

GazClear⁺

Multilayer Tablets

Simethicone & Active Carbon

40 double layer swallowable tablets with modified release

Medical Device

1. Identification, composition and intended use of the Medical Device

1.1 Description and method of use

GazClear is a medical device in tablet form, useful for the relief of uncomfortable symptoms related to swallowing of air and intestinal distention. It is recommended for the treatment of symptoms connected to stomach bloating or intestinal bloating due to the accumulation of gas. It mitigates connected pain and cramps and prevents flatulence and eructation.

1.2 Composition

One tablet contains:

- 50mg simethicone
- 300mg activate carbon

Excipients: maltodextrin, sucrose, microcrystalline cellulose, hydroxypropyl-methylcellulose, polyvinylpyrrolidone, colloidal silica, sodium croscarmellose, poyvinylpolypyrrolidone, glyceryl behenate, silicon dioxide, vegetal stearate magnesium.

1.3 Mechanism of Action

The efficacy of the device is due to simethicone's anti-foaming action combined with the gas absorbing action of carbon: the action is exclusively based on a mechanical phenomenon.

The double-layer tablet releases approximately 50% of the ingredients in the gastric environment within 15 minutes and completes its disintegration in the intestinal environment within one hour.

The components are not absorbed by the gastrointestinal tract and do not interfere with the absorbance of nutritional substances.

2. Content presentation

The box contains 40 mono-use double-layer tablets packaged in a blister-pack.

3. Dosage and method for use

Adults: It is recommended 1-2 tablets preferably at end of the main meal, up to maximum 4 tablets per day.

Children 14-18 years: 1 tablet per day at end of the main meal, up to maximum 2 tablets per day.

4. Known Side Effects

With the recommended dosage one can observe a dark brown colouration of the faeces, due to the presence of carbon. The phenomenon is absolutely normal and does not present any pathological significance.

No medium and long-term side effects have been observed.

The product does not negatively affect the sensory capacities (attention level, driving capacity or capacity of running an activity).

Side effects also different from those listed might occur: consult a doctor in case of onset of unexpected symptoms.

5. Storage conditions

Store the tablets in their blister in a dry place and away from direct light or heat sources, take out the tablets from the blister only when used.

Do not store the product above 25°C.



GazClear⁺

Multilayer Tablets

Relieve the symptoms associated with bloating and flatulence
Contracts gastrointestinal gas

Medical Device

6. Warnings and precautions

- Do not use before the age of 14 years.
- Keep out of reach of children.
- Do not take the tablet in the lying position.
- Do not take the product after the expiry date printed on the box and blister.
- Do not use the tablets if package is damaged.
- Each tablet is mono-use and must be extracted from the blister only before use; do not try to re-use tablets partially used (previously broken) or already extracted from the blister. This incorrect use could lead to product contamination.
- Do not exceed the recommended dosage.
- Do not use the product in case of known gastric or intestinal lesions.
- Do not use in case of intestinal blockage.
- Do not take the product when using other oral medical devices or medicinal specialities: the absorbing power of active carbon and simethicone can have a negative influence on efficacy.
- Consult your doctor before taking GazClear in case of ongoing pharmacology therapies.
- Simethicone may obstacle the effect of some reagents used in diagnostics, i.e guaiac gum.
- Do not take the product for more than 30 days, if symptoms persist consult a doctor.
- Do not take in case of intolerance to the product.
- Do not take in case of known hypersensitivity to the components.
- Do not use the product under the age of 14 years.

7. Contraindications

The use of the product is not recommended in case of hypersensitivity to any of the product ingredients. There are not sufficient data supporting the use of the product in case of pregnancy and breast-feeding, therefore during pregnancy and breast-feeding the product can be used only in case of real necessity and after having consulted your doctor.

8. Disposal


When the product is finished or expired, dispose of the product and its package properly in the environment, according to the current regulations in place.

Distributor:

Cf Pharma Ireland Ltd
73B Hebron Industrial Estate
Kilkenny, Ireland.



Manufacturer:

 S.I.L.T. Srl
Via Ariosto, 50/60
20090 Trezzano sul Naviglio (Mi)
Italy



Last Revision:

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PK1150-02



04/26



Formato aperto: 140x160 mm

Formato chiuso: 140x40 mm

Colori in bianca: 4 colori - CMYK

Colori in volta: 4 colori - CMYK

Codice componente Siit: 03007160/2
