PACKAGE LEAFLET: INFORMATION FOR THE USER

Eucarbon Tablets

Senna leaf Rhubarb root extract Vegetable charcoal Purified sulphur

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Eucarbon Tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen, or do not improve after a few days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- 1. What Eucarbon Tablets are and what they are used for.
- 2. Before you take Eucarbon Tablets.
- 3. How to take Eucarbon Tablets
- 4. Possible side effects.
- 5. How to store Eucarbon Tablets
- 6. Further information.

1. WHAT EUCARBON TABLETS ARE AND WHAT THEY ARE USED FOR

Eucarbon Tablets are used for the short-term relief of occasional constipation

Eucarbon Tablets do not help with weight loss.

The laxative effect of Eucarbon Tablets takes place approximately 8-12 hours after taking the product.

2. BEFORE YOU TAKE EUCARBON TABLETS

Do not take Eucarbon Tablets

• if you are allergic (hypersensitive) to Senna leaf, Rhubarb, vegetable charcoal, purified sulphur or any other ingredients of Eucarbon Tablets.

• If you have blockage or narrowing of the gastro-intestinal tract or bowel (ileus, intestinal obstruction or stenosis)

• If you have paralysis or lack of muscle tone in the bowel (atony)

• If you have appendicitis, inflammatory bowel disease such as Crohn's disease or ulcerative colitis

- If you have severe dehydration
- If you have persistent or undiagnosed abdominal complaints e.g. pain, nausea or vomiting

• If you have faecal impaction or rectal bleeding for which you don't know the cause, or have blood in your stools

- If you have already taken a laxative and you are still constipated
- If you have had a sudden change in bowel habit that has lasted for more than 2 weeks
- if you have kidney or heart failure

• if you are under 12 years of age

Consult your doctor, before taking this medicine:

• if you suffer from kidney disorders

• if you are taking medicines for a heart condition (e.g. cardiac glycosides, antiarrhythmic medicines e.g. quinidine), medicines inducing QT prolongation, diuretics, corticosteroids or liquorice root preparations

Taking other medicines:

You should consult your doctor or pharmacist for advice if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and Breastfeeding:

You should not use Eucarbon Tablets if you are pregnant or breastfeeding because there is no evidence that it is safe to do so.

Eucarbon Tablets is not a suitable slimming aid.

Taking Eucarbon Tablets with food and drink

Eucarbon Tablets can be taken during or after meals.

Important information about some of the ingredients of Eucarbon Tablets

One tablet contains 43.4 mg of sugar (sucrose). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE EUCARBON TABLETS

Always take Eucarbon Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

For oral use:

Adults, the elderly & children over 12 years:

Unless otherwise prescribed by the doctor, the usual dose is 1-2 tablets up to 3 times a day, during or after meals. The dosage necessary to obtain the desired effect may vary according to each person. For a stronger laxative effect, the dose may be increased up to 3 - 4 tablets in the evening.

The maximum daily dose is 8 tablets **Do not exceed the stated dose**

Eucarbon Tablets should be taken with an ample amount of liquid (at least one glass of water).

Use for more than 1 - 2 weeks requires medical supervision. Consult your doctor after taking this medicine:

- If symptoms worsen or persist
- if there is no bowel movement after 3 days and laxatives are needed every day
- if abdominal pain persists

If you take too much Eucarbon Tablets

It may be harmful to

- Take too much Eucarbon Tablets or
- Take Eucarbon Tablets for too long

This is because taking too much for too long may lead to:

- A "lazy bowel", where the muscle in the bowel becomes too relaxed. This means that bowel emptying happens less often. This can lead to long-term constipation.
- Imbalance of fluid and salts in the body. This can affect the tightness of muscles such as those in the bowel. It can also affect the salts in the blood.
- Low levels of potassium in the blood (called 'hypo-kalaemia'). This can make you tired, dizzy, make your muscles weak and cause an uneven heart-beat.
- Dehydration, making you thirsty, feel faint and giving you headaches. It can also mean you cannot pass enough urine.

If you take more Eucarbon Tablets than you should

Diarrhoea may be a sign of over dosage. In this case reduce the dose or discontinue use. If you feel unwell, consult your doctor.

If you forget to take Eucarbon Tablets

Take the next dose when it's due. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Eucarbon Tablets can cause side effects, although not everybody gets them.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

• abdominal pain, spasms and diarrhoea may occur, in particular in patients with irritable colon.

• chronic use may lead to albuminuria and haematuria which is albumin or red blood cells in the urine

• chronic use may cause pigmentation of the gastrointestinal tract which usually recedes when the product is no longer taken

• yellow or red-brown discolouration of urine may occur during the treatment, but is harmless

• allergic reactions such as local or more widespread, skin rash, hives (skin bumps) or itchiness around the anus. The frequency is not known.

Reporting of adverse effects

If you get any side-effects, talk to your doctor, pharmacist or nurse. This includes any possible side-effects not listed in this leaflet. You can also report side-effects directly via the Yellow Card Scheme at: <u>www.mhra.gov.uk/yellowcard</u>. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE EUCARBON TABLETS

- Keep out of reach and sight of children.
- Store in the original package, in order to protect the medicinal product from light.
- Do not use Eucarbon Tablets after the expiry date which is stated on the outer carton. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Eucarbon Tablets contains:

Each tablet contains: 105 mg of Senna leaf (*Cassia senna* L. (*C. acutifolia* Delile) and/or *Cassia angustifolia* Vahl,) 25 mg of extract (as dry extract) from Rhubarb root (*Rheum palmatum* L. or *Rheum officinale* Baillon, or hybrids of these two species or a mixture) (3- 5: 1) Extraction solvent : Ethanol 70% v/v Corresponding to 2.65-3.95 mg of hydroxyanthracene glycosides (calculated as Rhein) 180 mg of Vegetable Charcoal. 50 mg of purified Sulfur

The other ingredients are: sucrose, maize starch Heavy Kaolin (bolus alba), talc, gum Arabic, fennel oil, peppermint oil.

What Eucarbon Tablets looks like and contents of the pack:

Grey-black, non-coated tablets without a breaking crease, in packs of 20, 30 and 100 tablets. Not all pack size may be marketed.

Marketing Authorisation Holder and Manufacturer

F.TRENKA, Chem.-pharm. Fabrik Ges.m.b.H: Goldeggasse 5 A-1040 vienna Tel: +43 1 505 03 41 – 0 Fax: +43 1 505 03 41 – 31 E-mail: <u>office@eucarbon.at</u>

This leaflet was last revised May 2015