Instruction for use

Degasin®

280 mg

MD *medical device*

Simethicone

Medical device in the form of an orange soft gelatine capsule of size 8,3 mm x 13,2 mm wide/length, that improves intestinal and abdominal comfort in people affected by gastrointestinal problems linked to gas formation: bloating, flatulence and abdominal tension.

Indications: This medical device is indicated for prevention and attenuation of the symptoms of gastrointestinal troubles due to gas formation as bloated feeling and flatulence in adults. This medical device is indicated for patient preparation before a diagnostic examination of the abdominal area (endoscopy, radiography, ultrasound scan).

Intended purpose: This medical device is intended to be used by adults for prevention or attenuation of gastrointestinal troubles due to gas formation as bloated feeling and flatulence. It could also be used in preparation before a diagnostic examination of the abdominal area (endoscopy, radiography, ultrasound scan).

Intended users: Patients affected by gastrointestinal problems linked to gas formation: bloating, flatulence and abdominal tension. Patient before diagnostic examination of the abdominal cavity (endoscopy, radiography, ultrasound scan) according to doctor recommendation.

Intended patient population: This medical device is for adults only.

Contraindications:
- in case of known hypersensitivity to simethicone or to any of the ingredients
- in case of known or suspected perforation or obstruction of digestive tract
- in children.

Precautions: Concomitant administration of levothyroxine and simethicone may lead to decreased efficacy of levothyroxine and thus decrease function of thyroid gland. This medical device can be used by people with diabetes, as it does not contain sugar. Since Simethicone is excreted unchanged through the digestion, pregnant and breast-feeding women are allowed to take the product. If you are pregnant or breast-feeding ask your doctor or pharmacist for advice before taking this product. Safety of simethicone use during pregnancy has not been evaluated.

Side effects: Side effects have not yet been reported.

Warnings: Do not use this medical device after the expiry date which is stated on the carton and the blister after "EXP". The expiry date refers to the last day of that month. Contains fish gelatine. Do not use this medical device if it was exposed to temperatures outside the specified storage conditions or if the packaging is damaged and dispose it in accordance with local requirements.

Instructions for use: Improvement for gastrointestinal problems: 1 soft capsule after meal with a large glass of water. 3 soft capsules per 24 hours should not be exceeded. Soft capsules are to be taken orally. The maximum duration of treatment is 30 consecutive days. Preparation of diagnostic examinations: follow your doctor recommendations. For adults only. Keep out of the reach of children. For single use only

Mode of action: Simethicone acts by reducing the surface tension of air bubbles present in the gastrointestinal tract and causes their coalescence, thus aiding to reduce gas and gas tension by dispersion. Simethicone is not absorbed nor metabolized by organism; it is eliminated without any change in feces. The soft capsule is quickly disintegrated, then eliminated by the organism, it is only used as a vector to deliver the simethicone.

Please report any serious incident that has occurred in relation to the use of this medical device to the manufacturer and the competent authority (Malta Medicines Authority / email: mdvigilance.medicinesauthority@gov.mt).

If your symptoms are not improving or are worsening, it's advisable to consult your doctor or pharmacist.

Composition: simethicone 280 mg, soft capsule shell: fish gelatine 90,678 mg, glycerol, water purified, yellow iron oxide (E172, CI 77492), red iron oxide (E172, CI 77491).

Storage: Store at 15°C – 25°C.

The Summary of Safety and Clinical Performance (SSCP) is available in EUDAMED (https://ec.europa.eu/tools/eudamed) under the Basic UDI DI: 8596024DEGASIN280MG2K

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CE 2265

LOT	Batch code		Use by date
	Re-use is not allowed		Manufacturer
	Not to be used in case package is damaged		Temperature limitation (15-25°C)
CE	Conformité Européenne (European Conformity)	BIO	Contains biological material of animal origin
	Do not dispose the product or its packaging into environment.		Read usage instructions
UDI	Unique device identifier		Distributor

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