SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

GAZIM X

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

SIMETHICONE 125 MG

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablets for oral administration.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Antiflatulence.

4.2. Posology and method of administration

For oral administration:

The generally accepted dosage is:

For adults and children over 12 years of age: 1-2 tablets after meals or at bedtime as necessary. Do not take more than 4 tablets in 24 hours.

Do not exceed the stated dose.

Children under 12 years of age: Not recommended.

4.3. Contraindications

Hypersensitivity to the active substance or any of its excipients listed in section 6.1.

4.4. Special warnings and precautions for use

This medicinal product contains Dextrates (purified mixture of saccharides). Patients with rare glucose-galactose malabsorption should not take this medicine.

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

Levothyroxine may bind to simeticone. Absorption of levothyroxine may be impaired if Gazim X are given concurrently to infants treated for thyroid disorders.

4.6. Pregnancy and lactation

As simeticone is not absorbed, it is not anticipated that Gazim X will have any adverse effects on pregnancy and lactation. However, as with all drugs, caution should be exercised in these conditions.

4.7. Effects on ability to drive and use machines

None stated.

4.8. Undesirable effects

Minor adverse effects: nausea and constipation.

Rarely, hypersensitivity reactions such as rash, pruritis, facial oedema, tongue oedema and respiratory difficulty have been reported.

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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il/

4.9. Overdose

No cases of overdose have been reported. Theoretically, constipation may occur. Treat with fluids and keep under observation.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Gazim X contain simeticone, a chemically inert gastric defoaming agent which alters the elasticity of interfaces of mucous-embedded bubbles in the gastro-intestinal tract. The gas bubbles are thus broken or coalesced and in this form, the gas is more easily eliminated through belching or passing flatus.

5.2. Pharmacokinetic properties

Simeticone is not absorbed from the gastrointestinal tract and does not interfere with gastric secretion or absorption of nutrients. Following oral administration, it is excreted unchanged in the faeces.

5.3. Preclinical safety data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tribasic calcium phosphate, Dextrates, Microcrystalline cellulose, Sodium starch glycolate, Magnesium stearate, Colloidal silicon dioxide, FD&C blue no.1 lake

6.2 Incompatibilities

None known.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

Shelf life after first opening: 2 months

6.4 Special precautions for storage

Store below 25^{o}C in original package.

6.5 Nature and contents of container

Glass bottle containing 30 light, scored, blue oval tablets

7. MARKETING AUTHORISATION HOLDER

CTS CHEMICAL INDUSTRIES LTD

3 HAKIDMA ST., KIRYAT MALACHI 83057

8. MARKETING AUTHORISATION NUMBER

131-13-30853-00

Version 09/2021 according to the MOH guidelines.