**User information: Please read carefully!** 

# Phytohustil® Cough syrup

Active ingredient: Marshmallow root extract Herbal medicinal product







### **Content of user information:**

Indication group and	>
areas of application	
Contraindications	>
Warnings and precautionary measures for use	>
Interactions with other medicinal products and other remedies	>
Dosage, type and duration of application	<b>&gt;</b>
Side effects	>
Information about the shelf life of the medicinal product	>
<b>Composition and other informations</b>	>

#### **Indication group**

Herbal medicinal product for cold symptoms of the respiratory system

#### **Areas of application**

Mucous membrane irritations in the mouth and throat and the dry cough associated with this.

If symptoms persist for more than three days or recur periodically, as well as fever, consult a doctor.

#### **Contraindications**

Phytohustil® cough syrup must not be taken in case of hypersensitivity to marshmallow root, methyl-4-hydroxybenzoate and propyl-4-hydroxybenzoate as well as any of the other ingredients. Phytohustil® cough syrup should not be taken in case of a rare inherited fructose intolerance, a glucose-galactose malabsorption or a saccharase-isomaltase deficiency.

### Warnings and precautionary measures for use

During the long-term use of Phytohustil® cough syrup, there have been no spontaneous messages about any harmful effects with regard to pregnancy and breastfeeding. Nevertheless, please consult your doctor before using the product during pregnancy and breastfeeding to be safe.

There is not sufficient research about the use of Phytohustil® cough syrup for children under one year old. For this reason, Phytohustil® cough syrup should not be used for children under one year old. In general, a doctor should be consulted with regard to a cough in children under 3 years.

Phytohustil® cough syrup contains sucrose (sugar). If patients have a known intolerance to sugar, they should only take Phytohustil® cough syrup after consulting a doctor.

5 ml Phytohustil<sup>®</sup> cough syrup contains 4.2 g sucrose (sugar) equivalent to approx. 0.4 bread units. If patients must follow a diabetic diet, this should be considered.

## Interactions with other medicinal products and other remedies

The resorption of other medicinal products taken at the same time can be delayed.

# Dosage, type and duration of application

Unless otherwise prescribed, Phytohustil® cough syrup is taken daily by using the measuring cup included as follows:

Adults and adolescents

from 12 years 10 ml 3-6 times each Children from 6 to 12 years 5ml 5 times Children from 3 to 6 years 4ml 4 times Children from 1 to 3 years 3ml 4 times

Phytohustil® cough syrup can also be taken more frequently if required.

Before swallowing, the syrup should be kept in the mouth and throat area as long as possible.

If possible, do not eat or drink anything for 30 minutes after taking Phytohustil syrup.

The duration of use is generally not limited, but the information in section 'Areas of Application' should be observed.

#### Side effects

Methyl-4-hydroxybenzoate and propyl-4-hydroxy-benzoate can cause hypersensitivity reactions, also late reactions. Furthermore, there might be diarrhea, stomach ache, nausea as well as hypersensitivity reactions like itching, dermatitis.

Notification of side effects:

If you notice any side effects, contact your doctor or pharmacist or a medical expert. This also applies to side effects that are not indicated in this package insert. You can also notify the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices in Germany), Department for Pharmacovigilance, Kurt-Georg-Kiesinger Allee 3, D-53175 Bonn,

Website: https://www.bfarm.de directly of any side effects. By reporting side effects, you can contribute to more information being provided about the safety of this medicinal product.

## Information about the shelf life of the medicinal product

Do not store at temperatures exceeding +25 °C! Phytohustil® cough syrup must be used within 3 months after opening the repository.

Phytohustil® cough syrup must no longer be used after the expiration date specified on the repository and the outer package.

#### Composition

100 g (corresponding to 76.44 ml) syrup for ingestion contains the following active ingredient:

Extract from marshmallow root (1: 19.5-23.5) 35.61 g (extracting agent: Purified water)

#### Other ingredients:

Ethanol 90 vol.-% (V/V), methyl-4-hydroxybenzoate (Ph. Eur.), propyl-4-hydroxybenzoate (Ph. Eur.), sucrose (saccharose). The medicinal product contains 1.1 vol.-% alcohol.

### **Dosage form and content**

Syrup
OP with 150 ml syrup for ingestion

#### Pharmaceutical company

Bayer Vital GmbH Kaiser-Wilhelm-Allee 70 51373 Leverkusen Germany

Phone: +49 (0)214 30 51 348

Fax: +49 (0)214 3057209

Email: bayer-vital@bayerhealthcare.com

#### **Manufacturer**

Steigerwald Arzneimittelwerk GmbH Havelstrafle 5 64295 Darmstadt Germany

### Information last updated

May 2017

### Keep this medicinal product out of the reach of children!

Over-the-counter Auth. no. 6939102.00.00

A measuring cup is included with this medicinal product. This is a medicinal product, CE 0408 from the manufacturer Kunststoffwerk Kremsmünster GmbH & Co KG, A–4550 Kremsmünster.

### Valuable information for your health

#### Dear patient,

A common side effect of a cold is mucous membrane irritations in the mouth and throat. In particular at the start of a cold, dry or irritated mucous membranes in the upper respiratory tract often cause a dry cough.

The active ingredients from extracts of the marshmallow root (mucilage) can be used to treat common colds that are accompanied by mucous membrane irritations in the mouth and throat.

# How Phytohustil® cough syrup can help you:

The marshmallow root extract contained in Phytohustil® soothes the irritated mucous membrane with the mucilage it contains and relieves the irritability by forming a protective layer and keeping the irritant effects away from the mucous membrane. This way, the cause of the cough can be gently alleviated.

#### What you can do yourself:

You yourself can actively look after your health by strengthening your bodyis defenses. Sufficient vitamin supply should be ensured. Sporting activities keep fit. Alternating hot/cold showers and brush massages invigorate. A scarf is also useful and can serve you well during the cold season.

Bayer wishes you a speedy recovery!

Bayer