

PACKAGE LEAFLET: INFORMATION FOR THE USER

Aspecton[®] Cough Syrup

Thyme soft extract

For adults and children aged 1 year 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.
- You must talk to a doctor if you do not feel better or if you feel worse after seven days.

What is in this leaflet

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1. WHAT ASPECTON[®] COUGH SYRUP IS AND WHAT IT IS USED FOR

Aspecton[®] Cough Syrup is an herbal medicine for common cold ailments of the respiratory tract.

Aspecton[®] Cough Syrup is used to improve symptoms in common cold ailments of the respiratory tract with thick mucus, as well as to improve symptoms in acute bronchitis.

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ASPECTON[®] COUGH SYRUP

Do not take Aspecton[®] Cough Syrup

- if you are allergic to thyme or other *Lamiaceae* (members of the Labiatae family) or any of the other ingredients of this medicine (listed in section 6.),
- if you have rare hereditary problems of fructose intolerance.

There are no adequate studies on the use of this medicinal product in children below 1 year of age. It should therefore not be used in children below 1 year of age.

Warnings and precautions

If symptoms last for more than one week, if you experience shortness of breath or fever, or if your phlegm contains pus or blood, a doctor must be consulted immediately.

This medicine contains sorbitol. If you have been told that you have an intolerance to some sugars, please consult your doctor before taking Aspecton[®] Cough Syrup.

The calorific value is 2.6 kcal/g sorbitol.
Sorbitol may have a mild laxative effect.

10 ml contains 3.9 g sorbitol (a source of 0.98 g fructose), equivalent to about 0.33 bread units (BU).

Macrogol glycerol hydroxystearate may cause stomach upset and diarrhoea.

Other medicines and Aspecton[®] Cough Syrup

There are no known interactions with other medicines.

No studies have been performed with Aspecton[®] Cough Syrup to investigate possible interactions with other medicines that are administered at the same time.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Aspecton[®] Cough Syrup with food and drink

There are no special points to consider.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking/using any medicines.

Aspecton[®] Cough Syrup should not be used during pregnancy and breast-feeding due to a lack of sufficient studies.

Driving and using machines

There are no special points to consider.

3. HOW TO TAKE ASPECTON[®] COUGH SYRUP

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	3 – 4 times daily 10 ml
Children from 11 – 12 years	3 times daily 5 ml
Children from 5 – 10 years	3 – 4 times daily 2.5 ml
Children from 1 – 4 years	twice daily 2.5 ml

Each pack of Aspecton[®] Cough Syrup contains a dosing cup.

Method of administration:

For oral use.

Aspecton[®] Cough Syrup should be taken with sufficient liquid (preferably water). It can be taken with or without meals.

Duration of use:

The duration of treatment depends on how the disease progresses and should be determined by the doctor, as appropriate.

However, please observe the precautions listed in section 2 and the information under “Side effects” at all times.

Please talk to your doctor or pharmacist if you have the impression that the effect of Aspecton[®] Cough Syrup is too strong or too weak.

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

To date, there have been no reported cases of intoxication with Aspecton[®] Cough Syrup. If excessive amounts of Aspecton[®] Cough Syrup have been taken, it is possible that the symptoms described in “Side effects” may occur in exaggerated form. In this case, please tell a doctor, who can decide on any measures that may be required.

If you forget to take Aspecton[®] Cough Syrup

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

If you stop taking Aspecton[®] Cough Syrup

In general, no harm will result from discontinuing or ending treatment too early. If in doubt, ask your treating doctor for more information.

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

4. POSSIBLE SIDE EFFECTS

Hypersensitivity reactions may occur, such as shortness of breath, skin rashes, nettle rash and swelling of the face, mouth and/or throat region.

Stomach complaints can also occur, such as cramps, nausea and vomiting.

The frequency of side effects is unknown.

If side effects occur, the product should be discontinued and a doctor consulted. He/she will be able to assess their severity and decide on any further measures that may be required. At the first signs of a hypersensitivity reaction, you must stop taking Aspecton[®] Cough Syrup.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ASPECTON[®] COUGH SYRUP

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.

Note on shelf life after opening:

After opening, Aspecton[®] Cough Syrup has a shelf life of 6 months.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Aspecton[®] Cough Syrup contains

100 ml syrup contains: 6.69 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, glycerol 85%, propylene glycol, sorbitol solution 70% (non-crystallising), macrogol glycerol hydroxystearate, purified water, bitter-fennel fruit oil.

Note: Aspecton[®] Cough Syrup contains no alcohol (ethanol).

What Aspecton[®] Cough Syrup looks like and contents of the pack

Aspecton[®] Cough Syrup is a brown, slightly cloudy liquid.

Aspecton[®] Cough Syrup is available in packs of 100 ml and 200 ml.

Each pack is supplied with a dosing cup (medical device marked CE 0123).

Marketing Authorisation Holder and Manufacturer

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Other information

Aspecton[®] Cough Syrup contains no added sugar and is therefore suitable for diabetics (0.33 bread units). Aspecton[®] Cough Syrup contains no alcohol (ethanol) and is therefore also suitable for patients who must avoid alcohol (ethanol).

As it contains plant-based extraction agents, cloudiness and/or slight sedimentation may occasionally form in Aspecton[®] Cough Syrup; however, this will have no influence on the effect of the product.

Dear Patient,

Aspecton[®] Cough Syrup is a medicine containing an herbal active substance known as “thyme soft extract”.

The active substance is manufactured from dried thyme leaves.

Thymi herba can help you cough up thick mucus associated with common cold ailments of the respiratory tract. As a result, Aspecton[®] Cough Syrup can relieve your symptoms.

You can also obtain Aspecton[®] Cough Syrup from your pharmacist without a prescription.

KREWEL MEUSELBACH, your cold-care specialist, wishes you a speedy recovery.