SUMMARY OF PRODUCT CHARACTERISTICS OF DANACID SUSPENSION

1. NAME OF THE MEDICINAL PRODUCT

Danacid Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml dose contains:

Aluminium Hydroxide Gel BP	400mg
Magnesium Hydroxide BP	100mg
Simeticone BP	125mg

3. PHARMACEUTICAL FORM

Antacid suspension for oral administration.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Antacid therapy in gastric and duodenal ulcer, gastritis, heartburn, gastric hyperacidity. Treatment of indigestion. Relief of symptoms of heartburn and dyspepsia associated with gastric reflux in hiatus hernia, reflux esophagitis and similar conditions.

4.2 Posology and method of administration

Adults, elderly and children over 12 years of age:

10-20ml three times daily 20 minutes to one hour after meals, and at bedtime, or as required.

Children under 12 years of age:

Not recommended.

4.3 Contraindications

Should not be used in patients who are severely debilitated or suffering from kidney failure.

4.4 Special warnings and precautions for use

Paediatric population

In young children the use of magnesium hydroxide can produce a hypomagnesaemia, especially if they present renal impairment or dehydration.

4.5 Interaction with other medicinal products and other forms of interaction

Antacids inhibit the absorption of tetracyclines and vitamins and should not be taken concomitantly.

Urine alkalinisation secondary to administration of magnesium hydroxide may modify excretion of some drugs; thus, increased excretion of salicylates has been seen.

4.6 Pregnancy and lactation

For Mucogel Suspension no clinical data on exposed pregnancies are available.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.

Caution should be exercised when prescribing to pregnant women.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Gastrointestinal side-effects are uncommon. This formulation minimises the problems of diarrhoea and constipation.

Frequency not known:

Abdominal pain.

Frequency very rare:

Hypermagnesemia. Observed after prolonged administration of magnesium hydroxide to patients with renal impairment.

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 address in the leaflet.

4.9 Overdose

Serious symptoms are unlikely to follow over dosage.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics' properties

The product contains two established antacids, magnesium and aluminium hydroxides with an acid neutralising capacity in excess of 25ml of 0.1N HC1 consumed, per gram of suspension.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol liquid 70% (not crystallising) (E420)

Xantham Gum

Methyl P-Hydoxybenzoate

Propyl P-Hydroxybenzoate

Xantham Gum

Simethicone Emulsion 30%

Aspartame

Peppermint Oil

Purified Water

6.2 Incompatibilities

None stated.

6.3 Shelf life

Unopened – 3 years from the day of manufacture.

Opened - 30 days

6.4 Special precautions for storage

Do not freeze. Store in a cool and dry place, protect from sun light.

6.5 Nature and contents of container

High density polyethylene bottle with a high density polyethylene closure fitted with a tamper evident ring.

Pack sizes: 200ml. and 200ml x 5 x 5 or 4

6.6 Special precautions for disposal and other handling

None.

7. MARKETING AUTHORIZATION HOLDER

Dana Pharmaceuticals Ltd,

Shiroro Dam Road, Maitumbi,

Minna. Niger State. Nigeria.

8. MARKETING AUTHORIZATION NUMBER(S)

A4-2892

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

6/8/2015

10. DATE OF REVISION OF THE TEXT

5/8/2019