MECURE INDUSTRIES PLC

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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1. Name of the medicinal product

ACDT ZERO Antacid Suspension

2. Qualitative and quantitative composition

Each 10ml contains:
Dried Aluminium Hydroxide gel……. 9.5ml
Magnesium Hydroxide ……. 200mg
Activated Polymethylsiloxane….250mg
For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Suspension

A pink coloured suspension with a pleasant taste.

4. Clinical particulars

4.1. Therapeutic indications

ACDT ZERO Antacid suspension 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 method of administration

Posology
Adults over 12 years: 10 ml 3 to 4 times daily

Children 6-12 years: 5ml 3 to 4 times daily
Or as directed by the Physician.

For oral administration.

4.3 Contraindications

This product 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.

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

Antacids may interact with a number of other drugs by altering their absorption and, sometimes, their elimination, thereby reducing their effectiveness. Antacids may also damage enteric coatings designed to prevent dissolution in the stomach. In order to minimise the risk of interactions, this product should not be taken within two to four hours of other medications (allow at least 4 hours before or 2 hours after erlotinib).

Examples of other medications which may be affected include, but are not limited to ACE inhibitors, salicylates e.g. aspirin, atazanavir, azithromycin, barbiturates, bile acids, bisphosphonates, cephalosporin antibiotics, fluoroquinolone antibiotics, chloroquine and hydroxychloroquine, deflazacort, digoxin, dipyridamole, eltrombopag, erlotinib, fexofenadine, gabapentin, iron preparations, isoniazid, itraconazole, ketoconazole, lansoprazole, levothyroxine, lithium, methenamine, mycophenolate, nitrofurantoin, penicillamine, phenothiazines, phenytoin, proguanil, rifampicin, rosuvastatin, sulpiride, tetracyclines, tipranavir, ulipristal (avoid use with antacids).

There is a risk of metabolic alkalosis when oral magnesium salts are given with polystyrene sulphonate resins.

4.6 Fertility, pregnancy and lactation

Animal studies are insufficient with respect to effects on pregnancy, embryonal/foetal development, parturition and postnatal development. The potential risk for humans is unknown. As there is no specific data for this product.

Caution should be exercised when prescribing to pregnant women

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects
Gastrointestinal side effects are uncommon. This formulation minimizes the problems of diarrhea and constipation.
Frequency not known: Abdominal pain
Frequency very rare: Hypermagnesemia. Observed after prolonged administration of magnesium hydroxide to patients with renal impairment

4.9 Overdose
Serious symptoms are unlikely following overdosage.
Reported symptoms of acute overdose with aluminium hydroxide salt include diarrhoea, abdominal pain,vomiting.

5. Pharmacological properties

5.1 Pharmacodynamic properties
Aluminium Hydroxide: It is a non-systemic gastric antacid. It binds with phosphate in the gastrointestinal tract to inactivate pepsin and neutralize gastric acid. This action provides relief from symptoms associated with stomach ulcers and hyperacidity.
Magnesium Hydroxide: Has mild laxative effect and is slightly alkaline in nature.

ATC code: A02AF02

5.2 Pharmacokinetic properties

Not Applicable.

5.3 Preclinical safety data
None Known

6. Pharmaceutical particulars

6.1 List of excipients
Aerosil, Methylparaben, Propyl paraben, Peppermint, Sodium CMC, Peppermint,

6.2 Incompatibilities

None

6.3 Shelf life

2 years

6.4 Special precautions for storage

Keep bottle tightly closed. Protect from light and moisture.

Store this medicine at temperature below 30^0C and keep away from children.

6.5 Nature and contents of container

Available 10ml unit dose and 200ml white opaque bottle

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 Marketing authorization holder

Me Cure Industries PLC
Plot 6 Block H Debo Industries Compound,
Oshodi Industrial Scheme,
Oshodi,Lagos,
Nigeria

8 Marketing Authorisation Number

NAFDAC NO: A4-6061