



SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Each 10 ml suspension contains 500 mg sodium alginate, 213 mg sodium bicarbonate and 325 mg calcium carbonate.

Excipient(s):

Each 10 ml suspension contains

Methylparaben.....	20 mg
Propylparaben.....	2 mg
Sodium saccharine.....	15 mg
Sodium hydroxide.....	4.40 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension

Mint odoured, cream colored, homogenous suspension when shaken.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

GASVIN DUO is indicated for treatment of symptoms of gastro-esophageal reflux, such as acid regurgitation, heartburn and indigestion after meals including during pregnancy, and for symptoms of excess stomach acid (hyperacidity).

4.2. Posology and method of administration

Posology/frequency and duration of administration

10-20 ml (2-4 teaspoons) after meals and at bedtime, up to four times a day.

Method of administration

For oral use.

Additional information on special populations

Renal impairment

Since it contains calcium carbonate, caution should be exercised in patients in the treatment of hypercalcemia, nephrocalcinosis and recurrent renal calcium stone, and in cases where a highly restricted salt diet is recommended because it contains sodium.

Hepatic impairment

No data available.



Pediatric population

For children over 12 years of age, the dose is 10-20 ml (2-4 teaspoons) after meals and at bedtime, up to four times a day.

It should be given to children under 12 years of age only on doctor's advice.

Geriatric population:

No dose adjustment is required.

4.3. Contraindications

GASVIN DUO Oral Suspension should not be used in patients with known or suspected hypersensitivity to any of the active substances or excipients (parabens) (See section 4.4).

4.4. Special warnings and precautions for use

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 also should be taken into account in cases where a highly restricted salt diet is recommended, as in some cases of congestive heart failure and kidney failure.

Each 20 ml contains 260 mg (6.5 mmol) of calcium. Care needs to be taken in treating patients with hypercalcemia, nephrocalcinosis and recurrent calcium containing renal calculi.

If symptoms do not improve after seven days, the clinical situation should be reviewed. Longer use than necessary should be avoided.

As with other antacid products, the use of GASVIN DUO, an antacid-alginate combination, can mask more serious underlying medical conditions.

GASVIN DUO oral suspension should not be used in the following situations:

- In patients with severe/partial kidney function/failure
- In patients with hypophosphatemia

There is a possibility of decreased efficacy in patients with very low gastric acid level.

Children with gastroenteritis or suspected kidney failure are at a greater risk of hypernatremia.

Treatment of children younger than 12 years of age is not generally recommended unless recommended by a physician

It contains methyl paraben (E218) and propyl paraben (E216) which may cause allergic reactions (possibly delayed).

4.5. Interaction with other medicinal products and other forms of interaction

Due to the antacid feature of the calcium carbonate in the product composition, a time-interval of 2 hours is recommended between intake and the administration of other medicinal products, (especially H₂ antihistamines, tetracyclines, digoxin, fluoroquinolone, iron salts, ketoconazole, neuroleptics, penicillamine, beta blockers (atenolol, metoprolol, propranolol), glucocorticoid, chloroquine and bisphosphonates, etc.), estramustine (for prostate gland cancer).



Since the absorption of drugs containing levotroxine is impaired when taken together with sodium alginate/sodium bicarbonate/calcium carbonate combination, a time-interval of 2 hours should be considered between the intake of these drugs.

Additional information on special populations

No interaction studies have been conducted.

Pediatric population

No interaction studies have been conducted.

4.6 Fertility, pregnancy and lactation

General recommendation

Pregnancy category is B.

Women of childbearing potential / Birth Control (Contraception)

There is no data indicating the use of additional contraceptive methods during GASVIN DUO oral suspension use.

There is no data of GASVIN DUO oral suspension use affecting any contraceptive methods.

Pregnancy

In open controlled studies in 281 pregnant women, the combination of the active ingredients, sodium alginate, sodium bicarbonate and calcium carbonate, did not have any significant adverse effects on the course of pregnancy or on the health of the fetus/newborn. Based on this information and previous experience, this product can be used during pregnancy. However, considering the presence of calcium carbonate, it is recommended to keep the treatment period as short as possible.

Breastfeeding

In open controlled studies, the combination of the active ingredients, sodium alginate, sodium bicarbonate and calcium carbonate, did not have any significant adverse effects on newborn health. Based on this information and previous experience, this product can be used during breastfeeding.

Reproductive ability / Fertility

The effect of GASVIN DUO oral suspension on reproductive ability / fertility is unknown.

4.7. Effects on ability to drive and use machines

It has no effect on the ability to drive and use machines.

4.8. Undesirable effects

Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$); not known: cannot be estimated from the available data.

Immune system disorders

Very rare: Allergic symptoms such as urticaria, anaphylactic or anaphylactoid reactions may develop very rarely in patients sensitive to the ingredients of the product.

Metabolism and nutritional disorders

Not known: High dose of calcium carbonate can cause alkalosis, hypercalcemia, acid rebound, milk-alkali syndrome or constipation. These side effects usually occur after taking



higher than recommended doses.

Respiratory, thoracic and mediastinal disorders

Very rare: Respiratory symptoms like bronchospasm

Gastrointestinal disorders

Not known: Constipation

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

4.9. Overdose

In the event of overdose, symptomatic treatment should be given. The patient may experience abdominal tension.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Other drugs for peptic ulcer and gastro-esophageal reflux disease.

ATC code: A02BX13

This medicinal product is a combination of two antacids (calcium carbonate and sodium bicarbonate) and an alginate.

After ingestion of GASVIN DUO oral suspension, it reacts rapidly with gastric acid to form a raft of alginic acid gel having a near neutral pH. In severe cases the raft itself may be refluxed into the esophagus, in preference to the stomach contents, and exert a demulcent effect.

Calcium carbonate neutralizes gastric acid to provide fast relief of indigestion and heartburn. This effect is increased by the addition of sodium bicarbonate which also has a neutralizing action. The total neutralizing capacity of the product at the lowest dose of two tablets is approximately 10 mEqH⁺.

5.2. Pharmacokinetic properties

General properties

Absorption:

The mechanism of action of this product is physical and does not depend on absorption into the systemic circulation.

Distribution:

No data available.

Biotransformation:

No data available.

Elimination:

No data available.



Linearity/Nonlinearity:

No data available.

5.3. Preclinical safety data

No preclinical findings have been reported that should be considered in prescribing the product.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Carbomer 974 P
Methylparaben
Propylparaben
Sodium saccharin
Peppermint flavour
Xanthan gum
Sodium hydroxide
Deionized water

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

36 months

6.4. Special precautions for storage

Store at room temperature below 30°C.
Store in a cool and dry place and in its original package.
Do not refrigerate or freeze.
Use within 6 months after opening.

6.5. Nature and contents of container

As the primary packaging of GASVIN DUO Oral Suspension, 28 PP 200 ml amber colored glass bottle and 28/20 white HDPE cap have been used. The bottles are packed in cardboard boxes. Each cardboard box contains a glass bottle of 200 ml and a package leaflet.

6.6. Special precautions for disposal and other handling

There are no special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORIZATION HOLDER

DEVA Holding A.Ş.
Halkalı Merkez Mah. Basın Ekspres Cad. No:1
34303 Küçükçekmece – ISTANBUL/TURKEY

8. MARKETING AUTHORIZATION NUMBER(S)



2017/301

9. DATE OF FIRST AUTHORIZATION/ RENEWAL OF THE AUTHORIZATION

Date of first authorization : 10.05.2017

Date of latest renewal :

10. DATE OF REVISION OF THE TEXT

21.09.2021