



PACKAGE LEAFLET: INFORMATION FOR THE USER

GASVIN 500 mg + 267 mg + 160 mg/10 ml Oral Suspension **Taken by mouth.**

Active substance: Each 10 ml suspension contains 500 mg sodium alginate, 267 mg sodium bicarbonate and 160 mg calcium carbonate.

Excipients: Carbomer 974P, sodium hydroxide, methyl paraben (E218), propyl paraben (E216), xanthan gum, sodium saccharin, peppermint flavor, deionized water.

Read all of this PACKAGE LEAFLET carefully before you start using 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.*
- *During the period when you take this medicine, tell your doctor that you take this drug when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher** or **lower** dose other than recommended to you for this medicine.*

In this leaflet:

- 1. What GASVIN is and what it is used for***
- 2. Before you use GASVIN***
- 3. How to use GASVIN***
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1. WHAT GASVIN IS AND WHAT IT IS USED FOR

GASVIN is mint flavored, cream colored suspension. Each 10 ml suspension contains sodium alginate 500 mg, sodium bicarbonate 267 mg and calcium carbonate 160 mg. It is presented in a bottle of 200 ml.

GASVIN is used for the treatment of symptoms of gastro-esophageal reflux such as acid regurgitation, heartburn and indigestion, which may occur for example following meals or during pregnancy.

2. BEFORE YOU USE GASVIN

DO NOT USE GASVIN

Do not use GASVIN, if you have any hypersensitivity to any of its ingredients.

Take special care with GASVIN

If you have any of the symptoms given below, the treatment should be prescribed carefully by your doctor.

- If you have restricted sodium and/or calcium diet
- If you have kidney or heart disease or had in the past (some salts can affect these conditions)
- If the acidity level of stomach is low (the efficacy of the medicine may decrease)
- If you have severe kidney failure



- If symptoms do not improve after 7 days

If these warnings are valid for you, even at any time in the past, please consult your doctor.

Using GASVIN with food and drink

GASVIN is administered orally after meals.

Pregnancy and breast-feeding

Consult your doctor or pharmacist before taking this medicine.

Alginates are not absorbed from the gastrointestinal system; therefore GASVIN may be used if you are pregnant or breast-feeding.

Driving and using machines

This product has no influence on the ability to drive and use machines.

Important information about some of the ingredients of GASVIN

GASVIN contains 5.63 mmol (129.6 mg) sodium each 10 ml; to be taken into consideration by patients on a controlled sodium diet.

GASVIN contains methylparaben (E218) and propylparaben (E216) which may cause allergic reactions (possibly delayed).

Using other medicines

When used with some medicines, the effect of GASVIN or other medicines may change. A break of 2 hours should be given between the use of GASVIN with the following medicines:

- Quinolone group antibiotics such as tetracyclines, norfloxacin (for infection treatment),
- Medicines containing iron,
- Penicillamine (ion trap that increases copper excretion in urine)
- Ketoconazole (for fungus),
- Beta-blockers such as atenolol, metoprolol, propranolol and digoxin (for heart disease),
- Neuroleptics (for neurological diseases)
- Glucocorticoid (a type of hormone drug)
- Chloroquine (for malaria)
- Bisphosphonates (for bone resorption)
- Estramustine (for prostate gland cancer)
- Antihistamics (Drugs to prevent allergies and itching)

Since the absorption of drugs containing levotroxin is impaired when taken with a sodium alginate/ sodium bicarbonate/ calcium carbonate combination, the two drugs should be taken at least 4 hours apart.

If you are taking or have recently taken any other medicines, including medicines obtained without prescription, please tell your doctor or pharmacist.

3. HOW TO USE GASVIN

Always use GASVIN in accordance with your doctor's recommendations. Take your medicine regularly every day. If you have any further questions about the use of this product, ask your doctor or pharmacist for advice.



Instructions for proper use and dose/frequency of administration:

Taken by mouth. Shake well before use.

The dosage for adults and children 12 years and over is 10-20 ml (2-4 coffee spoons) after meals and at bedtime, (up to 4 times per day).

Method and route of administration:

Taken by mouth. Shake well before use.

Different age groups

Use in children

Children 6-12 years: 5-10 ml (1-2 coffee spoons) after meals and at bedtime.

Children under 12 years of age: Should only be given on doctor's advice.

Children under 6 years of age: Use is not recommended.

Use in elderly

No dose adjustment necessary for elderly patients.

Special conditions

Kidney failure:

Since GASVIN contains calcium and sodium, if sodium and or calcium restriction has been recommended by your doctor, you should consult your doctor before using this drug.

Liver failure:

There are no special conditions for use.

If you have the impression that the effect of GASVIN is too strong or too weak, talk to your doctor or pharmacist.

If you take more GASVIN than you should

If you have used GASVIN more than you should, it is not expected to do you any harm, but you may feel bloated.

If you stop taking GASVIN

If you stop your treatment without consulting your doctor, the symptoms of your disease may reappear.

4. POSSIBLE SIDE EFFECTS

Like all medicines, GASVIN may cause side effects in people sensitive to ingredients.

If you have any of the following, stop taking GASVIN and tell your doctor IMMEDIATELY or go to the nearest hospital emergency department

- Increased skin rash anywhere of your body
- Swelling of the hands, feet, ankle, face and lips
- Swelling of the mouth and throat which may cause difficulty in swallowing or breathing

All of these are very serious side effects.



If you have any of these side effects, you are seriously allergic (hypersensitivity) to GASVIN. You may need urgent medical attention or hospitalization. All of these very serious side effects occur rarely.

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 to Turkey Pharmacovigilance Center (TÜFAM) via clicking on the icon of ‘Side Effect Reporting for Medicines’ at www.titck.gov.tr or calling +90 800 314 00 08 as the line of side effect reporting. By reporting side effects you can help provide more information on the safety of this medicine.

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

5. HOW TO STORE GASVIN

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

Store at room temperature below 30°C in a cool and dry place and in its original package. Use within 6 months of opening.

Use in line with the expiry date.

Do not use GASVIN after the expiry date which is stated on the package.

Do not use GASVIN if you notice any defect or damage on the product and/or 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:

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34303 Küçükçekmece – ISTANBUL/TURKEY

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