

 **PACKAGE LEAFLET:**
Information for the patient

TUSIPEKTOL

SYRUP

**100 mg (Codeine Phosphate Hemihydrate,
Benzaldehyde, Thyme Liquid Extract ,
Tolu Balsam 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 Tusipektol is and what it is used for
2. Before you take Tusipektol
3. How to take Tusipektol
4. Possible side effects
5. How to store Tusipektol
6. Other information

1. WHAT TUSIPEKTOL IS AND WHAT IT IS USED FOR

Tusipektol contains as 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.

Tusipektol – 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 TUSIPEKTOL

Do not take Tusipektol if you:

- have hypersensitivity 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 Tusipektol

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.

Tusipektol contains ethanol 96%, 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 96%) 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

Tusipektol is not recommended during pregnancy and breastfeeding.

Driving and using machines

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

Important information about some of the ingredients of Tusipektol:

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

This product contains ethyl alcohol (ethanol 96%). 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 TUSIPEKTOL

Always take this medicine exactly as your doctor 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 Tusipektol than you should

Do not take more Tusipektol than you should. If you take more Tusipektol 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 Tusipektol

If you forget taking 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, Tusipektol 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 TUSIPEKTOL

Keep out of the sight and reach of children!

Do not use Tusipektol after the expiry date which is stated on the package.

Do not store above 25°C!

Protect Tusipektol from light and from humidity!

6. OTHER INFORMATION

What Tusipektol contains

The active substance are: codeine phosphate hemihydrate, benzaldehyde, Thyme liquid extract and Tolu balsam extract.
1 gram syrup contains: 0.6 mg codeine phosphate hemihydrate, 0.08 mg benzaldehyde, 40 mg Tolu balsam extract and 90 mg thyme liquid extract

The other ingredients are: glycerol, ethanol 96%, methyl hydroxybenzoate (nipagine), sucrose and purified water.

Contents of the pack

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

Explanatory of the illustration icons on the packaging:



Ask your doctor or pharmacist.



Content.



Warning.



Syrup.

Marketing Authorisation Holder and Manufacturer:



PROFARMA Sh.a.
Rruga "Myslym Keta"
Tel./Fax: 00355 4 23 62 800
Tirana - Albania

This leaflet was last revised in May 2014.

Informacione të rëndësishme mbi disa nga përbërësit e Dexa – Neo:

 SPECIFICATION



CROPING AREA 15 X 25 cm

PAY ATTENTION, all the layers are visible.

If you have to print this document please check or uncheck the specific layers.