1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE DRUG PRODUCT

PRODUCT NAME: Aluminium hydroxide (dried), Magnesium hydroxide, and Simethicone USP

BRAND NAME: Digicid Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition

Each 5 ml Contains:
Aluminium Hydroxide……..... 250 mg
Magnesium Hydroxide USP ..... 250 mg
Simethicone USP .....50 mg
Excipients: ..... q.s

For complete list of excipients refer section 6.1.

3. *PHARMACEUTICALS FORM:*

Oral Suspension

Pink coloured flavored suspension

4. *CLINICAL PARTICULARS*

4.1 Therapeutic Indication:

The symptomatic relief of:

1. Dyspepsia.
2. Heartburn.
3. Flatulence.

4.2 Posology and method of administration:

Posology

For oral administration:

Adults and Elderly

5-10ml taken 20 minutes to 1 hour after meals and at bedtime or as required.

Children

As an appropriate proportion of the adult dose.

Children under 5 years

Maximum of 5 ml

4.3 Contraindications:

Should not be used in patients who are hypersensitive to any of the active substances or excipients, are severely debilitated or suffering from kidney failure, or hypophosphataemia.

4.4 Special warning 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-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 encephalopathy, dementia, microcytic anemiaor worsen dialysis-induced osteomalacia
- Aluminium hydroxide may be unsafe in patients with porphyria undergoing hemodialysis. The prolonged use of antacids in patients with renal failure should be avoided.
- This product contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take this medicine.

Paediatric population

In young children the use of magnesium hydroxide can produce a hypermagnesemia, especially if they present renal impairment or dehydration

4.5 Drug Interactions

Digicid Suspension should not be taken simultaneously with other medicines as they may interfere with their absorption if taken within 1 hour.

Aluminium-containing antacids may prevent the proper absorption of drugs such as tetracyclines, vitamins, ciprofloxacin, ketoconazole, hydroxychloroquine, chloroquine, chlorpromazine, rifampicin, cefdinir, cefpodoxime, levothyroxine, rosuvastatin, H_2 antagonists, atenolol, cyclines, diflunisal, digoxin, bisphosphonates, ethambutol, fluoroquinolones, sodium fluoride, glucocorticoids, indomethacin, isoniazid, lincosamides, metoprolol, phenothiazine neuroleptics, penicillamine,propranolol and iron salts.

Levothyroxine may also bind to simeticone which may delay or reduce the absorption of levothyroxine. Polystyrene sulphonate

Caution is advised when used concomitantly with polystyrene sulphonate 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).

Quinidine:

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

Tetracycline:

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

Citrates:

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

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

4.6 Pregnancy & Lactation

The safety of Digicid Suspension in pregnancy has not been established.

Pregnancy:

There are no available data on Digicid Suspension use in pregnant women. No conclusions can be drawn regarding whether or not Digicid Suspension is safe for use during pregnancy. Digicid Suspension should be used during pregnancy only if the potential benefits to the mother outweigh the potential risks, including those to the feotus.

Lactation:

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.

Simeticone is not absorbed from the gastrointestinal tract.

No effect on the breastfed newborn/infant are anticipated since the systemic exposure of the breast- feeding woman to aluminium hydroxide, magnesium hydroxide and simeticone is negligible

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 (≥1/10,000 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.

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

Reporting of suspected adverse reactions

If the patient has developed SJS or TEN with the use of piroxicam, piroxicam must not be re-started in this patient at any time.

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

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

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 - antiforming agent / antifluatulent

Digicid Suspension is a balanced mixture of two 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.

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical Safety Data:

Not applicable

6. *PHARMACEUTICAL PARTICULARS*

6.1 List of excipients

Sr. No.	Name of Ingredients
01.	Sorbitol Solution 70%
02.	Methyl Paraben Sodium
0.3	Propyl Paraben Sodium
04.	Tween 80
05.	Sodium Carboxy Methyl Cellulose
06.	Xanthan Gum
07	Sodium benzoate
08	Sodium Saccharine
09	Colour Erythrosine supra
10	Glycerine
11	Flavor Raspberry
12	Peppermint Oil
13	Menthol

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

3 years.

6.4 Special precautions for storage:

Store in a cool dry place

6.5 Nature and contents of container

200 ml. Pink coloured, mint flavored suspension filled in amber colour glass bottle duly sealed with silver colour metallic cap having printed "DIGICID" on the top

NAFDAC Reg.No : A4-8712

6.6 Special precautions for disposal and other handling

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

7. *APPLICANT*

Name of the Applicant:

SAGAR VITACEUTICALS NIGERIA LIMITED

Business Address:
Plot 6, New Makun City,
Along Lagos/Ibadan expressway,
K/m 53/55 Sagamu.
Ogun State,
NIGERIA

Manufactured by:

SAGAR VITACEUTICALS NIGERIA LIMITED.
Plot 6, New Makun City,
Along Lagos/Ibadan expressway,
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Ogun State,
NIGERIA

8. *WHO PREQUALIFICATION REFERENCE NUMBER-*
Not applicable

9. *DATE OF PREQUALIFICATION / RENEWAL OF PREQUALIFICATION-*
Not applicable

10. *DATE OF REVISION OF THE TEXT-*
Not applicable