

Summary of medical product characteristics

1. Name of the medicinal product

Gaspan®

90 mg peppermint oil and 50 mg caraway oil / gastro-resistant soft capsule

2. Qualitative and quantitative composition

1 gastro-resistant soft capsule contains:

Active substances: Peppermint oil 90 mg, caraway oil 50 mg

Other excipient(s) with known effect:

This drug contains less than 1mmol sodium (23 mg) per soft capsule.

Contains 12 mg sorbitol per soft capsule, A doctor has to be consulted in case of intolerance to sugars.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Gastro-resistant soft capsules

4. Clinical particulars

4.1 Therapeutic indications

Herbal medicinal product for the treatment of adult patients with gastrointestinal complaints, particularly with mild cramps, flatulence, fullness and abdominal pain.

4.2 Posology and method of administration

Adults over the age of 18 years, take one capsule twice a day.

The capsules are swallowed whole with adequate liquid (e.g., a glass of water) and taken at least 30 minutes before a meal, preferably in the morning and at midday. The capsules can also be taken without a subsequent meal.

The capsules have to be swallowed whole: they must be undamaged and should not be chewed. This ensures that the active substance is not released prematurely. A premature release of the active substance may cause local irritation in the mouth and the oesophagus.

There is no general limit as to how long it should be taken. Patients are to consult with their physician if complaints last for more than a week or periodically recur.

4.3 Contraindications

Not to be used when there are known sensitivities to peppermint, menthol, caraway, other members of the umbellifer family or any other excipients of the drug; achlorhydria (inability to produce gastric acid); liver disease; gall stones; inflammatory conditions of the bile ducts (cholangitis) or other diseases of the gallbladder.

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

Gastrointestinal complaints can be symptoms of diseases which require medical attention and treatment; consequently, complaints which persist for more than one week or periodically recur should be discussed with a physician.

There is not adequate research into the use of this medicinal product in children. Gaspan® is thus not to be used by children and adolescents under the age of 18.

4.5 Interactions with other medicinal products and other forms of interaction

Studies about interactions with other drugs have not been conducted.

Use of antacids administered at the same time can cause early release of the capsule content of Gaspan®. As a result, Gaspan® and antacids should be taken separately from each other at an interval of at least one hour.

Since the gastro-resistant capsule coating can dissolve prematurely if it is taken when eating, Gaspan must be taken at least 30 minutes before a meal.

Other medicinal products used to decrease stomach acid such as histamine-2 blockers and proton pump inhibitors may increase the intragastric pH value especially during digestion. This may prematurely dissolve the gastro-resistant capsule coating in the stomach. Consequently, there may be eructation with a typical taste. To prevent this situation, the dosage recommendation is to be followed exactly: it states that Gaspan® is to be taken at least 30 minutes before a meal, ideally in the mornings and at midday. Furthermore, Gaspan® should not be taken within one to three hours of taking a proton pump inhibitor.

4.6 Fertility, pregnancy and lactation

Pregnancy

To date there has been no experience with the use of Gaspan® in pregnant women. There have not been enough animal studies with regard to reproductive toxicity. The use of Gaspan® is not recommended during pregnancy.

Lactation

It is not known whether constituents of peppermint oil and / or caraway oil or their metabolites pass into breast milk. A risk to the infant / child cannot be ruled out. Gaspan® should not be used during breastfeeding.

Fertility

No studies have been done about the effects on fertility.

4.7. Effects on ability to drive and use machines

None known.

4.8. Adverse effects

Gastric complaints (e.g. eructation) may occur in sensitive individuals.

Allergic reactions may occur in very rare cases (Less than 1 in 10,000, including individual cases).

Reporting suspected adverse effects

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: <https://sideeffects.health.gov.il>

In addition, suspected adverse events can be reported to Dr. Samuelov's drug safety department at: drugsafety@drsamuelov.co.il

4.9 Overdose

Overdoses of Gaspan® have not been reported to date.

Overdose symptoms can occur after larger quantities of essential oils are ingested, and small children are especially sensitive. These symptoms can consist of gastrointestinal complaints such as vomiting, abdominal pain, diarrhoea, rectal ulcerations or dizziness. Potential symptoms of severe overdose are epileptic seizures, loss of consciousness, apnoea, arrhythmia, ataxia and other disorders of the central nervous system.

Gastric lavage via endotracheal intubation is indicated after the ingestion of large quantities or following severe clinical symptoms. Furthermore, the patient is to undergo observation and, where appropriate, symptomatic treatment.

5. Pharmacological properties

Pharmacotherapeutic group: Herbal medicinal product for functional gastrointestinal disorders.

ATC code: A03AX

5.1. Pharmacodynamic properties

Human pharmacology studies in healthy volunteers showed a motility-inhibiting effect on the duodenum after taking a capsule of Gaspan®.

5.2. Pharmacokinetic properties

Since this is a gastro-resistant soft capsule, the onset of action can be delayed by 1 to 1½ hours.

After taking one dose of two capsules of Gaspan®, in healthy volunteers a half-life period of 3.5 ± 0.9 h was determined for menthol, the main component of peppermint oil; the half-life of carvone, the main component of caraway oil, was 2.5 ± 0.7 h.

5.3 Preclinical safety data

The preclinical data are incomplete. Safety in humans has been adequately proven due to the many years of medical use.

Studies on reproductive toxicology, genotoxicity and carcinogenicity are not available.

6. Pharmaceutical particulars

6.1 List of excipients

Gelatin succinylated; medium-chain triglycerides; methacrylic acid ethyl acrylate copolymer (1:1) dispersion 30% - dry substance ;glycerol 85%; sorbitol liquid solution 70% (non crystallizing), dry substance; propylene glycol; glycerol monostearate 40-55 (type II); polysorbate 80; iron oxide yellow (E 172); titanium dioxide (E 171); quinoline yellow 70% (E104); patent blue V 85%(E 131).

6.2 Incompatibilities

n/a

6.3 Shelf-life

The expiry date of the product is indicated on the packaging materials

6.4 Special precautions for storage

Do not store at temperatures above 30°C

6.5. Nature and contents of container

The container (blister pack) is made of PVC/PVDC foil and aluminium foil.
Original packs with 14, 42 or 84 soft capsules.
Not all pack sizes may be marketed

6.6 Special precautions for disposal / handling of the product

No special requirements.

7. Israeli marketing authorization holder and importer:

Dr. Samuelov Importing & Marketing Ltd.
13 Hasadna st, POB 2486
Ra'anana 4365007 Israel
Phone: 09 7483769

8. Manufacturer:

Dr. Willmar Schwabe GmbH & Co. KG
Willmar-Schwabe-Strasse 4
76227 Karlsruhe, Germany

9. Marketing authorisation number

165-98-36182-00

10. Date of first authorisation

November 2020

11. Sales restrictions

OTC, For sale in pharmacies only