1.3
PRODUCT INFORMATION

1.3.1
Summary Of Product Characteristics (SPC)

1.3.1 Product information for health professionals

1. NAME OF THE MEDICINAL PRODUCT

1.1 Invented Name of the Medicinal Product

ULCEGEL

Aluminium Hydroxide Gel, Magnesium Hydroxide, Activated Dimethicone, Deglycyrrhizinated Liquorice Suspension

1.2 Strength

Aluminium Hydroxide Gel BP ….. 6 gm

Magnesium Hydroxide BP……..80 mg

Activated Dimethicone BP …….100 mg

Deglycyrrhizinated Liquorice

Eq. to Liquorice BP…….400 mg

1.3 Pharmaceutical Form

Oral Suspension

white coloured, flavoured suspension.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of Contains:

Aluminium Hydroxide Gel BP ….. 6 gm

Magnesium Hydroxide BP……..80 mg

Activated Dimethicone BP …….100 mg

Deglycyrrhizinated Liquorice

Eq. to Liquorice BP…….400 mg

Colour: Permitted colour

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Oral Suspension

Off white coloured, flavored suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ULCEGEL Suspension provides Relief of Pains associated with gastric acid secretion, heartburn, Flatulence and indigestion.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

One to two teaspoons three to four times daily or as directed by the physician.

4.3 CONTRAINDICATIONS

Not generally contraindicated but precaution should be exercised when administered along with other drugs.

4.4 WARNING AND PRECAUTIONS

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-phosphorous 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.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Antacids are generally known to interfere with absorption of drugs such as tetracyclines, vitamins, Ciprofloxacin, Ketoconazole, Levothyroxine, Hydroxychloroquine, chloroquine, chlorpromazine, rifampicin, Cefdinir, Cefpodoxime, rosuvastatin. Caution is advised when used concomitantly with polystyrene sulphonate due to the potential risks of effectiveness of the resin in binding potassium, of metabolic alkalosis, in patients with renal failure (reported with aluminum hydroxide, and magnesium hydroxide), and of intestinal obstruction (reported with aluminium hydroxide). Aluminium hydroxide and citrates may result in increased aluminium levels, especially in patients with renal impairment.

4.6 PREGNANCY AND LACTATION

PREGNANCY:

No clinical data on exposed pregnancies are available. Use of antacids should be avoided in the first trimester of pregnancy. Caution should be exercised when prescribing to pregnant and lactating women. Because of the limited maternal absorption, when used as recommended, minimal amounts, if any, of aluminium hydroxide and magnesium salt combinations, are expected to be excreted into breast milk.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

None stated.

4.8 UNDESIRABLE EFFECTS

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

Frequency not known: hypersensitivity reactions, such as pruritus, urticaria, angioedema and anaphylactic reactions

Gastrointestinal disorders

Gastrointestinal side-effects are uncommon.

Uncommon: diarrhoea or constipation

Frequency not known: Abdominal pain

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 which may result in increased bone resorption hypercalciuria, osteomalacia.

4.9 OVERDOSE

Serious symptoms are unlikely following overdosage.

Reported symptoms of acute overdose with aluminium hydroxide and magnesium salts combination include diarrhoea, abdominal pain, vomiting.

Large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at risk.

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs for acid related disorders; Antacids with antiflatulents.

ATC code: A02AF02

Dried aluminium hydroxide gel	- antacid
Magnesium Hydroxide	- antacid
Simeticone	- antifoaming agent/antiflatulent

ULCEGEL is a balanced mixture of three antacids and an antiflatulent/antifoaming agent simeticone. The two antacids are magnesium hydroxide which is fast acting and aluminium hydroxide which is a slow acting antacid. The combination produces a fast onset of action and an increase in total buffering time. Aluminium hydroxide on its own is an astringent and may cause constipation. This effect is balanced by the effect of the magnesium hydroxide which is in common with other magnesium salts may cause diarrhoea.

Aluminium hydroxide: It directly neutralizes gastric acid because of trivalent Aluminium ion. It has higher acid neutralizing capacity than calcium and sodium salts & has poor bio-absorption.

Magnesium hydroxide: It directly neutralizes gastric acid because of divalent magnesium ion. It has higher acid neutralizing capacity than calcium or sodium salts. It facilitates bowel movements. Both Aluminium hydroxide and Magnesium hydroxide are insoluble in compounds and not absorbed through GI tract.

Activated Dimethicone: Used as anti-foaming, antiflatulent agent. It reduces the surface tension of film formed by gastric acid and thus coalesces the smaller gas bubbles into large ones effectively, providing rapid relief from flatulence (uneasiness due to gas formation.)

Deglycyrrhizinated Liquorice: Deglycyrrhizinated Liquorice root or DGL is a natural antacid, where the glycyrrhizinated acid component of the root has been removed. DGL stimulates our

bodies defense mechanism resulting in improved quality of mucous, lengthening of intestinal cell life and enhanced microcirculation in the gastrointestinal lining.

5.2 Pharmacokinetic properties:

None stated.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol solution 70%
Methyl paraben sodium
Propyl paraben sodium
Bronopol
Aspartame
Xanthan gum
Sodium citrate
Sodium saccharin
Chloroform
Sodium hypochloride
Polysorbate 80
Flavour Peppermint
Peppermint oil
Menthol
Sodium carboxymethyl cellulose
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months from the date of manufacturing.

6.4 Special precautions for storage

Store below 30°C. Protect from light.

Keep all medicines out of reach of children.

6.5 Nature and contents of container

ULCEGEL is available as a bottle pack of 200 ml packed in a carton along with pack insert.

6.6 Special precautions for disposal and other Special handling

None

7. Marketed by:

AQUATIX PHARMACEUTICALS LTD.

No. 14, Prince Bode, Oluwo Street, Mende, Maryland,

Lagos Nigeria

8. Manufactured by

MCW HEALTHCARE PVT LTD.
236, Sector – E, Industrial Area, Sanwer Road,
Indore (M.P)