**INSTRUCTION LEAFLET**

for medical use of the medicinal product

**Eucabal®**

**Product licence number:**П N003014/01

**Brand name:** Eucabal ®

**Generic name:** Plantain extract liquid + Thyme extract liquid

**Pharmaceutical form:** syrup

**Product formulation:**

100 g of the syrup contain:

*active ingredients:* plantain extract liquid (1: 2-2.5) - 3.00 g (extractant: ethanol 44.7% (V / V)), thyme extract liquid (1: 2-2.5) - 15, 00 g (extractant: ammonia solution 10% (m / m): glycerin 85%: ethanol 90% (V / V): water (1: 20: 70: 109));

*excipients:* methyl parahydroxybenzoate - 0.07 g, propyl parahydroxybenzoate - 0.03 g, invert sugar solution - 81.90 g (glucose - 19.8 g, fructose - 19.8 g, sucrose - 19.8 g, purified water - 22 , 5 d).

*Description:* a transparent or slightly turbid liquid of dark brown color with a characteristic odor. A slight sediment or turbidity may form during storage.

**Pharmacotherapeutic group:** herbal expectorant.

**ATC code:** R05CA10

**Pharmacological properties:** the drug has an expectorant, anti-inflammatory effect.

**Indications**

As part of the complex therapy of inflammatory diseases of the upper respiratory tract, accompanied by a cough with difficult sputum (tracheitis, bronchitis, tracheobronchitis), as well as spastic cough.

**Contra-indications**

- individual intolerance to the components of the drug (in the presence of hypersensitivity to plantain, thyme, or other plants of the labiate family and the components of methyl parahydroxybenzoate and propyl parahydroxybenzoate);
- deficiency of sucrase / isomaltase, fructose intolerance, glucose-galactose malabsorption;
- liver disease, alcoholism, epilepsy, traumatic brain injury (due to the possible negative effect of ethanol);
- pregnancy and the period of breastfeeding (due to the possible negative effects of ethanol);
- children's age up to 1 year (due to the possible negative effect of ethanol).

**Carefully**

The drug should be prescribed with caution to children from 1 year old, because of the possible negative effect of ethanol (there is not enough research on the use of this drug for the treatment of children), patients with diabetes mellitus and people on a diet low in carbohydrates.

**Administration during pregnancy and breast-feeding period**

The use of the drug is contraindicated during pregnancy and during breast-feeding.

**Posology and method of administration**

Orally. The syrup should be taken undiluted after meals, shake well before use.

In the absence of other prescriptions, the following dosage is recommended:

*Children 1 - 5 years old:* 1 teaspoon (5 ml) 3 times a day.

*Children 6 - 12 years old:* 1 teaspoon (5 ml) 5 times a day.

*Adults and children over 12 years old:* 1 dessert spoon (10 ml) 3-5 times a day.

The duration of the drug intake is determined by the attending physician, depending on the severity of the disease. Without a doctor's prescription, the drug can be used for no more than 1 week; it is recommended to take the drug for another 2-3 days after the symptoms of the disease disappear.

If the symptoms of the disease persist for more than 1 week or if shortness of breath, fever or purulent sputum or sputum streaked or blood clots appear, you should immediately consult a doctor.

If you miss one or more doses of a drug, you should not take a double dose of the drug.

**Adverse drug reaction**

According to the World Health Organization (WHO), unwanted effects are classified according to their frequency of development as follows: very often (≥ 1/10), often (≥ 1/100, <1 / 10), infrequently (≥ 1/1000, < 1/100), rarely (≥ 1/10000, <1 / 1000) and very rarely (< 1/10000); the frequency is unknown (the frequency of occurrence of the events cannot be determined from the available data).

*Allergic reactions are very rare* (including due to the content of alkyl parahydroxybenzoates in the drug).

*Regarding the gastrointestinal tract:*

*Very rare* - abdominal pain, nausea, vomiting, diarrhea.

*Regarding the immune system:*

*Very rare* - hypersensitivity reactions, including angioedema, skin rashes, urticaria, pruritus.

The drug can have a negative effect on teeth (caries).

If side effects appear, the use of the drug should be discontinued and the attending physician should be consulted.

**Overdosage**

When using the drug in doses exceeding the recommended ones, dose-dependent side effects may increase. Treatment is symptomatic.

**Interaction with other medicinal products**

Due to the ethanol content, the drug enhances the action of sedatives, hypnotics and other drugs that depress the central nervous system.

The simultaneous appointment of antitussive drugs is not recommended, due to the difficulty in the discharge of secreted sputum.

**Precaution**

The drug contains ethyl alcohol 8.1% (volume in percent).

Subject to the dosage instructions, at each dose of the drug, adults and children over 12 years old will consume up to 0.64 g of absolute ethyl alcohol in the maximum single dose of the drug (10 ml) and up to 3.2 g of absolute ethyl alcohol in the maximum daily dose of the drug (50 ml); children 6 - 12 years old - up to 0.32 g of absolute ethyl alcohol in the maximum single dose of the drug (5 ml) and up to 1.6 g of absolute ethyl alcohol in the maximum daily dose of the drug (25 ml); children 1 - 5 years old - up to 0.32 g of absolute ethyl alcohol in the maximum single dose of the drug (5 ml) and up to 0.96 g of absolute ethyl alcohol in the maximum daily dose of the drug (15 ml).

The drug contains a solution of invert sugar: 1 teaspoon of the drug contains 3.8 g of a mixture of fructose and glucose, which corresponds to 0.316 XE, in 1 dessert spoon - 7.6 g of the mixture, which corresponds to 0.632 XE. This information should be taken into account by persons suffering from diabetes mellitus and who are on a diet low in carbohydrates.

**Effects on ability to drive and use machines**

When using the drug, it is not recommended to perform hazardous activities that require an increased concentration of attention and speed of psychomotor reactions (including driving, working with moving mechanisms).

**Pharmaceutical form and presentation**

Syrup.

100 ml or 250 ml of the drug in a dark glass bottle equipped with a plastic divider and a plastic screw cap. One bottle in a cardboard box along with instructions for use.

**Storage conditions**

Store at a temperature not higher than 25ºC.

Keep out of reach of young children.

**Expiry date**

3 years.

After opening the bottle, use the drug within 12 weeks.

Do not use after the expiry date.

**Dispensing requirements**

No prescription.

**Marketing authorization holder:**

Esparma GmbH, Bielefelderstrasse 1, 39171 Sulcetal, Germany.
Manufactured by: Pharma Wernigerode GmbH, Dornbergsweg 35, 38855 Wernigerode, Germany.

**Organization accepting complaints from consumers:**

**Representative office of the company "EsparmaGmbH" (Germany) in Moscow:**

Letnikovskaya street, 16, 6th floor, room 21/1, 23-27, 115114, Moscow,

tel.: +7 (499) 579 33 70

fax: +7 (499) 579 33 71

e-mail: info@esparma-gmbh.ru