1.6 Product Information

1.6.1 Prescribing information (Summary of Product Characteristics) (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

1.1 Trade name of the medicinal product

ULGICID SUSPENSION

1.2 Strength:

Each 15 mL Contains:

Alginic Acid BP	200 mg
Dried Aluminium Hydroxide BP	250 mg
Magnesium Hydroxide BP	250 mg
Magnesium Trisilicate BP	250 mg
Simeticone BP	125 mg

1. 3 Pharmaceutical form

Suspension

2. Qualitative and quantitative composition:

Each 15 mL Contains:

Alginic Acid BP	200 mg
Dried Aluminium Hydroxide BP	250 mg
Magnesium Hydroxide BP	250 mg
Magnesium Trisilicate BP	250 mg
Simeticone BP	125 mg

S. No.	Raw Materials	Spec.	Qty/15mL (mg)	Functional Category
1	Alginic Acid	BP	200.00	Active
2	Dried Aluminium Hydroxide	BP	250.00	
3	Magnesium Hydroxide	BP	250.00	
4	Magnesium Trisilicate	BP	250.00	
5	Simeticone	BP	125.00	
6	Liquid Sorbitol 70 % (Non - crystallising)	BP	2100.00	Sweetening Agent
7	Propylene Glycol	BP	525.00	Co Solvent
8	Methyl Hydroxybenzoate	BP	37.50	Preservative
9	Propyl Hydroxybenzoate	BP	3.75	
10	Saccharin Sodium	BP	16.50	Sweetening Agent
11	Disodium Edetate	BP	7.50	Complexing Agent
12	Sodium Citrate	BP	45.00	Buffering Agent
13	Xanthan Gum	BP	60.00	Suspending Agent
14	Mentholyptus Flavour	In-House	0.0825 mL	Flavoring Agent
15	Erythrosine Supra	In-House	0.24	Colouring Agent
16	Purified Water	BP	q.s. to 15 mL	Vehicle

3. Pharmaceutical Form: Suspension

Description: Light pink coloured suspension with mint flavour

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For relief from ulcer, non-ulcer dyspepsia, reflux oesophagitis, heartburn and for the symptomatic relief of gastritis, flatulence, hyperacidity associated with peptic ulceration

4.2 Posology and method of administration

Adults : One tablespoonful (15 mL) twice daily

Children's : One teaspoonful (5 mL) twice daily

4.3 Method of Administration : Oral

4.4 Contraindications:

Ulgicid should preferably not be taken at the same times as other drugs as they may impair their absorption. Antacids may also damage the entire coatings designed to prevent dissolution in the stomach. Most drugs interaction can be avoided by taking antacid 2 hours before or after ingestion of other drugs.

4.5 Special warnings and precautions for use

Precautions:

Children:

In addition, Aluminium or Magnesium containing medicines should not be given to premature or very young children because they may cause serious side effect, especially when given to children who have kidney diease or who are dehydrated.

Older adults :

Elderly persons with bone problems or with alzheimers diease should not use aluminium containing antacids. The aluminium cause their condition to get worse.

4.5 Interactions with other medicinal products and other forms of interaction

Antacids used with other drugs or over the counter products at the same time, the effects of Ulgicid Suspension may change. This may increase the risk for side-effects or cause drug not to work properly. Ulgicid Suspension may interact with the following drugs and products:

- Abacavir
- Acetaminophen
- Aluminium hydroxide
- Aspirin
- Ciprofloxacin
- Clomipramine

4.6 Overdose

For Aluminium-containing antacids

Bone pain; constipation (severe continuing); feeling of discomfort (continuing); loss of appetite (continuing); mood or mental changes; muscle weakness; swelling of wrist or ankles; weight loss (unusual)

For Magnesium -containing antacids

Difficult or painful urination (with magnesium trisilicate); dizziness or light headedness; feeling of discomfort (continuing); irregular heartbeat; loss of appetite (continuing); mood or mental changes; muscle weakness; unusual tiredness or weakness; weight loss (unusual)

5.0 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Drugs for acid related disorders; Antacids with antiflatulents.

ATC code: A02AF02

Aluminium & Magnesium in ulgicid : Ulgicid contains the right

balance of aluminium &

magnesium compounds so as not to significantly change bowel function.

Simethicone in ulgicid: Either alone or with antacid mixture acts as an antifoaming agent to reduce flatulence. It is a silicon polymer that lowers surface tension and allows the small bubbles of froth to coalesce into large bubbles that can be more easily passed up from the stomach or down from the colon. Antacid Simeticone combination may also be useful for the relief of hiccup in palliative care.

Alginic acid in ulgicid: It is combined with antacids to encourage adherence of the mixture to the mucosa. Alginate as mucosal protectant is useful in reflux oesophagitis. As the ingredients used in this drug are well established, tolerated and accepted all over the world and hence test confirming its physiological availability pharmacological effects studies are not conducted.

Pharmacology: Antacids neutralize gastric acidity, resulting in an increase in the pH of the stomach and duodenal bulb.

5.2 Pharmacokinetic properties

Mixtures of alginic acid and antacid, when given orally, react with gastric acid to form a viscous barrier (raft) which floats on the surface of the gastric contents. In vivo, raft formation was significantly better in normal subjects who ingested dilute acid with the labeled alginate/antacid than in subjects who ingested the labeled alginate/antacid with plain water. Gastric emptying of the labeled alginate was also slowed by the presence of acidified gastric contents. These results suggest that the formation of an effective alginic acid antireflux barrier requires acidic gastric contents.

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

Liquid Sorbitol 70% (Non crystallising), Propylene Glycol, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Saccharin Sodium, Disodium Edetate, Sodium Citrate, Xanthan Gum , Mentholyptus Flavour, Erythrosine Supra, Purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

30 months

6.4 Special precautions for storage

Store below 30°C. Protect from light .

6.5 Nature and contents of container

Pack Size: 200 mL

200 mL Amber coloured glass brute bottle sealed with 25 mm Aluminium PP cap and 10 mL measuring cup packed in an individual carton with a package insert.

Primary Packaging	200 mL Amber coloured glass brute bottle with 25 mm Aluminium PP cap.
Secondary Packaging	Label, Printed carton, 10 mL measuring cup & package insert.

6.6 Special precautions for disposal and other handling

No special requirements. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

MARKETINF AUTHORISATION HOLDER

Prisma Pharma FZE
P.O.Box 17269
Jebel Ali Free Zone
Dubai
U.A.E.

MANUFACTURER

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Website: www.saimirra.com

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Not applicable