Summary of product characteristics (SmPC)

1. NAME OF THE MEDICINAL PRODUCT:

MAGNESIUM TRISILCATE 50MG,ALUMINIUM HYDROXIDE 300MG,MAGNESIUM HYDROXIDE 25MG,SIMETHICONE 20MG

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Composition:

Each Chewable tablet contains: MAGNESIUM TRISILCATE 50MG,ALUMINIUM HYDROXIDE

300MG,MAGNESIUM HYDROXIDE 25MG,SIMETHICONE 20MG

List of excipients:

Sugar, peppermint oil, talc, magnesium stearate, methyl paraben, propyl paraben, Ethyl alcohol.

3. PHARMACEUTICAL FORM:

Chewable tablets .

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications:

It is administered for the reduction of acidity and relief from post-operative gaseous distension, gastric ulcers.

The symptomatic relief of:

1. Dyspepsia
2. Heartburn
3. Flatulence

4.2 Posology and Administration:

Adults including the elderly

Take one or two tablets 4 times each day

Take 20 minutes to one hour after meals and at bedtime or as required

Children

Aluminium Hydroxide Tablets are not recommended for children.

4.3 Contra indications:

Should not be used in patients who are severely debilitated or suffering from kidney failure.
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.Hypersensitivity to the active ingredients or to any of the excipients.

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 aluminium increase. In these patients, a long-term exposure to high doses of aluminium salts may lead to dementia, microcytic anemia.

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

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine

4.5 Interaction with other medicinal products and other forms of interaction

Aluminium compounds used as antacids interact with many other drugs, both by alterations in gastric PH and emptying, and by direct absorption and formation of complexes that are not absorbed. Interactions can be minimized by giving the aluminium compound and any other medication 2 to 3 hours apart. The absorption of aluminium from the GIT may be enhanced if aluminium compounds are taken with citrates or ascorbic aicd.

Aluminium hydroxide tablets should preferably not to be taken at the same time as other drugs as they may impair their absorption. Antacids may also damage enteric coatings designed to prevent dissolution in the stomach. Most drug interactions can be avoided by taking aluminium hydroxide tablets 2 hours before or after ingestion of other drugs.

4.6 Pregnancy & Lactation:

Aluminium hydroxide has not been formally assigned to a pregnancy category. There are no controlled data in human pregnancy. Aluminium hydroxide is only recommended for use during pregnancy when benefit outweighs risk.

Also there are no data on the excretion of aluminium hydroxide into human milk. Consult your physician before taking this drug.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

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

Immune system disorders

Frequency 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)

Frequency not known: Abdominal pain

Metabolism and nutrition disorders

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, which may result in increased bone resorption, hypercalciuria, osteomalacia (see section 4.4).

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.

4.9 Overdose

Serious symptoms are unlikely following overdosage.

Reported symptoms of acute overdose with aluminium hydroxide salt include diarrhoea, abdominal pain, vomiting.

Large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at risk (see section 4.4)

Aluminium 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.

5. PHARMACOLOGICAL PROPERTIES*:*

5.1 Pharmacodynamic properties:

Dried aluminium hydroxide gel - antacid

Aluminium hydroxide tablet acts by neutralizing hydrochloric acid secreted by gastric parietal cells. Antacids such as aluminium hydroxide, being relatively insoluble in water, are long- acting if retained in the stomach.

Aluminium decreases the intestinal motility; thus antacids containing aluminium tend to be constipating.

5.2 Pharmacokinetics:

Aluminium salts given my mouth, slowly reacts with the hydrochloric acid in the stomach to form soluble aluminium chloride, some of which is absorbed. The presence of food or other factors that decrease gastric emptying prolongs the availability of aluminium hydroxide to react and may increase the amount of aluminium chloride formed.

Absorbed aluminium is eliminated in the urine, and patients with renal failure are therefore at particular risk of accumulation (especially in bone and the CNS), and aluminium toxicity.

The aluminium compounds remaining in the GIT, which account for most of a dose, form insoluble, poorly absorbed aluminium salts in the intestines including hydroxides, carbonates, phosphates and fatty acid derivatives, which are excreted in the faeces.

5.3 Preclinical safety data

None stated

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients

Sugar, peppermint oil, talc, magnesium stearate, methyl paraben, propyl paraben, Ethyl alcohol.

6.2 Incompatibilities

None stated

6.3 Shelf life:

36 Months from the date Manufacture

6.4 Special precautions for storage

Store below 30°C, Keep all the medicine out of reach of children.

6.5 Nature and contents of container

Aluminium Hydroxide Tablets B.P. Skillet contains 10 blister strips of 10 tablets each with plain sheet in between layers with packing insert.

6.6 Special precautions for disposal and other handling

None stated

7. Manufactured by:

Emzor Pharmaceutical Inustries Limited

Flowergate Mixed Development Scheme.Km 1 Sagamu/Benin Expressway,
Sagamu,Ogun State.