

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### Hustagil

480 mg / 5 ml syrup

STANDARDIZED THYME LIQUID EXTRACT

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

1. What HUSTAGIL is and what it is used for
2. Before you take HUSTAGIL
3. How to take HUSTAGIL
4. Possible side effects
5. How to store HUSTAGIL
6. Further information

#### *1. WHAT HUSTAGIL IS AND WHAT IT IS USED FOR*

Hustagil - cough syrup with thyme is a herbal remedy that is used in diseases of the respiratory tract caused by cold.

Indications:

Hustagil - cough syrup with thyme is taken undiluted to mitigate the symptoms of respiratory diseases caused by cold, with phlegm and to relieve symptoms of acute bronchitis.

#### *2. BEFORE YOU TAKE HUSTAGIL*

##### **Do not take HUSTAGIL**

- Hustagil - cough syrup with thyme should not be used in known hypersensitivity to thyme or other labiate (sage, lavender, peppermint, rosemary, lemon balm) or any of the other components of the medicine;
- it should not be used in alcoholics.

### **Take special care with HUSTAGIL if you**

If symptoms last longer than 5 days, accompanied by heavy breathing, fever or purulent or bloody sputum, you should contact a doctor.

### **Taking Hustagil with foods and drinks**

The syrup should be taken between meals, undiluted. No other advice in this regard.

### **Taking other medicines**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription.

### **Use in children**

There are not enough studies concerning the use of this medicine in children under 1 year of age. For this reason, but also because the syrup contains alcohol, it should not be used in children younger than 1 year.

### **Pregnancy and breast-feeding**

From the wide application of thyme in the form of medicine and grocery, until now there was no evidence of risk in pregnancy and during breastfeeding. The results of experimental studies do not exist. Therefore, but also because it contains alcohol, this medicine is should not be used in pregnancy and during breastfeeding.

### **Driving and using machines**

HUSTAGIL should not affect your ability to drive and use machines.

## **3. HOW TO TAKE HUSTAGIL**

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

If the doctor has not ordered otherwise, the usual dose is:

Children from 1-5 years:

3-4 times a day 7.5 ml (corresponding to about 0.75 g of liquid extract of thyme)

Children from 6-12 years:

3-4 times a day 15 ml (corresponding to about 1.5 g of liquid extract of thyme)

Adults and adolescents older than 12 years:

3-4 times a day 25 ml (corresponding to about 2.5 g of liquid extract of thyme)

### **Method of administration:**

Syrup should be taken undiluted.

Shake the bottle before use; amount of intake is measured with an attached measuring cup.

Take the syrup between meals.

### **Duration of use:**

Without medical advice, up to 5 days. In case of symptoms which last longer than 5 days, shortness of breath, fever or purulent or bloody sputum, you should contact a doctor.

### **If you take more HUSTAGIL than you should**

If you have taken more medicine than you should, talk to your doctor or pharmacist.

Poisoning with preparations of thyme liquid extract is not known till now.

There is a possibility for occurrence of side effects listed below.

### ***If you forget to take HUSTAGIL***

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

If you miss a dose, take the next dose at the usual time and continue to use the medicine as instructed by a doctor.

Talk to your doctor or pharmacist if you have any additional questions.

### ***4. POSSIBLE SIDE EFFECTS***

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

Side effects are listed according to the following categories of frequency:

**Very common:** more than 1 treated person of 10

**Common:** 1 to 10 treated persons of 100

**Uncommon:** 1 to 10 treated persons of 1000

**Rare:** 1 to 10 treated persons of 10000

**Very rare:** less than 1 treated person of 10000

**Not known:** frequency cannot be estimated from the available data

Hypersensitivity reactions may occur, such as suffocation (air loss), skin rashes, hives and swelling of the face, mouth and / or throat.

There may be symptoms in the stomach and intestines, such as cramps, nausea, vomiting or diarrhea.

The frequency of side effects is not known.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

### ***5. HOW TO STORE HUSTAGIL***

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use HUSTAGIL after the expiry date which is stated on the label.

The bottle after use should be kept tightly closed in a box in order to preserve the contents from light and moisture.

Note regarding the shelf life of medicine after the opening of the bottle:

Shelf life after first opening is 3 months.

### ***6. FURTHER INFORMATION***

#### ***What HUSTAGIL contains***

6 g (5 ml) of syrup contains: standardized thyme liquid extract (1: 2-2.5) with min. 0.03% thymol (DAB) 480 mg.

150 ml (183 g) of a solution containing as an active ingredient:

14, 64 g of liquid extract of thyme (1: 2-2.5), extraction means: liquid ammonia 10% (m / m) of NH<sub>3</sub>: 85% glycerol: ethanol 90% (V / V) water (1:20, 70: 109) (m / m).

(1 ml corresponds to about 1.22 g).

Additional ingredients are:

18.3 g of xylitol, sorbitol solution 70% (non-crystalline) (D-glucitol 51.2 g), glycerol 85%, purified water.

***What HUSTAGIL looks like and contents of the pack***

Hustagil - with thyme syrup is a liquid (solution). The syrup is light brown, due to herbal substances (liquid extract of thyme).

Hustagil - cough syrup with thyme is available in packs of 150 ml (183 g) of the solution.

***Regime of dispensing***

The medicine is issued without doctor`s prescription.

***Manufacturer***

Nycomed GmbH

Byk-Gulden-Straße 2, D-78467 Konstanz, Germany

***Manufacturer of the medicinal product***

Dentinox Gesellschaft für Pharmazeutische Präparate

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