

Package leaflet: Information for the patient

Aspecton[®] Eukaps 100 mg gastro-resistant 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 100 mg is and what it is used for
2. What you need to know before you take Aspecton[®] Eukaps 100 mg
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1. What Aspecton[®] Eukaps 100 mg is and what it is used for

Aspecton[®] Eukaps 100 mg is a herbal medicine used to treat colds affecting the airways.

Aspecton[®] Eukaps 100 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 100 mg

Do not take Aspecton[®] Eukaps 100 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.
- Children under 12 years of age must not take Aspecton[®] Eukaps 100 mg.

Warnings and precautions

Talk to your doctor or pharmacist before taking Aspecton[®] Eukaps 100 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.

Other medicines and Aspecton[®] Eukaps 100 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 100 mg regarding possible interactions are not available to date.

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 widespread use of eucalyptus oil as a flavouring and orientative animal studies have not yet produced any evidence to suggest risks during pregnancy and when breast-feeding. Out of general safety considerations, Aspecton[®] Eukaps 100 mg should, however, not be taken during the first trimester of pregnancy.

Driving and using machines

No special precautions are necessary.

3. How to take Aspecton[®] Eukaps 100 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.

Unless prescribed otherwise by your doctor, the recommended dose is:

Adults and children over 12 years of age take 1-2 capsules Aspecton[®] Eukaps 100 mg 3 times daily.

Method of administration

The capsules should be taken half an hour before a meal without chewing, with plenty of liquid (e.g. a glass of water), which, however, must not be warm.

Talk to your doctor or pharmacist if you think that the effect of Aspecton[®] Eukaps 100 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 100 mg than you should

When taking Aspecton[®] Eukaps 100 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 100 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 100 mg into the blood.

If you forget to take Aspecton[®] Eukaps 100 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 100 mg

Treatment with Aspecton[®] Eukaps 100 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.

The stated frequencies of the side effects are based on the following categories:

Very common: may affect more than 1 in 10 treated
Common: may affect 1 to 10 in 100 treated
Uncommon: may affect 1 to 10 in 1,000 treated

Rare: may affect 1 to 10 in 10,000 treated
Very rare: may affect less than 1 in 10,000 treated
Not known: cannot be estimated from the available data

Possible side effects:

Gastrointestinal disorders:

Rare: nausea, vomiting and diarrhoea.

General disorders and administration site conditions:

Rare: hypersensitivity reactions.

Countermeasures:

If you experience any of the side effects listed above, you should stop taking Aspecton® Eukaps 100 mg. Depending on the severity of the gastrointestinal disorder, you might need to consult a doctor.

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 100 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:

Store in a dry place. Do not store above 25 °C.

6. Contents of the pack and other information

What Aspecton® Eukaps 100 mg contains

The active substance is eucalyptus oil.

One capsule contains: 100 mg eucalyptus oil.

The other ingredients are:

medium-chain triglycerides, gelatin, glycerol 85 %, hydrochloric acid 25 %.

Film-coating:

methacrylic acid ethyl acrylate copolymer (1:1) (Ph. Eur.), macrogol (400), talc, simethicone, purified water.

What Aspecton[®] Eukaps 100 mg looks like and contents of the pack

Aspecton[®] Eukaps 100 mg are round soft gastro-resistant capsules with film-coating.

Aspecton[®] Eukaps 100 mg is available in packs of 20, 50 and 100 soft gastro-resistant capsules.

Marketing Authorisation Holder and Manufacturer

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Additional information:

This medicine does not contain any phthalates.