User information: Information for the user

## **Phytohustil®**

### Cough lozenges

Active ingredient: Marshmallow root dry extract

Traditional herbal medicinal product

For use by adults and children from 6 years





## Read the entire package insert carefully before starting to use this medicinal product, as it contains important information.

Always use this medicinal product precisely as described in this package insert or accurately according to your doctor or pharmacist.

- // Keep the package insert. You might want to read it again later.
- // Ask your doctor or pharmacist if you require further information or advice.
- If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects that are not indicated in this package insert.
- // If you do not feel any better after a week or you feel even worse, contact your doctor

## Information included in this package insert:

6. Additional information

1. What are Phytohustil® cough lozenges and what are thev used for? 2. What should you consider before using Phytohustil® cough lozenges? 3. How are Phytohustil® cough lozenges to be used? 4. What side effects might occur? 5. How are Phytohustil® cough lozenges to be stored?

## 1. What are Phytohustil® cough lozenges and what are they used for?

Phytohustil® cough lozenges are a traditional herbal medicinal product for the relief of mucous membrane irritations in the mouth and throat and the dry cough associated with this.

The medicinal product is a traditional product that is solely registered based on long-standing use in the specified indication and intended for use by adults and children from 6 years.

In case of continuing symptoms of illness or in case of side effects other than those mentioned in the package insert, the user should contact a doctor or other qualified health professional.

## 2. What should you consider before using Phytohustil® cough lozenges?

Phytohustil® cough lozenges must not be used if there is a known allergy to marshmallow root dry extract or one of the other components specified for this medicinal product in section 6.

### Warnings and precautionary measures

If shortness of breath, fever or purulent discharge occurs, contact a doctor immediately.

Phytohustil® cough lozenges contain sorbitol and maltitol solution. Please only use Phytohustil® cough lozenges after consulting your doctor of you have a known intolerance to certain sugars.

#### Children and adolescents

The use for children under 6 years is not recommended, as there is a risk of choking.

## Use of Phytohustil® cough lozenges with other medicinal products

There are no studies relating to any interactions with Phytohustil® cough lozenges. There are no known cases of interactions with marshmallow root preparations. The resorption of substances taken at the same time (e.g. medicinal products) can be delayed by the mucilage contained in marshmallow root. For this reason, you should wait for at least 2 hours before you take any other medicinal products.

### Pregnancy and breastfeeding

The safety of using this product during pregnancy and breastfeeding has not been tested. Due to the lack of information, use during pregnancy and breastfeeding is not recommended.

## Fitness to drive and operation of machines

There are no known effects.

### 3. How are Phytohustil® cough lozenges to be used?

Always take Phytohustil® cough lozenges precisely according to instructions in this package insert. Please double-check with your doctor or pharmacist if you are not quite sure.

### The usual dosage is:

- // Adults and adolescents from 12 years take 1 lozenge several times a day as required, but nor more than 10 lozenges per day.
- // Children between 6 to 12 years take1 lozenge 3 lozenges per day as required.

Phytohustil® cough lozenges are for sucking. Let Phytohustil® cough lozenges melt slowly in your mouth.

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

Use by children younger than 6 years is not recommended.

There is no information regarding the recommended dosage in case of reduced kidney/liver function.

If symptoms persist after taking Phytohustil® cough lozenges for more than a week, you should consult a doctor.

# If you have taken a larger quantity of Phytohustil® cough lozenges than is recommended:

If you have taken a large quantity of Phytohustil® cough lozenges, you should continue with the quantity prescribed by your doctor or as specified in the dosage instructions the next time.

There are no known cases of overdosage.

## If you have forgotten to take Phytohustil® cough lozenges:

If you have forgotten to take Phytohustil® cough lozenges, you should continue as prescribed by your doctor or as specified in the dosage instructions the next time.

**Note:** If you have further questions about how to use the medicinal product, please consult your doctor or pharmacist.

### 4. What side effects might occur?

Like all medicinal products, Phytohustil® cough lozenges can have side effects, which might however not manifest in each person.

There might be hypersensitivity reactions. Their frequency is not known.

If these symptoms occur during the course of the treatment, you should stop taking the medicinal product and notify your doctor. When the first signs of a hypersensitivity reaction occur, stop taking Phytohustil® cough lozenges again.

#### 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.

## 5. How should Phytohustil® cough lozenges be stored?

Keep this medicinal product out of the reach of children!

Do not store at temperatures exceeding +25 °C!

Particularly when storing plant extracts for longer periods or if the specified storage conditions are not complied with, there may occasionally be minor deviations, for example with regard to color, which do however not affect the properties and which are harmless with regard to health. The medicinal product can still be taken until the end of the shelf life.

Phytohustil® cough lozenges should no longer be used after the expiration date specified on the repository and the outer package. The expiration date refers to the last day of the specified month.

Ask your doctor or pharmacist about how to dispose of the medicinal product when you no longer need it.

#### 6. Additional information

## What is contained in the Phytohustil® cough lozenges:

1 lozenge contains the following active ingredient:

Dry extract of marshmallow root (3-9:1) 160.0 mg extracting agent: Water.

The other ingredients include: Arabic gum, bleached wax, purified water, medium-chain triglycerides, maltitol solution, black currant flavor, sorbitol solution 70 % (non-crystallizing), citric acid.

## What do Phytohustil® cough lozenges look like and content of packaging:

Aluminum/PVC/PVDC blister with 10 brown lozenges each.

Original packaging with 20, 30, 40, 60 and 100 lozenges each.

Not all package sizes might be brought into circulation.

### Pharmaceutical company

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