



PACKAGE LEAFLET

SPAZZI 60 mg/300 mg Soft Capsules

Taken by mouth.

Active substances: Each soft capsule contains 60 mg alverine citrate and 300 mg simethicone.

Excipients: Gelatin (bovine gelatin), glycerin, purified water, titanium dioxide.

Read all of this PACKAGE LEAFLET carefully before you start taking this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *While you are taking this medicine, tell your doctor that you use this medicine, when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take this medicine in either **higher** or **lower** dose other than recommended to you.*

What is in this leaflet:

- 1. What SPAZZI is and what it is used for**
- 2. What you need to know before you take SPAZZI**
- 3. How to take SPAZZI**
- 4. Possible side effects**
- 5. How to store SPAZZI**

1. WHAT SPAZZI IS AND WHAT IT IS USED FOR

SPAZZI soft capsules are oblong, cream-colored, and opaque.

Each capsule of SPAZZI contains 60 mg alverine citrate and 300 mg simethicone as active substances.

SPAZZI is offered in packs containing 40 capsules.

SPAZZI belongs to the class of medicines called papaverine and derivatives, and class of medicines called antispasmodics and other drugs altering gut motility (bowel movements).

SPAZZI is used in the symptomatic treatment of flatulence and bloating, as well as functional bowel disorders.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SPAZZI

DO NOT TAKE SPAZZI

- If you are hypersensitive to the active substances alverine citrate and simethicone, or any of the other ingredients of SPAZZI,
- If you have had an allergic reaction after the use of any medication in the past,
- If your doctor has told you that you have an intestinal obstruction or that your intestine is not functioning properly.

TAKE SPECIAL CARE with SPAZZI

- Consult your doctor if new symptoms develop or your complaints continue or worsen, or if your constipation persists despite 2 weeks of treatment.
- SPAZZI may increase liver enzyme levels in the blood (see section 4). Your doctor may order blood tests during your treatment to check the condition of your liver. Elevated liver enzyme levels may cause your doctor to discontinue treatment.
- Other causes of gastrointestinal pathology should be ruled out and patients not improving after 2 weeks of treatment should be evaluated by a doctor.

If these warnings apply to you, even at any time in the past, please consult your doctor.

Taking SPAZZI with food and drinks

Take SPAZZI before meals.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

There is insufficient data on the use of SPAZZI in pregnant women. Therefore, it is recommended not to use it during pregnancy.

If you realize that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

Since there is no data on whether it passes into breast milk, the use of SPAZZI, which contains alverine citrate and simethicone, should be avoided during breastfeeding. Do not take this medicine if you are breast-feeding.

Driving and using machines

SPAZZI has a minor influence on the ability to drive and use machines. Side effects such as dizziness have been reported in some patients. These types of disorders may affect the ability to drive and use machines.

Important information about some of the ingredients of SPAZZI

It does not contain any excipients that require warning.

Taking with other medicines

Since the absorption of medicines containing levothyroxine is impaired when taken together with simethicone, these two medicines should only be taken with a break of at least 2 hours.

Please tell your doctor or pharmacist if you are currently taking or have recently taken any other medicines, including medicines obtained without a prescription.

3. HOW TO TAKE SPAZZI

• Instructions for proper use and dose/frequency of administration:

SPAZZI is taken as one capsule 2-3 times a day, for the specified indications.

• Route and method of administration:

It is taken by mouth. Take it with a sufficient amount of fluid before meals or during pain.



- **Different age groups:**

Use in children:

For use by adults only.

Use in the elderly:

There is no special use.

- **Special conditions for use:**

Liver / Kidney failure:

There is no special use.

If you notice that the effect of SPAZZI is too strong or weak, consult your doctor or pharmacist.

If you take more SPAZZI than you should

Dizziness has been reported after taking more than the recommended dose. Consult your doctor or pharmacist immediately.

If you have taken more SPAZZI than you should, please consult a doctor or pharmacist.

If you forget to take SPAZZI

Do not take a double dose to make up for a forgotten dose.

Side effects that may occur when treatment with SPAZZI is stopped

No effect is expected. If you want to get more information about the use of this medicine, consult your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, SPAZZI can cause side effects in patients who are sensitive to its ingredients.

If any of the following occur, stop taking SPAZZI and IMMEDIATELY inform your doctor or go to the emergency department of the nearest hospital:

- Signs of a severe allergic reaction, particularly swelling of the face, lips, mouth, tongue and/or throat that can cause difficulties in breathing or swallowing, skin rash, itching, severe dizziness with increased heart rate and copious sweating.

These are all very serious side effects. If you have any of these, it means that you are severely allergic to SPAZZI. You may need emergency medical intervention or hospitalization.

Side effects are listed as shown in the following categories:

Very common : may affect at least 1 in 10 patients.

Common : may affect less than 1 in 10 patients but more than 1 in 100 patients.

Uncommon : may affect less than 1 in 100 patients but more than one in 1,000 patients.

Rare : may affect less than 1 in 1,000 patients but more than 1 in 10,000 patients.

Very rare : may affect less than 1 in 10,000 patients.

Not known : Frequency cannot be estimated from the available data.

Very rare:

- Signs of a severe allergic reaction, particularly swelling of the face, lips, mouth, tongue and/or throat that can cause difficulties in breathing or swallowing, skin rash, itching, severe dizziness with increased heart rate and copious sweating.

- Symptoms suggestive of a liver dysfunction, such as yellowing of the skin or eyes, dark color of urine, loss of appetite, nausea or vomiting.

Not known:

- Skin rash
- Urticaria
- Itching
- Dizziness
- Headache
- Nausea
- Increased blood levels of liver enzymes (transaminases, alkaline phosphatase) and bilirubin (see section 2).

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE SPAZZI

Keep SPAZZI out of the reach and sight of children and in its original package.

Store at room temperature below 25°C.

Use it in accordance with the expiry date.

Do not use SPAZZI after the expiry date stated on the package.

Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Marketing Authorization Holder:

DEVA HOLDİNG A.Ş.

Küçükçekmece / İSTANBUL / TÜRKİYE

Manufacturing Site:

Deva Holding A.Ş.

Kapaklı / TEKİRDAĞ / TÜRKİYE

This package leaflet was approved on 24/05/2021.