

1.3 PRODUCT INFORMATION

1.3.1 Summary of product characteristics (SmPC)

Provided in the following pages.

SUMMARY OF PRODUCT CHARACTERISTICS

(PRODUCT DATA SHEET)

1. Name of the Medicinal Product:

1.1 Product Name: GAZGO

1.2 Strength: Please see the product composition

1.3 Pharmaceutical Dosage Form:

2. Quality and Quantitative Composition: Soft capsule

2.1 Qualitative Declaration

2.2 Quantitative Declaration

| Composition | Quantity per capsule (mg) |
|------------------|---------------------------|
| Active Substance | |
| Simethicone | 200.00 |
| Excipients | |
| Gelatin | 92.06 |
| Glycerin | 41.85 |
| Purified Water | 6.39 |
| Titanium Dioxide | 1.26 |

3. Pharmaceutical Form: Clear, colourless, oily liquid, filled in 5 minim, oval, white opaque, soft gelatin shell capsule.

4. Clinical Particulars:

4.1 Therapeutic indications:

- Treat the symptoms of gas such as uncomfortable or painful pressure, fullness, and bloating.
- Use as an adjunct in the treatment of many conditions in which gas retention may be a problem, such as postoperative gaseous distention, air swallowing, functional dyspepsia, peptic ulcer, spastic or irritable colon or diverticulosis.

4.2 Posology and method of administration:

Adults : Take 1 capsule once or twice daily after meals or at bedtime or as directed by physician.

Children : As directed by physician.

Capsule should not be chewed.

4.3 Contraindications:

Hypersensitivity or intolerance to product.

4.4 Special warning and precautions for use:

Not applicable.

4.5 Pregnancy & Lactation:

Should not be used during pregnancy and lactation without medical advice.

4.5 Side effects:

GazGo usually has no side effects.

4.6 Drug Interactions:

None known.

4.7 Overdose & Treatment:

Not applicable.

5. Pharmacological Properties:**5.1 Pharmacodynamics Properties:**

Not applicable.

5.2 Pharmacokinetic Properties:

Not applicable.

5.3 Preclinical Safety Data:

Not applicable

6. Pharmaceutical Particulars:**6.1 List of excipients:**

| | |
|------------------|----------|
| Gelatin | 92.06 mg |
| Glycerin | 41.85 mg |
| Purified Water | 6.39 mg |
| Titanium Dioxide | 1.26 mg |

6.2 Shelf life: 2 years from manufacturing date.

6.3 Special precautions for storage: Store below 25 °C in a dry place, away from direct sunlight.

6.4 Nature and contents of container:

Aluminium foil : Aluminium foil
Outer carton : Printed cardboard carton

7. Marketing Authorization Holder:

MEGA LIFESCIENCES Public Company Limited
384 Moo4, Patana 3 Road, Bangpoo Industrial Estate, Soi 6
Preaksa, Muang Samutprakarn
Samutprakarn 10280, Thailand

8. Marketing Authorization Numbers:**9. Date of first authorization / renewal of the authorization:****10. Date of revision of the text:**