

INSTRUCTION
for use of medical product

Eucabal® Balsam S

Registration number: П N016297/01

Trade name of medical product:

Eucabal® Balsam S

Group name:

Common pine needles oil + Eucalyptus leaves oil

Dosage form

Emulsion for inhalations and external use

Composition

100 gm of emulsion contain:

Active substances:

Eucalyptus leaves oil – 10.0 gm

Common pine needles oil - 3.0 gm

Excipients: cetostearyl alcohol [cetyl alcohol 60 %, stearyl alcohol 40 %] – 4.50 gm, glyceryl monostearate – 3.00 gm, macrogol stearate 400 – 2.00 gm, sodium cetylstearylsulfate – 0.50 gm, trometamol – 0.61 gm, citric acid monohydrate – 0.39 gm, guayazulen – 0.05 gm, purified water – 75.95 gm.

Description

Light blue emulsion with odor of eucalyptus oil.

Pharmacotherapeutic group

Expectorant drug of plant origin.

ATC code: R05CA10

Pharmacological action

Medical product shows expectorant, antiinflammatory action. Intended for local use in case of upper respiratory airway infections.

Indications for use

Is used in case of complex therapy of upper respiratory airway infections (bronchitis, inflammations of nose and pharynx mucous).

Contraindications

Hypersensitivity to components of medical product, bronchial asthma, pertussis, false croup, hypersensitivity of respiratory airways.

For inhalation – children below 5 years.

For baths and chirapsia – children below 2 months.

Do not use medical product for chirapsia of face area (especially nose) for children below 2 years.

Do not use medical product for chirapsia in case of damages of skin covers, presence of skin illnesses in the areas of intended use, do not apply onto mucous membranes.

Contraindications for baths: non-compensated coronary heart diseases (arterial hypertension, heart failure, arrhythmia, angina pectoris), body temperature rise (above 38 °C) in case of infection diseases.

Administration during pregnancy and breast-feeding period

Therapeutic experience of medical product during pregnancy is absent. During breast-feeding period do not apply medical product onto skin.

Posology and method of administration

For chirapsia:

In case of absence of other prescriptions it is recommended to apply 2-3 times a day band of emulsion with length about 3-5 cm (adults and children above 12 years), about 3-4 cm (children between 2 and 11 years) onto chest skin and interscapular region and spread thoroughly.

For children between 2 months and 2 years it is recommended to apply band of emulsion with length 2-3 cm only onto interscapular region and spread thoroughly.

For steam inhalations:

In case of absence of other prescriptions it is recommended to apply 2-3 times a day band of emulsion with length about 4-6 cm (adults and children above 12 years), about 4 cm (children between 5 and 11 years) add in 1-2 L of hot water, mix and breath steam under towel.

For baths (mainly use for children between 2 months and 2 years):

Add band of emulsion with length about 8-10 cm to 20 L of water with temperature 36-37 °C (for children at the age of 2 months), or two bands of emulsion with length 10 cm - in 40 L (for children at the age of 2 years), wash children for about 10 minutes. Repeat baths until full disappearance of illness symptoms. Baths can be used for a week 3-4 times. Besides, in case of need, spread emulsion 2-3 times a day into chest skin and interscapular region. In case of such actions for children bed rest is recommended.

Side effects

In system-organ classes the following categories are used based on frequency of appearance of side effects: very frequent ($\geq 1/10$); frequent ($\geq 1/100, <1/10$); non-frequent ($\geq 1/1,000, <1/100$); rare ($\geq 1/10,000, <1/1,000$); very rare ($<1/10,000$).

Rare allergic reactions, contact eczema, irritating cough, bronchospasm strengthening are possible. Very rare asphyxia.

In case of appearance of side effects stop use of medical product and consult to a doctor.

Overdosage

Cases of overdosage are not registered until now.

Drug-to-drug interaction

In case of simultaneous use with medical products, that are metabolized in liver, weakening of intensity or shortening of their action time is possible, since components of eucalyptus oil, which is included into medical product, stimulate liver enzyme systems.

Special warnings

Medical product is intended only for inhalations and external use!

In case of false oral use development of dizziness, vomiting, diarrhea are possible. In especially hard cases headache, dizziness, impaired judgement, convulsions, asphyxia, circulation failure, blood in urine are possible. In case of appearance of the stated symptoms it is necessary to stop treatment and consult to a doctor. In case of convulsions inject intravenously 5-10 mg of diazepam or us short-term barbiturates, or wash stomach (30 gm of sodium sulfate per 250 mL of water).

After use of medical product wash hands with soap thoroughly.

After bath do not use douche bath and rub with towel.

Avoid contact of medical product with eyes.

Water baths may be used only after consulting to a doctor.

Medical product does not influence doing potentially dangerous types of activity, that require especial attention and quick reactions (using machines and other transport machines, working with moving machinery, operator work, etc.)

Dosage form

Emulsion for inhalations and external use.

40 mL or 100 mL of medical product into aluminum tubes, with internal protective laquer covering and screw-on plastic cap with membrane punch. Place tube together with leaflet into carton box.

Storage conditions

At the temperature not more than 25 °C.

Keep out of reach of children.

Shelf life

3 years.

After opening of a vial use medical product for 8 weeks.

Do not use after expiration of shelf-life.

Prescription status

OTC.

Manufacturer

Esparma GmbH,

Bielefelder strasse 1, 39171 Suelzetal, Germany.

Manufactured:

Lichtenheldt GmbH Pharmazeutische Fabrik,

Industriestrasse 7-9, 23812 Wahlstedt, Germany.

Make customer claims to:

Representation of company «Esparma GmbH» (Germany) city Moscow:

115114, Moscow city, Letnikovskaya str., 16, floor 6, office 21/1, 23-27

tel.: +7 (499) 579-33-70

fax: +7 (499) 579-33-71

e-mail: info@esparma-gmbh.ru