

Bloat^eze

TABLETS

Simethicone + Active Carbon

20 double-layer swallowable tablets with modified release*

1. Identification, Composition and Intended Use of the Medical Device

1.1 Description and method of use

BLOATEZE 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:

- 50 mg simethicone
- 300 mg activated carbon

Excipients: maltodextrins, saccharose, microcrystalline cellulose, hydroxypropylmethylcellulose, polyvinylpyrrolidone, colloidal silica, sodium crosscarmellose, polyvinylpolypyrrolidone, glyceryl behenate, silica 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 20 mono-use double-layer tablets packaged in a blisterpack.

3. Dosage, way and time for administration

Adults: 4 tablets per day, preferably 2 tabs after any main meal.

Extract the tablet from blister, taking care not to break it and take the tablets with a glass of water.

4. Known Side effects

With the recommended dosage one can observe a dark brown coloration 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)

5. Storage conditions

Store the tablets into 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.

6. Warnings and precautions

- Do not use in case of children under 14 years of age.
- Keep out of the reach of children.
- Do not take the tablet in lying position.
- Do not use the product after the expiry date reported on the box and blister.
- Do not use the tablets in case of damaged package.
- 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 specialties: the absorbing power of active carbon and simethicone can have a negative influence on efficacy.
- Consult your doctor before taking BLOATEZE in case of ongoing pharmacology therapies.
- Simethicone may obstacle the effect of some reagents used in diagnostics, i.e. guaiac gum.

7. Contraindications

The use of the product is not recommended in case of hypersensitivity to any of the product ingredients.

There are no 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, accordingly to the current regulations in place.



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