SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

EUCARBON

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet contains:	Senna folium	105 mg
	Rhubarb	25 mg
	Medicinal charcoal	180 mg
	Purified sulfur	50 mg

Excipient with known effect:
Each tablet contains 43.4 mg of sucrose.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Black, round tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Mild laxative, anti-flatulent**.**

4.2 Posology and method of administration

Posology
Adolescents over 12 years of age, adults, elderly
1-2 tablets with or after meals with liquid up to 3 times daily to obtain a laxative and purgative effect. If a stronger laxative effect is desired, the evening dose can be increased to 3-4 tablets of the product.
Herbal substance/preparation corresponding to 2.65 to 3.95 mg of hydroxyanthracene glycosides (calculated as Rhein) in one tablet.
The maximum daily dose of hydroxyanthracene glycosides is 30 mg. This is equivalent to 8 tablets. The correct individual dose is the smallest required to produce a comfortable soft-formed motion.

Paediatric population
The use in children under 12 years of age is contraindicated (see section 4.3 Contraindications).

Method of administration
For oral use.

Duration of use
Use for more than 1-2 weeks requires medical supervision.

If the symptoms persist during the use of the medicinal product, a doctor or a pharmacist should be consulted. See also section 4.4 Special warnings and precautions for use.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.
Intestinal obstruction, acute inflammatory diseases of the intestine, abdominal pain of unknown origin.
Severe disorders of water and electrolyte balance.
Pregnancy and lactation (see section 4.6 and 5.3).
Children under 12 years of age.

4.4 Special warnings and precautions for use

The dose necessary for a safe effect can vary individually. The occurrence of diarrhoea is a sign of overdose.

Not suitable as a slimming agent.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-

isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

In the event of EUCARBON-induced hypokalaemia, the effect of cardiac glycosides is increased.

4.6 Fertility, pregnancy and lactation

EUCARBON must not be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

At the recommended dosage, side effects are very rare (abdominal pain and diarrhoea).
A faint red colouring of the urine can occasionally be observed on an alkaline reaction and is without clinical significance.
CNS-related nausea and vomiting have been described with anthraquinone laxatives; this can also not be excluded with senna and rhubarb.
When used at high doses over a long period, electrolyte losses can occur, particularly of potassium, which can increase the sluggish intestinal transit still further (intestinal atony and constipation).

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 event

should be reported to the Ministry of Health according to the National Regulatory by using an online form: https://sideeffects.health.gov.il

4.9 Overdose

The occurrence of diarrhoea is a sign of overdosage and either the medicinal product should be discontinued or the dosage reduced.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Contact laxatives, ATC code: A06AB06

EUCARBON contains plant and mineral active substances only. Its mildly laxative, antiflatulent effect (adjuvant support by the ethereal oil content) is due to the capacity of charcoal to bind various toxic substances and to eliminate them via the laxative effect of senna leaf and rhubarb extract. EUCARBON also has a slightly disinfectant effect in the digestive tract.
For the laxative effect by anthraquinone glycosides from senna leaf and rhubarb extract, a total of 15-30 mg sennosides (A and B) must usually be taken. As the content of sennosides in EUCARBON tablets is relatively low, the dosage for the treatment of various forms of constipation can be adjusted simply and individually by observing the stool consistency.

The laxative effect begins about 8 - 10 hours after taking EUCARBON tablets.

5.2 Pharmacokinetic properties

No special studies with EUCARBON tablets have been conducted.

5.3 Preclinical safety data

A preliminary acute toxicity study in rats showed that after administration of 6-12 EUCARBON tablets/kg of body weight – via a gastric tube – no unexpected reactions occurred other than the anticipated laxative effects. None of the 10 animals studied died.
The data are supported by decades of use during which no serious side effects have been observed.

There are no preclinical data available for senna leaves or preparations thereof. It can be assumed that data obtained with senna pods can be transferred to senna leaf preparations.

Senna pods, extracts thereof and several hydroxyl anthracene derivatives (except sennosides, rhein and sennidins) were mutagenic and genotoxic in several *in vitro* test systems. However, for senna and aloe-emodin this was not proven in *in vivo* systems.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Sucrose
Talc
Heavy kaolin

Gum acacia
Peppermint oil
Fennel oil

6.2 Incompatibilities

Not applicable.

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

PVC-aluminium blister x 10, 30, and 100 tablets.

6.6 Special precautions for disposal and other handling

For oral administration.

7. MARKETING AUTHORISATION HOLDER

Trupharm Marketing 1985, P.O.B. 8105, Netanya, Israel

8. MARKETING AUTHORISATION NUMBER

120-36-25951-00

9. MANUFACTURER

F. Trenka Chem-Pharm Fabric GmbH.
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10. DATE OF REVISION OF THE TEXT

Revised in August 2022 according to MOH guidelines.

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