

Package leaflet: Information for the patient

Aspecton[®] Cough Drops

Oral liquid

Thyme soft extract

For adults and children aged 2 years and older

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 7 days.

What is in this leaflet

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1. What Aspecton[®] Cough Drops are and what they are used for

Aspecton[®] Cough Drops are a herbal medicine used to treat colds affecting the airways.

Aspecton[®] Cough Drops are used for relieving discomfort of colds of the respiratory tract with viscous mucus and for relieving discomfort with acute bronchitis.

You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

2. What you need to know before you take Aspecton[®] Cough Drops

Do not take Aspecton[®] Cough Drops:

- if you are allergic to thyme or other Lamiaceae, birch, mugwort, celery, menthol or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Seek medical advice if your symptoms last more than 1 week or you develop shortness of breath, fever, purulent or bloody sputum.

No adequate studies are available on the use of this medicine in children under 2 years of age. It should therefore not be used in children under 2 years of age.

Other medicines and Aspecton[®] Cough Drops

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

No interactions with other medicines have been reported to date.

Studies on Aspecton[®] Cough Drops regarding possible interactions with other medicines given at the same time are not available to date.

Aspecton[®] Cough Drops with food, drink and alcohol

No special precautions need to be taken.

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.

Since no adequate studies are available, Aspecton[®] Cough Drops should not be used during pregnancy and breastfeeding,.

Driving and using machines

No special precautions need to be taken.

3. How to take Aspecton[®] Cough Drops

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:

Adults and children aged 12 years and older	Three to four times daily between 31 and at most 61 drops
Children aged between 11 and 12 years	Three times daily 15 drops
Children aged between 5 and 10 years	Three to four times daily 10 drops
Children aged between 2 and 4 years	Two times daily 10 drops

Method of administration:

For oral use.

Aspecton[®] Cough Drops can be taken undiluted or in water. They can be taken with or without meals.

Duration of use:

The duration of treatment depends on the course of the disease and is to be determined by your doctor if required.

However, please in any case take note of the precautions listed in section 2 as well as the information under "Possible side effects".

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

If you take more Aspecton[®] Cough Drops than you should

No intoxications with Aspecton[®] Cough Drops have been reported to date. If you take more Aspecton[®] Cough Drops than you should, the symptoms described under "Possible side effects" may occur in a stronger form. In this case, please consult a doctor. The doctor can then decide which measures are to be taken, if any.

If you forget to take Aspecton[®] Cough Drops

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

If you stop taking Aspecton[®] Cough Drops

Interrupting or stopping treatment early is usually safe. If in doubt, please ask your doctor or pharmacist.

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.

Hypersensitivity reactions such as shortness of breath, skin rashes, hives as well as swelling in the face, mouth and/or throat can occur.

Stomach troubles such as cramps, nausea and vomiting may also occur.

The frequency of the side effects is unknown.

If side effects occur, the product should be discontinued and a doctor consulted. The doctor can then assess the severity and decide which measures are to be taken, if any. Aspecton[®] Cough Drops must not be taken again if there are any signs of a hypersensitivity reaction.

Menthol can trigger allergic reactions (including shortness of breath) in sensitised patients.

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[®] Cough Drops

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 label after "EXP". The expiry date refers to the last day of that month.

Storage conditions:

This medicinal product does not require any special storage conditions.

Shelf life after opening:

Aspecton[®] Cough Drops have a shelf life of 6 months after opening.

6. Contents of the pack and other information

What Aspecton[®] Cough Drops contain

10 ml liquid (1 ml equivalent to 27 drops) contain: 4.23 g thyme soft extract (1.7-2.5:1).

Extraction solvent: ammonia solution 10 % (m/m), glycerol 85 % (m/m), ethanol 90 % (V/V), water (1:20:70:109).

The other ingredients are:

glycerol 85 %, propylene glycol, star aniseed oil, eucalyptus oil, levomenthol.

Please note: Aspecton[®] Cough Drops do not contain alcohol (ethanol).

What Aspecton[®] Cough Drops look like and contents of the pack

Aspecton[®] Cough Drops are a brown to dark brown hazy solution.

Aspecton[®] Cough Drops are available in packs of 30 ml and 50 ml.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in June 2014.

Further information

Aspecton[®] Cough Drops are free of sugar and therefore suitable for diabetics (< 0.01 bread units per dose). Aspecton[®] Cough Drops are free of alcohol (ethanol) and therefore also suitable for patients who must avoid alcohol (ethanol).

Since the product contains herbal components, in rare instances Aspecton[®] Cough Drops may become hazy or a small sediment may form at the bottom of the bottle; however, this does not affect the effect of the medicine.

You would like to learn more about colds, their causes and treatment options?
Visit us at www.aspecton.de or send as a request for information by fax to +49 (0)2243 / 87-173.

Your specialists for colds at KrewelMeuselbach^{KM}