1. NAME OF THE MEDICINAL PRODUCT
Rulox Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains:

Dried Aluminium Hydroxide 300mg

Magnesium Hydroxide 25mg

Activated Methylpolysiloxane (Simethicone) 10mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable Tablet.
Pink tablets engraved with "RULOX" on one side.

4. Clinical particulars

4.1 Therapeutic indications
Rulox Tablet reduces hyperacidity and protects the gastric mucosa from the irritant effect of excessive gastric acid secretion.

It is a protective antacid and deflatulant used in peptic ulcer, dyspepsia, heartburn, reflux oesophagitis, gastritis, hyperacidity, flatulence and discomfort due to excess stomach gas.

4.2 Posology and method ofadministration

Posology

Adults and children over 12 years (including the elderly):
1 to 2 tablets to be chewed up to 4 times daily

Children (6 – 12 years):
Half tablet to be chewed up to 3 to 4 times daily.

To be taken between meals and at bed time not exceeding 10 tablets in a 24-hour period (for adults) and 2½ tablets (for children).

Paediatric population:
Not recommended for children under 12 years.

Method of administration
For oral administration.
Tablets should be chewed thoroughly before swallowing. To be chewed when symptoms occur.

4.3 Contraindications
Rulox Tablet is contraindicated in patients with:
- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
- Patients who are severely debilitated or suffering from renal insufficiency, or if there is severe abdominal pain and/or the possibility of bowel obstruction.
- Rulox is contra indicated in Appendicitis and hypophosphataemia

4.4 Special warnings and precautions for use
Aluminium hydroxide may cause constipation and magnesium salts overdose may cause hypomotility of the bowel; large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at higher risk such as those with renal impairment, or the elderly.

Aluminium hydroxide is not well absorbed from the gastrointestinal tract, and systemic effects are

therefore rare in patients with normal renal function. However, excessive doses or long-term use, or even normal doses in patients with low-phosphorus diets may lead to phosphate depletion (due to aluminium-phosphate binding) accompanied by increased bone resorption and hypercalciuria with the risk of osteomalacia. Medical advice is recommended in case of long-term use or in patients at risk of phosphate depletion.

In patients with renal impairment, plasma levels of both aluminium and magnesium increase. In these patients, a long-term exposure to high doses of aluminium and magnesium salts may lead to dementia, microcytic anemia.

Aluminium hydroxide may be unsafe in patients with porphyria undergoing hemodialysis.

Pronlonged use with antacids may mask symptoms of more serious diseases, such as gastrointestinal ulceration or cancer.

4.5 Interaction with other medicinal products and other forms of interaction

Antacids are known to interfere with the absorption of drugs such as levothyroxine, rifampicin and rosuvastatin.

Aluminium hydroxide may form complexes with certain drugs, e.g. digoxin and vitamins, resulting in decreased absorption. This should be borne in mind when concomitant administration is considered.

Because of the aluminium content, Avrocid should not be concomitantly administered with tetracycline containing antibiotics or any tetracycline salts.

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

Concomitant use with quinidines may increase the serum levels of quinidine and lead to quinidine and lead to quinidine overdosage.

Aluminium-containing antacids may prevent the proper absorption of H2 antagonists, atenolol, cefdinir, cefpodoxime, hydroxychloroquine, chloroquine, cyclines, diflunisal, digoxin, diphosphonates, ethambutol, fluoroquinolones, sodium fluorure, glucorticoids, indometacine, isoniazide, kayexalate, ketoconazole, lincosamides, metoprolol, neuroleptics phenothiazines, penicillamine, propranolol, iron salts.
Staggering the administration times of the interacting drug and the antacid by at least 2 hours (4 hours for the fluoroquinolones) will often help avoid undesirable drug interactions.

Polystyrene sulfonate (Kayexalate)
Caution is advised when used concomitantly with polystyrene sulfonate (Kayexalate) due to the potential risks of reduced effectiveness of the resin in binding potassium, of metabolic alkalosis in patients with renal failure (reported with aluminium hydroxide and magnesium hydroxide), and of intestinal obstruction (reported with aluminium hydroxide).

Aluminium hydroxide may result in increased aluminium levels, especially in patients with renal impairment.

