SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

CARBOSYLANE, capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Activated charcoal ..... 140 mg
Simethicone ..... 45 mg
For one blue or red capsule

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules.

4. CLINICAL DATA

4.1. Therapeutic indications

Anti-flatulent, for symptomatic treatment of stomach ache resulting from accumulation of gas, relief of sensation of fullness, meteorism, bloating and flatulence.

4.2. Posology and method of administration

Posology

Restricted for adults and children over 6 years old.

The usual posology is 3 dosage forms per day (i.e. one blue capsule and one red capsule 3 times a day to be taken before meals with a glass of water).

Method of administration

Oral route.

One dosage unit (a gastrosoluble blue capsule and a gastroresistant red capsule to be taken simultaneously with a glass of water before meals.

Duration of treatment

The usual duration of treatment is of 10 days.

4.3. Contraindications

Hypersensitivity to the active substances or to one of excipients mentioned in the section 6.1.
Children under 6 years old (risk of choking).

4.4. Special warnings and precautions for use

In case of a concomitant treatment, take CARBOSYLANE remotely (more than 2 hours, if possible).

If the symptoms persist or worsen or if constipation is prolonged, the patient is advised to take medical advice.

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

Due to the properties of the charcoal, the possible reduction of the absorption of drugs **makes any other medication be administered remotely from CARBOSYLANE (more than 2 hours if necessary).**

4.6. Fertility, pregnancy and breast-feeding

Pregnancy
No teratogenicity study is available in animals.

In clinical use, the use of charcoal does not seem to have revealed any malformative or fœtotoxic effect up to date. However, epidemiological studies are required to confirm that there is no risk. Consequently, and due to no resorption of charcoal, the use of this drug should not be envisaged during pregnancy unless necessary.

Breast-feeding
This medicine may be prescribed during breast-feeding.

Fertility

The effect on human fertility has not been studied.

4.7. Effects on ability to drive and use machines

Not applicable

4.8. Undesirable effects

The use of high dose levels of this medicine can result in dark colouration of the stools.

The following table presents the adverse reactions reported during the use of CARBOSYLANE® in clinical trials and while marketed. Adverse reactions are classified by organ system and frequency using the following convention: very frequent (1/10), frequent (1/100 to 1/10), infrequent (1/1,000 to 1/100), rare (1/10,000 to 1/1,000), very rare (1/10,000), indeterminate frequency (cannot be estimated on the basis of available data).

	Adverse Reactions			
System Class Organ	***Frequent***	***Uncommon***	***Rare***	***Undetermined frequency***
Skin and subcutaneous tissue disorders				*Urticaria*
Immune system disorders				*Anaphylactic-like allergic reaction*
Gastro-intestinal conditions				*Pain, vomiting, discomfort, constipation or diarrhea*

Reporting of suspected undesirable effects

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/
Side effects can also be reported to the following email: safety@trima.co.il

4.9. Overdose

Not relevant

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic class: ANTIFLATULENT/ INTESTINAL ADSORBENT (A: digestive system and metabolism), ATC code: A07BA51

Carbosylane combines 2 active ingredients:
- charcoal, which has adsorbing properties,
- simethicone, a physiologically inert substance, which has no pharmacological activity and acts by altering the surface tension of the bubbles of gas, thus causing them to coalesce.

5.2. Pharmacokinetic properties

The twin capsules that constitute a dosage unit of this medicine both contain the same active ingredients: activated charcoal and simethicone.

This medicine acts at two complementary levels; the blue capsule releases its active ingredients in the stomach, whereas the red capsule dissolves in the intestine.

Neither of both active ingredients of this medicine is resorbed by the gastrointestinal mucosa.

5.3. Preclinical safety data

No information is available

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

blue capsule (acts in the stomach):
gelatin, sorbitan oleate, polysorbate 80, titanium dioxide, indogotin.

red capsule (acts in the intestine):
gelatin, sorbitan oleate, cellulose acetate phthalate, polysorbate 80, diethyl phthalate, erythrosine, titanium dioxide, indigotin.

6.2. Incompatibilities

Not relevant

6.3. Shelf life

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

6.4. Special precautions for storage

Store below 25°C.

6.5. Nature and contents of container

24 blue capsules + 24 red capsules in blister (PVC/Aluminium).

6.6. Special precautions for disposal and handling

Any unused medicinal product or waste material should be disposed of in accordance with current .

7. MUNUFACTURER

Laboratoires Grimberg ,44 avenue Georges Pompidou, 92300 Levallois-Perret, France.

8. MARKETING AUTHORISATION HOLDER-

Trima, Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

9. MARKETING AUTHORISATION NUMBER(S)

134-82-21600-07