

PACKAGE LEAFLET: Information for the patient

TUSSIGO

Syrup

(Codeine phosphate hemihydrate, Benzaldehyde, Balsam Tolu fluid extract and Thyme liquid extract)

Read all of this leaflet carefully before you start taking this medicine.

- 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 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.

In this leaflet:

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

1. WHAT TUSSIGO IS AND WHAT IT IS USED FOR

TussiGo contains the active substances codeine phosphate, benzaldehyde, Tolu balsam extract and thyme extract.

Codeine causes suppression of the cough reflex by a direct effect on the cough center relieving cough with different origins. Codeine or its salts, especially the phosphate, are given by mouth in the form of syrup for the relief of cough.

Thyme extract and Tolu balsam are herbal ingredients with mucolytic properties, which are used for cough relieving.

TussiGo syrup is indicated as an aid in acute and chronic diseases of airways such as cough with different origins (influenza, cold), bronchitis, laryngitis.

2. BEFORE YOU TAKE TUSSIGO

Do not take TussiGo if you:

- are hypersensitive to codeine, the other active substances or to any of the excipients of this medicinal product;
- are under 18 years old;
- are an ultra rapid metaboliser of codeine;
- suffer from asthma;
- have respiratory failure;
- have cough with viscous secretions.

Avoid prolonged use and high doses in cases of chronic constipation.

If you think you have any of the above-mentioned conditions, before taking it, talk first to your doctor and follow his/her advice.

Take special care with TussiGo

Inform your doctor if you:

- have renal and hepatic impairment;
- are a person with a history of drug abuse;
- have raised intracranial pressure, hypovolemia and convulsive disorders with central origin;
- are being treated with another cough or cold preparation because different preparations may contain the same active ingredients, causing overdose;
- have intolerance to some sugars.

TussiGo contains ethanol, thus special care should be taken in pregnant or breast-feeding women (in these cases is not recommended!) and high-risk groups such as patients with liver disease or epilepsy. Ethyl alcohol (ethanol) is harmful for those suffering from alcoholism.

Taking other medicines

Codeine may potentiate the effects of other opiate agonists, general anesthetics, tranquilizers, sedatives and hypnotics, tricyclic antidepressants, monoamine oxidase inhibitors, alcohol and other CNS depressants.

Pregnancy and breastfeeding

TussiGo is not recommended during pregnancy and breastfeeding.

Driving and using machines

Take care while using TussiGo since codeine may impair the ability to drive or use machines.

Important information about some of the excipients of TussiGo

TussiGo syrup contains methyl hydroxybenzoate, which may cause allergic reactions (possibly delayed).

This product contains ethyl alcohol (ethanol). Ethyl alcohol is harmful for those suffering from alcoholism. Also, to be taken in account in high-risk groups such as patients with liver disease or epilepsy.

This product contains sucrose (sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE TUSSIGO

Always take this medicine exactly as your doctor or pharmacist has told you or as described in this leaflet. Usual doses are described below:

Adults over 18 years old: 15 ml, 3 times a day.

The syrup should be used 1-2 hours after meals and before sleeping.

If you take more TussiGo than you should

Do not take more TussiGo than you should. If you take more TussiGo than you should, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures.

If you forget to take TussiGo

If you forget to take one dose, take it as soon as you can, unless it is time to take the next dose. Take the doses at the usual time.

4. POSSIBLE SIDE EFFECTS

Like all medicines, TussiGo can cause side effects, although not everybody gets them. Possible adverse effects are:

- constipation, generally develops with long-term use and high doses;
- nausea and vomiting, especially when syrup is taken by children;
- respiratory depression;
- erythema and pruritus in cases of hypersensitivity to the drug.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE TUSSIGO

Keep out of the sight and reach of children!

Do not take TussiGo after the expiry date which is stated on the package.

Do not store above 25°C!

Protect TussiGo from light and from humidity!

6. OTHER INFORMATION

What TussiGo contains

The **active substances** are: codeine phosphate hemihydrate, benzaldehyde, balsam Tolu fluid extract and thyme liquid extract.

1 gram syrup contains: 0.6 mg codeine phosphate hemihydrate, 0.08 mg benzaldehyde, 40 mg balsam Tolu fluid extract and 90 mg thyme liquid extract.

The **excipients** are: glycerol, sucrose, ethanol, methyl hydroxybenzoate (nipagin) and purified water.

Contents of the pack

Carton box that contains an amber glass bottle with 100 g syrup.

Carton box that contains an amber glass bottle with 150 g syrup.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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