Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Andrews Antacid Tablets Fruit Flavour

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains calcium carbonate 600mg and heavy magnesium carbonate 125mg.

For excipients see Section 6.1.

3 PHARMACEUTICAL FORM

Chewable Tablet
Pale lemon coloured ¾" diameter flat bevel edged chewable tablets with an odour and taste of lemon/lime, embossed double A on both sides.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Andrews Antacid Tablets are recommended for the relief of stomach upsets due to hyperacidity and heartburn.

4.2 Posology and method of administration

Andrews Antacid Tablets are for oral administration only.

Adults and Elderly: One-two tablets to be sucked or chewed up to a maximum of 12 tablets per day. The dose may be repeated as required. Do not take more than 16 tablets in 24 hours.

Children: Not suitable for children under 12 years of age.

4.3 Contraindications

There are no known contraindications.

4.4 Special warnings and precautions for use

If symptoms persist, consult your doctor. Keep out of the reach of children.
Do not exceed the stated dose except on medical advice.
If you are taking medication or suffer from kidney disease, consult your doctor before using.

4.5 Interaction with other medicinal products and other forms of interaction

Antacids may reduce the absorption of other drugs, including tetracyclines.

4.6 Pregnancy and lactation

There are no known contraindications relating to the use of calcium carbonate or magnesium carbonate during pregnancy or lactation. However, as with all medicines to be taken during pregnancy and lactation, the advice of a

doctor should be sought.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

No statement.

4.9 Overdose

There have been no cases of overdose stated. If a large amount is taken, it should be sufficient to empty the stomach by emesis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Calcium carbonate and Magnesium carbonate are converted to the respective chloride salts by the interaction with gastric hydrochloric acid. In this manner they act to neutralise hyperacidity in the stomach.

5.2 Pharmacokinetic properties

Calcium carbonate is converted to calcium chloride by gastric acid. Some of the calcium is absorbed from the intestine but about 85% is reconverted to insoluble calcium salts such as the carbonate and is excreted in the faeces.
Magnesium carbonate reacts with gastric acid to form soluble magnesium chloride and carbon dioxide in the stomach. Some magnesium is slowly absorbed from the gastro-intestinal tract and eliminated in the urine, otherwise excretion is via the faeces.

5.3 Preclinical safety data

There are no pertinent data not already described elsewhere in this SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Malic acid
Microtal DCE sugar
Magnesium stearate
Talc
Lemon/lime flavour
Saccharin sodium
Sodium hydrogen carbonate
Quinoline lake yellow (E104)

6.2 Incompatibilities

None.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

Roll pack (aluminium foil backed with bleached tissue) with outer paper wrap further packed into a cardboard box containing 6, 10, 12, 20, 24, 30, 48, 50, 60, 90, 96, 100, 120 and 150.
Roll pack enclosed in PVC/Cardboard display box containing 6 tablets.
Roll pack of 15 tablets enclosed in a HDPE plastic tube with fitted cap further packed into a cardboard box with an additional roll pack of tablets.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

GlaxoSmithKline Consumer Healthcare Limited
Stonemasons Way
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Dublin 16

8 MARKETING AUTHORISATION NUMBER

PA 678/48/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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