



## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **GASVIN 500 mg/267 mg/160 mg Chewable Tablets** **Taken by mouth.**

**Active substance:** Each chewable tablet contains 500 mg sodium alginate, 267 mg sodium bicarbonate and 160 mg calcium carbonate.

**Excipients:** Avicel CE 15 (microcrystalline cellulose and guar gum), compressible sugar (Compressuc MS), copovidone (Kollidon VA 64), lemon flavor, acesulfame potassium, aspartame, anhydrous citric acid, magnesium stearate

***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 IS AND WHAT IT IS USED FOR**

GASVIN a cream colored, flat, round, slightly mottled tablet supplied as 60 tablets in a plastic bottle.

GASVIN Chewable Tablets are 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, and for symptoms of excess stomach acid (hyperacidity).

### **2. BEFORE YOU USE GASVIN**

#### **DO NOT USE GASVIN**

Do not use GASVIN, if you have 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



- As it contains aspartame, patients with phenylketonuria should not use this product.

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

*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.*

GASVIN can 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**

#### This medicine contains sodium and calcium:

If you have been advised to follow a diet restricted in any of these salts please consult your doctor before taking this product.

GASVIN contains 5.49 mmol (126.31 mg) sodium in each tablet. Talk to your doctor or pharmacist if you need this product on a daily basis for a prolonged period of time, especially if you have been advised to follow a low salt (sodium) diet.

#### This product contains aspartame:

Due to its aspartame content this product should not be given to patients with phenylketonuria.

#### This product contains sugar:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **Using other medicines**

Do not take this product within two hours of taking other medicines by mouth as it can interfere with the action of some other medicines. This is especially important if you are taking:

- Tetracyclines and quinolones such as norfloxacin (for bacterial infections)
- Iron preparations
- Antifungals such as ketoconazole
- Neuroleptics (for mental illness)
- Digoxin and beta-blockers such as atenolol, metoprolol, propranolol (for heart disease),
- Glucocorticoid (a hormone drug)
- Chloroquine (for malaria)
- Bisphosphonates (for osteoporosis)
- Estramustine (for prostate cancer)

Since the absorption of levothyroxine-containing drugs (used in thyroid diseases) is impaired when taken with GASVIN, the two drugs should be taken with an interval of at least 2 hours.



*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.

#### **Method and route of administration:**

For oral administration. Chew thoroughly before swallowing.

Adults and children 12 year and over: When symptoms occur take 1-2 tablets after meals and at bedtime. Tablets should be chewed thoroughly. (It may be helpful to break the tablets into small pieces.). You may drink a glass of water thereafter.

Children under 12 years: Should only be taken on medical advice.

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.

**Other side effects:**

- Especially in patients with kidney failure: nausea, vomiting, muscle weakness, heart rhythm disorders, confusion, low blood pressure, low reflexes, bone pain, constipation, stomachache.
- Stomach disorders
- Diarrhea

**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](http://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 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

***Manufacturing site:***

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