacids can interfere with the absorption of some drugs, the amount of antacid in the recommended dose is unlikely to react with any other drugs.

4.6. Pregnancy and lactation

Data on a large number of exposed pregnancies indicate no adverse effects of magnesium carbonate or calcium carbonate on pregnancy or on the health of the foetus/newborn child. To date, no other relevant epidemiological data are available.

Caution should be exercised if used by pregnant or breast-feeding women.

4.7. Effects on ability to drive and use machines

None known.

4.8. Undesirable effects

No significant side effects have been encountered with Antacid Tablets.

4.9. Overdose

Overdose is unlikely to present a major problem. However, as with all antacids there is a theoretical danger of alkalosis.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

ATC code: A02A H, Antacids with sodium bicarbonate

Magnesium carbonate and calcium carbonate are both antacids which may be given in doses of up to about 1g each by mouth. Magnesium carbonate also possesses laxative properties and is therefore often used with calcium carbonate in order to reduce its constipating effects.

5.2. Pharmacokinetic properties

Calcium carbonate is converted to calcium chloride by gastric acid. Some of the calcium is absorbed from the intestines but about 85% is reconverted into soluble calcium salts, such as the carbonate which are excreted in the faeces.

Magnesium carbonate reacts with gastric acid to form soluble magnesium chloride and carbon dioxide. Some magnesium is absorbed but is usually excreted rapidly in the urine.

5.3 Preclinical safety data

There is no clinically relevant preclinical safety data.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Malic Acid, Microtal DCE Sugar, Magnesium Stearate, Talc, Saccharin Sodium, Sodium Bicarbonate, Orange flavouring.

6.2. Incompatibilities

No incompatibilities have been reported.

6.3 Shelf life

Two years.

6.4 Special precautions for storage

Do not store above 25°C. Store in a dry place.

6.5 Nature and contents of container

Antacid tablets are packed into a tissue/foil roll wrap over-wrapped in paper containing 15 tablets. Antacid tablets are available in cardboard cartons containing two rolls of tablets (30 tablets per carton) or four rolls of tablets (60 tablets per carton).

6.6 Special precautions for disposal

There are no specific instructions regarding use or handling.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 08977/0013

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

5 April 2003

10 DATE OF REVISION OF THE TEXT

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