

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Gattart 680 mg/ 80 mg Chewable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains 680 mg calcium carbonate and 80 mg magnesium carbonate, heavy.

Excipient with known effect: 299,079 mg xylitol per tablet.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Chewable tablet

Square, white to almost white, biconcave tablets with rounded corners. The dimensions of the tablets are: length 15 mm, breadth 15 mm and thickness 3.9 – 4.3 mm.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of heartburn and associated symptoms.

4.2 Posology and method of administration

Posology:

Adults and adolescents (> 12 years):

One to two tablets to be sucked or chewed as a single dose, preferably to be taken one hour after meals and before going to bed but also in between in case of heartburn or gastric pain. A maximum daily dose of 8 g calcium carbonate, corresponding to 11 tablets a day, must not be exceeded.

Paediatric population

Not recommended for children under 12 years of age.

Duration of treatment

If symptoms persist despite 7 days continuous treatment or only partly disappear, the patient should seek medical advice. If symptoms occur from time to time and there is a need for frequent administration of the drug, the patient should consult a doctor.

Method of administration

Tablets to be taken orally, sucked or chewed.

4.3 Contraindications

Gattart should not be administered to patients with:

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1
- Hypercalcaemia and/or conditions resulting in hypercalcaemia
- Nephrolithiasis due to calculi containing calcium deposits
- Severe renal insufficiency
- Hypophosphataemia

4.4 Special warnings and precautions for use

Prolonged use should be avoided.

The stated dose should not be exceeded. If, after 7 days of treatment, symptoms persist or only partly disappear the patient should consult a doctor.

As with other antacids, Gattart tablets may mask a malignancy in the stomach.

Caution should be exercised in patients with mild to moderate impairment of renal function (see section 4.3 – contraindication in severe renal insufficiency). If Gattart is used in such patients, plasma calcium, phosphate and magnesium levels should be regularly monitored.

Long term uses at high doses can result in undesirable effects such as hypercalcaemia, hypermagnesaemia and milk-alkali syndrome, especially in patients with renal insufficiency.

Gattart should not be used in patients with hypercalciuria (see also section 4.3). Prolonged use increases the risk of formation of renal calculi.

This product should not be taken with large amounts of milk or dairy products.

4.5 Interaction with other medicinal products and other forms of interaction

Changes in gastric acidity, such as that caused by the ingestion of antacids, can affect the rate and degree to which some concurrently administered medicines are absorbed.

It has been shown that antacids which contain calcium or magnesium may form complexes with certain substances e.g., antibiotics (such as tetracyclines and quinolones), and cardiac glycosides (e.g. digoxin), levothyroxine, and eltrombopag, resulting in decreased absorption. This should be borne in mind when concomitant administration is considered.

Calcium salts reduce the absorption of fluorides and iron-containing products, and calcium salts and magnesium salts can hinder the absorption of phosphates.

Thiazide diuretics reduce the urinary excretion of calcium. Due to an increased risk of hypercalcaemia, serum calcium should be regularly monitored during concomitant use of thiazide diuretics.

Therefore, it is preferable to take the antacid separately from other drugs, allowing at least 4 hours before or after taking eltrombopag and a 1-2 hour interval for all other drugs.

4.6 Fertility, pregnancy and lactation

Pregnancy and breast-feeding

No increased risk of congenital defects has been observed after the use of this product during pregnancy and it can be used during pregnancy and lactation if taken as instructed but prolonged intake of high dosages should be avoided. Pregnant women should limit the use of these products to the maximum recommended daily doses (see section 4.2).

During pregnancy and lactation, it has to be taken into account that the tablets provide a substantial amount of calcium in addition to dietary calcium intake. For this reason, pregnant women should strictly limit their use of tablets to the maximum recommended daily dose and avoid concomitant, excessive intake of milk and dairy products. This warning is to prevent calcium overload which might result in milk alkali syndrome.

Fertility

There is no evidence on the effects of this product on fertility in males or females.

4.7 Effects on ability to drive and use machines

Gattart has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The listed adverse drug reactions are based on spontaneous reports, thus an organisation according to CIOMS III categories of frequency is not possible.

Immune system disorders:

Hypersensitivity reactions have very rarely been reported. Clinical symptoms may include rash, urticaria, angioedema and anaphylaxis.

Metabolism and nutrition disorders:

Especially in patients with impaired renal function, prolonged use of high doses can result in hypermagnesaemia or hypercalcaemia and alkalosis which may give rise to gastric symptoms and muscular weakness (see below).

Gastrointestinal disorders:

Nausea, vomiting, stomach discomfort and diarrhoea may occur.

Musculoskeletal and connective tissue disorders:

Muscular weakness may occur.

Undesirable effects occurring in the context of milk-alkali syndrome (see section 4.9):

Nervous system disorders:

Headache may occur in the context of milk-alkali syndrome.

Gastrointestinal disorders:

Ageusia may occur in the context of milk-alkali syndrome.

Renal and urinary disorders:

Azotemia may occur in the context of milk-alkali syndrome.

General disorders and administration site conditions:

Calcinosis and asthenia may occur in the context of milk-alkali syndrome.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation 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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Especially in patients with impaired renal function, prolonged use of high doses of Gattart can result in renal insufficiency, hypermagnesaemia, hypercalcaemia and alkalosis which may give rise to gastrointestinal symptoms (nausea, vomiting, constipation) and muscular weakness. In these cases, the intake of the product should be stopped, and adequate fluid intake encouraged. In severe cases of overdosage (e.g. milk-alkali syndrome), a health care professional must be consulted because other measures of rehydration (e.g. infusions) might be necessary.

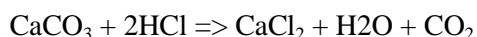
5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antacids

ATC code: A02AD01

Calcium and magnesium carbonate react with excess acid in the gastric juice to produce soluble chlorides



Calcium carbonate has a rapid and powerful neutralising action. This effect is increased by the addition of magnesium carbonate which also has a strong neutralising action.

In healthy volunteers, a significant increase in the pH of stomach contents above baseline pH was achieved between 1 and 6 minutes after dosing.

5.2 Pharmacokinetic properties

A small amount of calcium and magnesium may be absorbed, but in healthy subjects is usually rapidly excreted by the kidney. The soluble chlorides produced by the reaction of calcium and magnesium with gastric acid react, in turn, with intestinal, biliary and pancreatic secretions to form insoluble salts, which are excreted in the faeces.

5.3 Preclinical safety data

There is no information of relevance to the safety assessment in addition to what is stated in other parts of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Silica, colloidal anhydrous

Starch, pregelatinised

Copovidone

Xylitol (E 967)

Low-substituted hydroxypropylcellulose LH-11

Spearmint Flavour SD consists of:

Flavouring preparation(s)

Natural flavouring substance(s) - pulegone, menthofuran;

Maltodextrin

Gum arabic (E 414)

Menthol L flavour spraydried consists of:

Flavouring substance(s)

Gum arabic (E 414)

Talc

Magnesium stearate

6.2 Incompatibilities

None.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in the original package in order to protect from moisture. This medicinal product does not require any special temperature storage conditions.

6.5 Nature and contents of container

The tablets are packed in push-through PVC/PVDC/Al blister, each contains 8 tablets.

The cardboard box contains 16, 24, 48, 64 or 96 chewable tablets and a leaflet inside.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

ALKALOID-INT d.o.o.

Šlandrova ulica 4

Ljubljana-Črnuče, 1231, Slovenia

8 MARKETING AUTHORISATION NUMBER(S)

PL 34088/0046

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

04/10/2022

10 DATE OF REVISION OF THE TEXT

03/01/2024