

Package leaflet: Information for the patient

Aspecton[®] Eukaps 200 mg capsules, soft

Active substance: eucalyptus oil

For use in adults and adolescents from 12 years of age

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet

1. What Aspecton[®] Eukaps 200 mg is and what it is used for
2. What you need to know before you take Aspecton[®] Eukaps 200 mg
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1. What Aspecton[®] Eukaps 200 mg is and what it is used for

Aspecton[®] Eukaps 200 mg is a herbal medicine used to treat colds affecting the airways.

Aspecton[®] Eukaps 200 mg is used in people suffering from colds of the respiratory tracts with viscous mucus.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you take Aspecton[®] Eukaps 200 mg

Do not take Aspecton[®] Eukaps 200 mg:

- if you are allergic to eucalyptus oil (cineole, α -Pinene) or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from an inflammatory gastrointestinal disorder

- if you suffer from an inflammatory biliary tract disorder
- if you suffer from a severe liver disease
- if you suffer from asthma, pertussis, pseudocroup or other respiratory diseases with a marked hypersensitivity of the respiratory tract

Babies and infants under 2 years of age must not take Aspecton® Eukaps 200 mg.

Warnings and precautions

Talk to your doctor or pharmacist before taking Aspecton® Eukaps 200 mg.

Seek medical advice if your symptoms last more than three days or worsen or you experience shortness of breath, fever, purulent or bloody sputum.

Children

Studies in children aged 2 to 12 years are not available. Therefore, you should not apply Aspecton® Eukaps 200 mg in children of this age group.

Reports do exist on individual cases of apnoea in case of laryngismus with babies and infants after inhalation of eucalyptus oil (see section 2. „Do not take Aspecton® Eukaps 200 mg“).

Other medicines and Aspecton® Eukaps 200 mg

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

Medicines taken at the same may affect the effect of one another. Eucalyptus oil and its primary component cineole stimulate the enzyme system in the liver that breaks down foreign substances. Therefore, it cannot be ruled out that it might weaken and/or shorten the effect of other medicines. Cineole, which is the primary component of eucalyptus oil, is known to have such an effect on antiepileptic medications as well as soporifics and painkillers (barbiturates, pyrazolones).

Studies on Aspecton® Eukaps 200 mg regarding possible interactions are not available to date. Therefore therapy controls are carried out when co-administered with other drugs.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The safety and efficacy of this product has not been evaluated sufficiently during pregnancy and lactation period. Therefore, Aspecton® Eukaps 200 mg should not be ingested during pregnancy and lactation period.

Eucalyptus oil / cineole passes into breast milk.

Driving and using machines

No special precautions are necessary.

3. How to take Aspecton[®] Eukaps 200 mg

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Age	Single dose	Daily dose
Adults and adolescents from 12 years of age	1 soft capsule (equivalent to 200 mg eucalyptus oil)	2 to 3 soft capsules (equivalent to 400 - 600 mg eucalyptus oil)

Adults and children over 12 years of age take 1 capsule Aspecton[®] Eukaps 200 mg 2 - 3 times daily.

Method of administration

Aspecton[®] Eukaps 200 mg should be ingested without prior chewing during meals with plenty of liquid (e. g. with half a glass of water).

Talk to your doctor or pharmacist if you think that the effect of Aspecton[®] Eukaps 200 mg is too strong or too weak.

Duration of administration

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

If you take more Aspecton[®] Eukaps 200 mg than you should

When taking Aspecton[®] Eukaps 200 mg, please follow the maximum amount stated in the dosing instructions or the dose prescribed by your doctor. If you accidentally take one or two capsules too much, this usually does not result in any negative effects. However, significant issues (e.g. vomiting, abdominal pain, lightheadedness, trouble breathing) may develop if considerably more is taken. In such a case, contact your doctor even if no issues have arisen yet. This applies in particular if a small child has ingested a major amount of Aspecton[®] Eukaps 200 mg. In case of an overdose, do **not** drink milk or any alcohol. These drinks may increase the resorption of the active substances of Aspecton[®] Eukaps 200 mg into the blood.

If you forget to take Aspecton[®] Eukaps 200 mg

Do not take a double dose to make up for a forgotten dose.

If you have forgotten to take a capsule at the scheduled time, take the next capsule at the next scheduled time. You can also take the missed capsule if there are still a few hours between this and the next scheduled dose.

If you stop taking Aspecton[®] Eukaps 200 mg

Treatment with Aspecton[®] Eukaps 200 mg can be interrupted or continued at any time without any specific measures being required.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you are affected by one of the following side effects, stop taking Aspecton[®] Eukaps 200 mg and contact your doctor immediately.

Gastrointestinal disorders:

Nausea, vomiting and diarrhoea.

General disorders and administration site conditions:

Hypersensitivity reactions.

The frequency of side effects is not known.

In case of side effects, stop taking the product and consult your doctor.

Should you observe swelling in the face, mouth and/or pharynx or allergic respiratory reactions, acute respiratory distress, you should consult a doctor immediately.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Aspecton[®] Eukaps 200 mg

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister pack after "EXP". The expiry date refers to the last day of that month.

Storage conditions:

Do not store above 25 °C.

6. Contents of the pack and other information

What Aspecton[®] Eukaps 200 mg contains

The active substance is eucalyptus oil.

One soft gelatine capsule contains: 200 mg eucalyptus oil.

The other ingredients are:
gelatin polysuccinate, glycerol 85 %.

What Aspecton[®] Eukaps 200 mg looks like and contents of the pack

Aspecton[®] Eukaps 200 mg are oval, transparent, colourless soft capsules.

Aspecton[®] Eukaps 200 mg is available in packs of 20, 50 and 100 soft gelatine capsules.

Marketing Authorisation Holder and Manufacturer

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