	Biomedical Limited, 1, Ohimege Road, Industrial Estate, Ga-Imam, Ilorin, Kwara State		
	Doc No. BML/ULS/S001	**Date rev 06/2020**	**Next rev date: 05/2025**

Summary of Product Characteristics

For

Ulcamed Suspension

(Aluminium Hydroxide + Magnesium Hydroxide + Simethicone)

1. NAME OF MEDICINAL PRODUCT

Ulcamed suspension

2. QUALITATIVE AND QUANTITATIVE DESCRIPTION

Each 5ml contains

Dried Aluminium Hydroxide	BP 475mg
Magnesium Hydroxide	BP 100mg
Simeticone	BP 125mg

Excipient with known Effect

There is no excipient with known effect

3. PHARMACEUTICAL FORM

Pink coloured liquid oral preparation presented as sugar-based suspension and flavoured in 100ml and 200ml amber PET bottle with dose measurement cap to facilitate easy dosing.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Ulcamed is used treat to the symptoms of too much stomach acid such as stomach upset, heartburn, and acid indigestion. It is also used to relieve symptoms of extra gas such as belching, bloating, and feelings of pressure/discomfort in the stomach/gut. Simeticone helps break up gas bubbles in the gut. Aluminum and magnesium antacids work quickly to lower the acid in the stomach. Liquid antacids usually work faster/better than tablets or capsules.

This medication works only on existing acid in the stomach. It does not prevent acid production. It may be used alone or with other medications that lower acid production (including H2 blockers such as cimetidine/ranitidine and proton pump inhibitors such as omeprazole).

If you are self-treating with this medication, carefully read the package instructions before you start using this product to be sure it is right for you. Some products have similar brand names but different active ingredient with different uses. Taking the wrong product could harm you. Ask your pharmacist if you have any questions about your product or its use.

4.2 Posology and method of administration

Take medication by mouth, usually after meals and at bedtime as needed. Follow all the directions on the product package or use as directed by your doctor. If are uncertain about any of this information, consult your doctor or Pharmacist.

If you are using the liquid form this medication, shake the bottle well before pouring dose. Measure the dose out carefully using a medication spoon/cup. Do use a household spoon because you not get the right dose. Refrigerating the suspension may improve the flavor. Do not freeze. The liquid form works best if taken without other fluids. You can mix your dose with a little water if needed.

This product may react with other medications (including digoxin, iron, pazopanib, tetracycline antibiotics, quinolone antibiotics such ciprofloxacin), preventing them from being fully absorbed by your body. Talk with your doctor or pharmacist about how to schedule your medications to prevent this problem.

If your acid problems persist or worsen after you have used this product for week, or if you think have a serious medical problem, seek immediate medical attention. If you are using this medication regularly on a daily basis for more than 2 weeks, you may have medical problem that needs different treatment. Ask your doctor whether this is the right medication for you.

4.3 Contraindications

Hypersensitivity to any of the ingredient

4.4 Special warnings and Precautions for Use

Products to be used with caution on patient with impaired renal function.

4.5 Drug Interactions

If you are taking this medication under your doctor's direction, your doctor or pharmacist may already be aware of any possible drugs interaction and may be monitoring you for them. Do not start, stop, or change the dosage of any medicine before checking with your doctor or pharmacist first.

Before using this medication, tell your doctor or pharmacist if you are using any of the following prescription and nonprescription/herbal products, phosphate supplements (e.g potassium phosphate), sodium polystyrene sulfonate.

Antacids can interfere with the absorption of many other drugs. Be sure to check with your pharmacist before taking antacids with any other medication.

Therefore, before using product, tell your doctor or pharmacist products of all the products you use. Keep a list of your medications with you, and share the list with your doctor and pharmacist.

4.6 Pregnancy and Lactation

Pregnancy

No adequate data from the use of aluminium hydroxide and magnesium hydroxide on pregnant women as studies in animals have not been done. No data available to suggest harmful effect of simeticone in pregnant women. Therefore, care should be taken when administered in pregnant women.

Lactation

Concentration of aluminium and magnesium secreted in milk is too small to be harmful.

4.7 Effects on ability to drive and use machine

Ulcamed has no influence on ability to drive and use machines

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' renal impairment.

Reporting of suspected adverse reactions

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.

4.9 Overdose

Management

Symptomatic and supportive treatment are advised.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Heamatinics

ATC code:

Mechanism of Action/Pharmacodynamics effects

Aluminium hydroxide and magnesium hydroxide have antacid properties and are used to neutralise gastric acid. Simeticone has antifoaming/deflatulence activity by virtue of its ability to change the surface tension of gas bubbles thereby causing them to coalesce.

5.2 Pharmacokinetics Properties

Magnesium hydroxide react with hydrochloric acid in the stomach to form magnesium chloride. Small amount of magnesium salts may be absorbed and excreted in urine otherwise excretion is via the faeces.

Aluminium Hydroxides react with hydrochloric acid in the stomach to form aluminium chloride, some of which is absorbed. Absorbed aluminium is excreted in the urine. There is no data available on the pharmacokinetics of simeticone.

5.3 Preclinical Safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sodium carboxyl methyl cellulose, Sucrose, Sorbitol, Bronopol, Peppermint oil, Polysorbate 80, Allura red, Propylene glycol.

6.2 Incompatibilities

None

6.3 Shelf life

3 years

6.4 Special Precautions for Storage

Ulcamed should be stored in a cool dry place at temperatures not more than 30°C. Replace cap after use and protect from light. Keep away from children.

6.5 Nature and Contents of Container

Plain Amber-coloured 100ml and 200ml Polyethylene terephthalates (PET) bottle with ROPP cap placed inside a paperboard carton

6.6 Special Precautions for disposal

Container and/or any unused product should be disposed in accordance with the local requirement

7. MANUFACTURER

BIOMEDICAL LTD
1, Ohimege Road, Industrial Estate
Ilorin Kwara State, PMB 1449