SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

EUCARBON Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet contains:	Senna leaf	105 mg
	Rhubarb extract	25 mg
	Powdered charcoal	180 mg
	Purified sulphur	50 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Grey-black, non-coated tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Sluggish intestinal transit
- All forms of constipation
- In decomposition and fermentation processes of the small intestine
- Meteorism (elevation of diaphragm)
- Flatulence
- Intestinal auto-intoxication
- Haemorrhoidal constipation

4.2 Posology and method of administration

Take the tablets with a large amount of fluid at or after meals: adults and children over 12 years of age: 1 - 2 tables up to 3 times daily to obtain a mild laxative and purgative effect. If a stronger laxative effect is desired, the evening dose can be increased to 3 – 4 tablets of EUCARBON.

For intensive cleansing and elimination of gas from the digestive tract (e.g. before X-ray examinations, i.v. pyelography, etc.): 6 - 8 tablets EUCARBON in the evening. (Drink large amounts of fluid afterwards).
A reduction in effect can occur with long-term, uninterrupted 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.

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. Healthcare professionals are asked to report any suspected adverse reactions via ADR Reporting, Website:
www.medicinesauthority.gov.mt/adrportal

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 15-30mg 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

Mint oil, sucrose, gum Arabic, kaolin, talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

60 months

6.4 Special precautions for storage

Do not store above 25°C. Store in the original container in order to protect from light.

6.5 Nature and contents of container

PVC-aluminium blister x10, 30, 50, 100 and 500 tablets

6.6 Special precautions for disposal and other handling

For oral administration.

7. MARKETING AUTHORISATION HOLDER

F. Trenka chem.- pharm. Fabrik GmbH, Prinz-Eugen-Straße 70, 1040 Vienna, Austria

8. MARKETING AUTHORISATION NUMBER

MA193/00101

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24th November 2005 / 22nd November 2011

10. DATE OF REVISION OF THE TEXT

April 2024

LEGAL CATEGORY

Non-prescription, pharmacy-only medicine