



PACKAGE LEAFLET

GASVIN DUO 500 mg + 213 mg + 325 mg/10 ml Oral Suspension

Taken by mouth.

Active substances: Each 10 ml of oral suspension contains 500 mg sodium alginate, 213 mg sodium bicarbonate and 325 mg calcium carbonate.

Excipients: Carbomer 974 P, methylparaben, propylparaben, sodium saccharin, xanthan gum, peppermint flavour, sodium hydroxide and 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.*

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1. WHAT GASVIN DUO IS AND WHAT IT IS USED FOR

GASVIN DUO is mint odoured, cream colored, homogenous suspension when shaken.

Each 10-ml dose contains 500 mg sodium alginate, 213 mg sodium bicarbonate and 325 mg calcium carbonate. It is presented in a bottle of 200 ml.

GASVIN DUO is indicated for treatment of discomfort/complaints depending on excess stomach acid after meals or during pregnancy, and complaints related to the reflux of stomach contents into the esophagus (gastroesophageal reflux), such as bitter, sour taste in the mouth (acid regurgitation), burning sensation in the stomach or chest.

The medicinal product is a combination of two antacids and an alginate. The mode of action of the medicinal product is totally physical.

GASVIN DUO interacts with stomach acid after ingestion. As a result of this interaction, a raft of gel with neutral pH is formed that moves in the stomach. In this way, the frequency of acidic stomach contents to escape into the esophagus (gastroesophageal reflux) is reduced. In severe cases, this raft of gel passes into the esophagus and prevents the stomach contents from coming into contact with the esophagus, protecting the mucosa from irritation and healing begins.



GASVIN DUO relieves the pain resulting from the reflux of stomach acid and bile into the esophagus by directly suppressing reflux and reducing acidity.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE GASVIN DUO

Do not use GASVIN DUO in the following situations

Do not use if you are hypersensitive to any of the ingredients of this medicine.

Take special care with GASVIN DUO in the following situations

If you have any of the conditions listed below, your treatment should be carefully arranged by your doctor. Consult your doctor,

- If you have restricted salt diet,
- If you have renal or cardiac disease or you have experienced in the past (some salts can affect this symptoms),
- If the acidity level of stomach is low (for this reason effect of the medicine can decrease),
- If you have severe renal insufficiency or low levels of blood phosphate (hypophosphatemia),
- If symptoms do not improve after seven days,
- If you have an intestinal infection that causes vomiting and diarrhea, or if it will be used in children with suspected kidney failure.

Each 20-ml dose contains 10.06 mmol sodium and 6.5 mmol calcium. Patients with dietary restrictions should consult their doctor before using this medicine.

It is generally not recommended for use in the treatment of children under the age of 12, except on the advice of a doctor.

You should avoid from taking more than necessary.

As with other antacids, the use of GASVIN DUO may mask more serious underlying medical conditions.

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

Using GASVIN DUO with food and drink

It has no interaction with food and drink.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

You can use GASVIN DUO during pregnancy only with the advice of a doctor. It is not recommended to use GASVIN DUO for a long time during pregnancy, more than the amount recommended by your doctor, or with other medicines.

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

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

You can use this medicine while breastfeeding.



Driving and using machines

GASVIN DUO does not adversely affect the ability to drive and use machines.

Important information about some of the ingredients of GASVIN DUO

This medicinal product contains 5.03 mmol (or 115.74 mg) sodium per 10 ml. This should be considered for patients on a controlled sodium diet.

This medicinal product contains methyl paraben and propylene paraben, which may cause allergic reactions (possibly delayed).

Concomitant use with other medicines

When used with certain medicines, the effect of GASVIN DUO or other medicines may change. A break of 2 hours should be given between the use of GASVIN DUO 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)
- Antihistaminics (drugs to prevent allergies and itching)

Since the absorption of drugs containing levotroxin is impaired when taken with sodium alginate/sodium bicarbonate/calcium carbonate combination, these two medicines 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 DUO

Always use GASVIN DUO 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 teaspoons) after meals and at bedtime (4 doses per day).

Route and method of administration:

It should be used orally. Shake well before use.

Different age groups



Use in children

It is used in children under 12 years old only according to the doctor's recommendation.

Use in elderly

No dose adjustment necessary for elderly patients.

Special conditions

Kidney/Liver failure

There are no special conditions for use.

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

If you take more GASVIN DUO than you should

If you think you have taken more GASVIN DUO than you should, consult your doctor or pharmacist.

If you use more GASVIN DUO than necessary, the side effects of the medicine and their severity may increase.

Effects that may occur when treatment with GASVIN DUO is stopped

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

If you forget to take GASVIN DUO

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, there may be side effects in people who are sensitive to the ingredients of GASVIN DUO.

If any of the following occurs, stop using GASVIN DUO and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department

- Increasing redness in any part 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 have a serious allergy to GASVIN DUO. You may need urgent medical attention or hospitalization.

All of these very serious side effects occur very rarely.

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

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

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

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

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

Not known : cannot be estimated from the available data.

Tell your doctor if you notice any of the following:



(In case you use more than the specified doses)

Not known:

- Alkalosis (decrease in blood acidity), hypercalcemia (increase of calcium levels in the blood), acid rebound (increase of acid level in the stomach after meal)
- Milk alkali syndrome (increase in blood calcium, decrease in acid level, increase in blood nitrogen in laboratory tests, and calcium stone formation in the kidney due to excessive and long-term milk intake)
- Constipation

These are mild side effects of GASVIN DUO.

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.

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

5. HOW TO STORE GASVIN DUO

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

Store at room temperature below 30°C

Store in a cool and dry place and in its original package.

Use within 6 months after opening the bottle.

Use in line with the expiry date.

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

Do not use GASVIN DUO 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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Kapaklı – TEKIRDAG/TURKEY

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