SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
GASVIN 500 mg + 267 mg + 160 mg/10 ml Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Active substance:
Each 5 ml contains;
Sodium alginate ..... 250 mg
Sodium bicarbonate ..... 133.5 mg
Calcium carbonate ..... 80 mg

Excipient(s):
Sodium hydroxide ..... 1.4 mg/5 ml
Methyl paraben ..... 10 mg/5 ml
Propyl paraben ..... 1 mg/5 ml
Sodium saccharine ..... 7.5 mg/5 ml
For the full list of excipients see 6.1.

3. PHARMACEUTICAL FORM
Suspension
Mint odoured, cream coloured, homogenous suspension.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
It is used in the treatment of all epigastric or retrosternal disorders where the underlying cause is gastric reflux, heartburn during pregnancy, gastric reflux-induced flatulence and heartburn and gastric reflux.

4.2 Posology and method of administration
Posology/frequency and duration of administration:
- GASVIN is administered orally.
- Adults and children of 12 years and over*:* 10-20 ml (2-4 dessert spoons) after meals and at bedtime
- Children between 6-12 years*:* 5-10 ml (1-2 dessert spoons) after meals and at bedtime
- Children younger than 6 years: Not recommended.

Method of administration:
GASVIN is for oral use.
It should be shaken well before use.

Additional information on special populations
Renal impairment:
As GASVIN contains sodium and calcium, caution is advised in patients with renal impairment.

Hepatic impairment:
No data available.

Pediatric population:
In children under 6 years of age, the use of GASVIN is not recommended.

In children under 12 years of age, it should be given only on the advice of a doctor.

Geriatric population:
No dose adjustment is necessary.

4.3 Contraindications
GASVIN should not be used in patients with known or suspected hypersensitivity to any of the active ingredients or other excipients including hydroxybenzoate esters (Methyl paraben (E218) and Propyl paraben (E216)).

4.4 Special warnings and precautions for use
If symptoms do not improve after 7 days, the clinical situation should be reviewed

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

This medicinal product contains 5.63 mmol (or 129.6 mg) sodium per 10 ml. This should be taken into account in patients on a restricted sodium diet. It should be used with caution in certain cases of renal and congestive heart failure and those on a very strict salt regimen.

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

Each 10 ml of GASVIN contains 160 mg (1.6 mmol) calcium carbonate. Caution should be exercised in patients with hypercalcemia, nephrocalcinosis and recurrent kidney stones.

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
A time-interval of 2 hours should be considered between intake of other medicinal products, especially, tetracyclines, digoxine, fluoroquinolone, iron salts, ketoconazole, neuroleptics, penicilamine, beta-blockers (atenolol, metoprolol, propanolol), glucocorticoid, chloroquine, bisphosphonate (diphosphonates) and estramustine with GASVIN.

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: A

Women of child-bearing potential/Birth control (Contraception)
There is no data indicating the use of additional contraceptive methods during GASVIN use.

There is no data of GASVIN affecting any contraceptive methods.

Pregnancy
Clinical studies conducted on more than 500 pregnant women and post-marketing experience have shown that the active substances have no toxic or deforming effect on the fetus/newborn.
GASVIN can be used during pregnancy, if clinically needed.

Breast-feeding
No negative effects of these active substances on infants/newborns of treated and breastfeeding mothers have been observed.
GASVIN can be used during breast-feeding.

Fertility
Preclinical studies have revealed that alginate has no negative effect on reproductive ability and fertility.
Clinical studies have shown that the combination of sodium alginate / sodium bicarbonate / calcium carbonate has no negative effect on human fertility.

4.7 Effects on ability to drive and use machines
GASVIN has no negative effect on the ability to drive and use machines.

4.8 Undesirable effects
The undesirable effects observed with the use of GASVIN are listed below according to their frequency of incidence.

Very common (≥1/10); Common (<1/10 to ≥1/100); Uncommon (<1/100 to ≥1/1,000); Rare (<1/1,000 to ≥1/10,000); Very rare (<1/10,000); Not known (cannot be estimated from the available data).

Immune system disorders
Very rare: Allergic symptoms such as anaphylactic or anaphylactoid reactions, urticaria.

Respiratory, thoracic and mediastinal disorders
Very rare: Respiratory symptoms like bronchospasm

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 overdosage, symptomatic treatment should be given. The patient may notice abdominal distension which should be treated conservatively.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Other drugs for peptic ulcer and gastro-esophageal reflux disease.
ATC code: A02BX13

GASVIN prevents gastroesophageal reflux by reacting rapidly with gastric acid after oral

administration, forming a gel layer of alginic acid with a pH close to neutral, which remains on the gastric contents for about 4 hours. In severe cases, the gel layer itself may escape back into the esophagus before the stomach contents. In this case, the drug shows its protective effect on the esophageal mucosa.

5.2 Pharmacokinetic properties

General properties

Absorption:
The mode of action of GASVIN 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/non-linearity:
No data available.

5.3 Preclinical safety data

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer 974 P
Sodium hydroxide
Methyl paraben
Propyl paraben
Xanthan gum
Sodium saccharin
Peppermint flavor
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. Do not store in refrigerator or do not freeze. Shake well before use.

6.5 Nature and contents of container

In the box, 28 PP 200 ml amber colored glass bottles closed with 28/20 mm HDPE plastic seal.

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

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8. MARKETING AUTHORIZATION NUMBER(S)

2016/256

9. DATE OF FIRST AUTHORIZATION/ RENEWAL OF THE AUTHORIZATION

Date of first authorization : 12.04.2016
Date of latest renewal :

10. DATE OF REVISION OF THE TEXT