4.6 Pregnancy and Lactation

Pregnancy
There are no or limited amount of data from the use of aluminium hydroxide and magnesium hydroxide in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3).
Rulox is not recommended during the first trimester of pregnancy and in women of childbearing potential not using contraception. Caution should be exercised when prescribing to pregnant and lactating women. Rulox should be used during pregnancy only if the potential benefits to the mother outweigh the potential risks, including those to the foetus.

Breast-feeding
No effects on the breastfed newborns/infant are anticipated since the systemic exposure of the breast-feeding woman to aluminium hydroxide and magnesium hydroxide is negligible.
Because of the limited maternal absorption, when used as recommended, aluminium hydroxide and

magnesium salt combinations are considered compatible with lactation.

Fertility
No fertility data is available.

4.7 Effects on ability to drive and use machines
None stated.

4.8 Undesirable effects
Side effects are uncommon at recommended doses

The following CIOMS frequency rating is used, when applicable:

Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000), not known (cannot be estimated from available data)

Immune system disorders
Not known: hypersensitivity reactions, such as pruritus, urticaria, angioedema and anaphylactic reactions.

Gastrointestinal disorders
Gastrointestinal side effects are uncommon.

Uncommon: diarrhoea or constipation (see Section 4.4 Special warnings and precautions for use).

Metabolism and nutrition disorders
Very rare: hypermagnesemia including observations after prolonged administration of magnesium hydroxide to patients with renal impairment.

Frequency not known:
- hyperaluminemia,
- hypophosphatemia, in prolonged use or at high doses or even normal doses of the product in patients with low-phosphorus diets or in infants less than 2 years, which may result in increased bone resorption, hypercalciuria, osteomalacia (see Section 4.4 Special warnings and precaution s for use).

4.9 Overdose

SIGNS AND SYMPTOMS
Reported symptoms of acute overdose with aluminium hydroxide and magnesium salts combination include diarrhea, abdominal pain, vomiting.
Large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at risk (see Section 4.4 Special warnings and precautions for use)

MANAGEMENT
Aluminium and magnesium are eliminated through urinary route; treatment of acute overdose consists of administration of IV Calcium Gluconate, rehydration and forced diuresis. In case of renal function deficiency, haemodialysis or peritoneal dialysis is necessary.

Serious symptoms are unlikely following overdose. Discontinue medication and correct fluid deficiency if necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antacids; aluminium compound combinations

ATC code: A02AB10

Rulox is a balanced mixture of two antacids and simethicone: aluminium hydroxide is a slow-acting antacid and magnesium hydroxide is a fast-acting one. The two are frequently combined in antacids mixtures. Aluminium hydroxide on its own is astringent and may cause constipation.

This effect is balanced by the effect of magnesium hydroxide, which, in common with other magnesium salts, may cause diarrhoea. Gastro-intestinal side effects are thus rare with Rulox and this makes it especially suitable when long term therapy is necessary.
Simethicone is a surface-active agent included to disperse form. This reduces gastrooesophageal reflux. It does not have antacid properties.

5.2 Pharmacokinetic properties
The absorption of aluminium and magnesium from antacids is small. Aluminium hydroxide is slowly converted to aluminium chloride in the stomach. Some absorption of soluble aluminium salts occurs in the gastro-intestinal tract with urinary excretion.
Any absorbed magnesium is likewise excreted in the urine. Aluminium containing antacids should not be administered to patients with renal impairment where increased plasma concentration may occur.
Dimethicone is not absorbed from the gastro intestinal tract, it has no known systemic side effects and its safety has been well documented.

5.3 Preclinical safety data
Not relevant.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Lactose
Maize Starch
Peppermint Oil
Talc Powder
Aspartame Powder
Dry Tutti Frutti Flavour
FD & C Yellow No. 40 (Allura Red)

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
3 years.

6.4 Special precautions for storage
Store below 30^{o}C.
Protect from light. Keep tightly closed.

6.5 Nature and contents of container
PVC/aluminium blister packs in outer carton:
Pack size: 16 Tablets.

6.6 Special precautions for disposal
No special requirements.

7 APPLICANT/MANUFACTURER
SKG-Pharma Limited
7/9 Sapara Street,
Ikeja, Lagos State, Nigeria.
Tel: +234(1)44544640
Email: skgpharma@yahoo.com