National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

1. NAME OF THE MEDICINAL PRODUCT

Locid 325mg+100mg+125mg Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:
325mg of Dried Aluminium Hydroxide Gel USP (as Aluminium Hydroxide), 100 mg of Magnesium Hydroxide USP, 125 mg of Activated polydimethylsilioxane USP (Simethicone).

For the full list of Excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral Suspension
Light pink coloured, flavoured, viscous suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Antacid therapy in gastric and duodenal ulcer, gastritis, heartburn and gastric hyperacidity.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

The route of administration is oral.

Recommended Dosage
Adults: One to two x 5ml -10 ml spoonfuls four times a day (after meals and at bedtime) or as required. Children: Not recommended

4.3 CONTRAINDICATIONS

Use in severely debilitated patients or in those suffering from kidney failure.
Use in patients who are hypersensitive 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, infants less than 2 years, 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 or in infants less than 2 years, 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.

Magnesium salts may cause central nervous depression in the presence of renal insufficiency and should be used with extreme caution in patients with kidney disease.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

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 encephalopathy, dementia, microcytic anemia or worsen dialysis-induced osteomalacia.
The prolonged use of antacids in patients with renal failure should be avoided.

Aluminium hydroxide may be unsafe in patients with porphyria undergoing hemodialysis because it has been shown that aluminium may be involved in porphyrin metabolism abnormalities.

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

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

Concomitant use with quinidines may increase the serum levels of quinidine and lead to quinidine overdosage. Aluminium-containing antacids may prevent the proper absorption of H2 antagonists, atenolol, cefdinir, cefpodoxime, chloroquine, cyclines, diflunisal, digoxin, diphosphonates, ethambutol, fluoroquinolones, sodium fluorure, glucocorticoids, indometacine, isoniazide, kayexalate, ketoconalzole, lincosamides, metoprolol, neuroleptics phenothiazines, pencillamine, propranolol, iron salts.
Staggering the administration times of the interacting drug and the antacid by at least 2 hours (4 hours of 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 and citrates may result in increased aluminium levels, especially in patients with renal impairment.

4.6 FERTILITY, PREGNANCY AND LACTATION

The use of Locid should be avoided during the first trimester of pregnancy.

Because of the limited maternal absorption when used as recommended, aluminium hydroxide and magnesium salts combinations are considered as compatible with lactation.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

None.

4.8 UNDESIRABLE EFFECTS
Side effects are uncommon at recommended doses Immune system disorders
frequency unknown: hypersensitivity reactions, such as pruritus, urticaria, angioedema and anaphylactic reactions .

Gastrointestinal disorders
Uncommon: diarrhea or constipation (see Section 4.4 Special warnings and precautions for use)

Metabolism and nutrition disorders
frequency unknown: hypermagnesemia, 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 precautions for use).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important.

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 rehydration, forced diuresis. In case of renal function deficiency, haemodialysis or peritoneal dialysis is necessary.

Serious symptoms are unlikely following overdosage.

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Locid 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. Simethicone is a surface-active agent included to disperse form. This reduces gastroesophageal reflux. It does not have antacid properties.

5.2 PHARMACOKINETIC PROPERTIES

Magnesium hydroxide reacts with hydrochloric acid in the stomach to produce magnesium chloride. Small amounts of magnesium salts may be absorbed and excreted in the urine, otherwise excretion if via the faeces.

Aluminium hydroxide reacts with hydrochloric acid in the stomach to form aluminium chloride, some of which is absorbed. Absorbed aluminium is eliminated in the urine. The majority of aluminium remains in the gastrointestinal tract and forms insoluble poorly absorbed aluminium salts including hydroxide, phosphate, carbonate and fatty acid derivatives, which are excreted in the faeces. There is no data availability on the pharmacokinetics of activated methylpolysiloxane.

5.3 PRECLINICAL SAFETY DATA

None.

6. PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS
Butyl Hydroxybenzoate, Methylhydroxybenzoate, Propyl Hydroxybenzoate, Benzoic Acid, Xanthum Gum, Colloidal Silicon Dioxide (Aerosil 200),Sorbitol solution(70 % non-crystallizing),Citric Acid Anhydrous, Colour Allura Red Supra,Bronopol,Flavour Spearmint 13487(M/s Sonarome), Purified Water.

6.2 INCOMPATIBILITIES

Not applicable.

6.3 SHELF LIFE

3 years or 2 Years

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. Protect from light.
Shake well before use.
Keep bottle tightly closed.
Keep out of reach of children.

6.5 NATURE AND CONTENTS OF CONTAINER

PET bottle with 25mm PP Al. silver coloured Cap with CPL LOGO: 100 ml and 200 ml. Not all pack sizes may be marketed.

Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Cadila Pharmaceutical Limited
1389. Trasad Road, Dholka-382225
Dist: Ahmedabad, Gujarat,India

8. MARKETING AUTHORISATION NUMBER

04-4430

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

September 2009

10. DATE OF REVISION OF THE TEXT

January 2020