

Patient Package Insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold without a doctor's prescription

Gaspan

Gastro-resistant soft capsules

Active ingredients and their quantity in a dosage unit:

Each Gastro-resistant soft capsule contains:

peppermint oil 90 mg, Caraway oil 50 mg

For list of inactive ingredients/excipients – see section 6

For important information about some of the ingredients of the medicine – see section 2.

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist. Take the medicine Gaspan according to the instructions in the dosage section of this leaflet. Consult a pharmacist if you require further information. Consult a doctor if the symptoms worsen, do not improve, recur or if the symptoms persist for more than a week in a row. Tell the doctor or pharmacist if you feel that the effect of the medicine is too strong or too weak.

1. What is the medicine intended for?

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

Therapeutic group: Herbal medicinal product for the treatment of gastrointestinal complaints. Gaspan acts by reducing flatulence, cramps and gastrointestinal pain.

The medicine coating is gastro-resistant and therefore allows release of the active ingredients at the desired site of action in the intestine.

2. Before using the medicine

X Do not use the medicine:

- If you are hypersensitive (allergic) to the following plants: peppermint, caraway or other plants of the umbellifer family; menthol or to any of the other ingredients this medicine contains. The additional ingredients are listed in section 6.
- If you suffer from inability to produce gastric acid (achlorhydria).
- If you have liver disease
- If you have gallstones, inflammation of the bile ducts, or other diseases of the gallbladder.

Special warnings regarding the use of this medicine:

Before the treatment with Gaspan, tell the doctor if:

Gastrointestinal complaints can be symptoms of diseases which require medical attention and treatment; consult a doctor if you suffer from symptoms which persist for more than one week in a row or periodically recur.

Children and adolescents:

Gaspan should not be used by children and adolescents under the age of 18 as there is insufficient information on the use of the medicine in these ages.

Drug interactions:

If you are taking, or have recently taken other medicines, including non-prescription drugs and nutrition supplements, tell the doctor or pharmacist.

Studies to evaluate the interactions between Gaspan and other medicines have not yet been conducted.

Use of Gaspan at the same time with other antacids (medicines that reduce stomach acid) may damage the gastro-resistant coating and cause degradation of the contents of the capsule before it

reaches the desired site of action. Therefore, Gaspan should be taken separately and at an interval of at least an hour from taking antacids.

Take Gaspan separately and at an interval of one to three hours from medicines of the proton pump inhibitors class (which reduce gastric acid), in order to prevent damage to the gastro-resistant coating.

If you take other medicines to reduce stomach acid, be sure to take Gaspan exactly in accordance with the instructions given in section 3.

¶ Use of this medicine and food:

Taking Gaspan with food may damage the gastro-resistant coating of the medicine. Therefore, Gaspan should be taken at least 30 minutes before meal.

¶ Pregnancy and breastfeeding:

As there is insufficient data on the use of the medicine during pregnancy or breastfeeding, Gaspan should not be used in women who are pregnant or breastfeeding.

¶ Driving and use of machinery:

The effect of Gaspan on the ability to drive or use machines is unknown.

¶ Important information about some of the ingredients of this medicine:

Gaspan contains 12 mg of sorbitol per soft capsule.

You should consult a doctor before using the medicine if you have intolerance to sugars.

Gaspan contains less than 23 mg sodium per soft capsule.

3. How to use this medicine

Check with your doctor or pharmacist if you are not sure about the dosage and the manner of treatment with this medicine.

The usual recommended dosage in adults aged 18 and above is:

One capsule twice daily.

There is no information regarding the exact dosage in patients with impaired kidney function.

Do not exceed the recommended dose.

Treatment duration with the medicine: There is no limit as to how long Gaspan should be taken. Consult a doctor if symptoms of the disease last for more than a week or periodically recur.

How to take the medicine: The capsule should be swallowed whole with adequate liquid (such as a glass of water), at least 30 minutes before the meal, preferably in the morning and at midday. The capsules can also be taken without a meal.

Crushing/halving/chewing: Do not halve, cut or empty the contents of the capsule.

Before taking, make sure that the surface of the capsule is smooth and undamaged. Do not chew the capsule. This ensures that the active ingredient is not released before reaching the desired site of action. Premature release of the active ingredient may cause local irritation in the mouth and esophagus.

If you have accidentally taken a higher dosage:

Do not exceed the recommended daily dose within the framework of the usual dose or as recommended by your doctor. Accidentally taking one to two capsules more than the recommended daily dose does not usually cause side effects or negative consequences. However, taking a higher quantity may cause overdose side effects (such as: vomiting, abdominal pain, dizziness, disruption of cardiac function). In this case, refer to a doctor or hospital emergency room, even if no symptoms have yet developed. This instruction is especially important in case a child has accidentally taken an overdose.

In case of taking an overdose, do not drink milk or alcoholic beverages, as these may increase the

passage of active ingredients into the bloodstream.

If you forgot to take this medicine at the intended time, do not take a double dose. Take the next dose at the usual time and consult a doctor. Continue the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop the treatment with this medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. Side Effects

As with any medicine, the use of Gaspan may cause side effects in some users. Do not be alarmed while reading the list of side effects. You might not suffer from any of them.

The side effects listed below include all side effects reported during treatment with peppermint oil or caraway oil, including in cases of high dose and long-term use:

- Very rare side effects (appear in less than one out of 10,000 users):

An allergic reaction may occur. Stop using the medicine and refer to a doctor at the first sign of an allergic reaction.

- Side effects with unknown frequency (effects whose frequency has not been determined yet): Gastrointestinal discomfort (such as belching) may occur in patients with pre-existing gastrointestinal sensitivity.

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health via the link "Reporting Side Effects from Drug Treatment" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting, or via the following link: <https://sideeffects.health.gov.il>

Additionally side effects can be reported to Dr. Samuelov Import and Marketing Ltd. at the following address: drugsafety@drsamuelov.co.il

5. How to Store the Medicine

Avoid poisoning! This medicine and any other medicine, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (Exp. date) that appears on the package or the blister. The expiry date refers to the last day of that month.

Storage conditions: Do not store at a temperature above 30°C.

6. Additional Information

In addition to the active ingredient, the medicine also contains the following inactive ingredients:

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% (E 104); patent blue V 85% (E 131).

What the medicine looks like and contents of the package: Gaspan looks like a light green, soft, oval capsule. The soft capsules are packed in plastic trays ("blisters"), which are packed in cardboard boxes.

Package size: Gaspan is supplied in cardboard packages containing plastic trays with 14 soft capsules each. There are packages containing 14, 42 or 84 capsules. Not all package sizes may

be marketed.

Registration Holder and Importer: Dr. Samuelov Import and Marketing Ltd., Company ID 512260944, P.O.B 2486, Ra'anana 4365007. Tel.: 09-7483769, e-mail address: info@drsamuelov.co.il

Manufacturer: Dr. Wilmer Schwabe GmbH & Co. KG, Karlsruhe, Germany.

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Registration number of the medicine in the national drug registry of the Ministry of Health: 165-98-36182-00

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