Approved Package Insert: EUCARBON TABLETS

SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM

EUCARBON Tablets

COMPOSITION

Each tablet contains:

Vegetable Charcoal (carbo ligni plv.) 180 mg

Rhubarb dry extract 25 mg

Senna folium powder 105 mg

Excipients:

Acacia, fennel oil, peppermint oil, heavy kaolin, starch, sucrose and talc.

Contains sugar (sucrose).

PHARMACOLOGICAL CLASSIFICATION

A 11.6 Lubricants and faecal softeners.

PHARMACOLOGICAL ACTION

The properties of this product are traditionally being attributed to the plant material it contains.

INDICATIONS

Eucarbon is a traditional remedy for the symptomatic relief of constipation as a stool softener.

CONTRAINDICATIONS

Intestinal obstruction or undiagnosed abdominal symptoms.

WARNINGS AND SPECIAL PRECAUTIONS

This medicine should not be used in the presence of abdominal pain, nausea or vomiting. Frequent or prolonged use of this preparation may result in dependence.

If you have noticed a sudden change in bowel habits that has persisted for a period of greater than 2 weeks, consult your doctor before use.

Care should be taken in patients with inflammatory bowel disease.

Non-activated charcoal is relatively non-toxic when given by mouth but gastrointestinal disturbances such as vomiting and constipation have been reported. It may colour the faeces black

Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrose-isomeltase insufficiency should not take **EUCARBON.**

INTERACTIONS

Non-activated charcoal diminished the action of ipecacuanha and other emetics when given concomitantly by mouth. If indicated, emesis should be induced before non-activated charcoal is administered.

Non-activated charcoal has the potential to reduce the absorption of many drugs from the gastrointestinal tract and simultaneous oral therapy should therefore be avoided.

PREGNANCY AND LACTATION

The safety of this preparation in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Adults and elderly: 1 – 2 tablets at or after meals with some liquid. Where a stronger effect is desired, the evening dose should be 3 or 4 tablets.

Children: Not recommended.

If the recommended use of this product for 1 week has no effect, discontinue use and consult a doctor.

SIDE EFFECTS

Senna and rhubarb may cause abdominal discomfort such as colic or cramps.

Discoloration of the urine may occur with anthraquinone derivatives.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Prolonged use or overdosage with senna or rhubarb can result in diarrhoea with excessive loss of water and electrolytes, particularly potassium. There is also the possibility of developing an atonic non-functioning colon.

Treatment is symptomatic and supportive.

IDENTIFICATION

Biconvex, charcoal coloured tablets with a slight peppermint/fennel odour and a slightly sweet peppermint/fennel taste.

PRESENTATION

Tablets are blister packed in 1 x 10, 3 x 10, 5 x 10 or 10 x 10 tablets and packed in a carton.

STORAGE INSTRUCTIONS

Store at or below 25 °C in a dry place.

Keep blister in carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

Z/11.6/393

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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DATE OF PUBLICATION OF THE PACKAGE INSERT

Date on the registration certificate of the medicine: 26 May 1993