

<p style="text-align: center;"><b>MEDICATION GUIDE</b>  TUSSIGON (tuh-se-gone)  (Hydrocodone Bitartrate and Homatropine Methylbromide) Tablets, C-II</p>
<p><b>What is the most important information I should know about TUSSIGON tablets?</b></p> <ul style="list-style-type: none"> <li>• Taking TUSSIGON tablets with benzodiazepines or other central nervous system depressants, including alcohol can cause severe drowsiness, breathing problems (respiratory depression), coma, and death.</li> <li>• TUSSIGON tablets can cause you to be drowsy. Avoid driving a car or operating machinery during treatment with TUSSIGON tablets.</li> <li>• Women who breastfeed should talk to their healthcare provider before taking TUSSIGON tablets.</li> <li>• Call your healthcare provider or get emergency medical help right away if anyone taking TUSSIGON tablets has any of the symptoms below: <ul style="list-style-type: none"> <li>○ increased sleepiness</li> <li>○ confusion</li> <li>○ difficulty breathing</li> <li>○ shallow breathing</li> <li>○ limpness</li> <li>○ your baby has difficulty breastfeeding</li> </ul> </li> <li>• Keep TUSSIGON tablets in a safe place away from children. Accidental use by a child is a medical emergency and can cause death. If a child accidentally takes TUSSIGON tablets, get emergency medical help right away.</li> <li>• TUSSIGON tablets can cause serious side effects including death.</li> <li>• Take TUSSIGON tablets exactly as prescribed by your healthcare provider. If you take the wrong dose of TUSSIGON tablets, you could overdose and die.</li> <li>• TUSSIGON tablets are not for children under 6 years of age.</li> </ul>
<p><b>What are TUSSIGON tablets?</b></p> <ul style="list-style-type: none"> <li>• TUSSIGON tablets are a prescription medicine used to treat a cough in adults and children 6 years and older. TUSSIGON tablets contain hydrocodone and is a narcotic cough suppressant.</li> <li>• <b>TUSSIGON tablets are federal controlled substance (C-II) because they contain hydrocodone that can be abused or lead to dependence.</b> Keep TUSSIGON tablets in a safe place to prevent misuse and abuse. Selling or giving away TUSSIGON tablets may harm others, and is against the law. Tell your healthcare provider if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.</li> <li>• TUSSIGON tablets are not for children under 6 years of age.</li> </ul>
<p><b>Who should not take TUSSIGON tablets?</b></p> <ul style="list-style-type: none"> <li>• Do not take TUSSIGON tablets if you are allergic to hydrocodone or homatropine methylbromide. See the end of this Medication Guide for a complete list of ingredients.</li> </ul>
<p><b>Before you take TUSSIGON tablets, tell your healthcare provider about all of your medical conditions, including if you:</b></p> <ul style="list-style-type: none"> <li>○ have a drug dependence</li> <li>○ have lung or breathing problems</li> <li>○ have had a head injury</li> <li>○ have pain in your stomach-area (abdomen)</li> <li>○ have a history of severe or persistent cough</li> <li>○ have prostate problems</li> <li>○ have problems with your urinary tract (urethral stricture)</li> <li>○ plan to have surgery</li> <li>○ drink alcohol</li> <li>○ have kidney or liver problems</li> <li>○ have diabetes</li> <li>○ have thyroid problems, such as hypothyroidism</li> </ul>

- are pregnant or plan to become pregnant. It is not known if TUSSIGON tablets will harm your unborn baby. You and your healthcare provider should decide if you should take TUSSIGON tablets while you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if TUSSIGON passes into your breast milk. You and your healthcare provider should decide if you will take TUSSIGON tablets or breastfeed. You should not do both.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking TUSSIGON tablets with certain other medicines can cause side effects or affect how well TUSSIGON tablets or the other medicines work. Do not start or stop other medicines without talking to your healthcare provider. Especially tell your healthcare provider if you:

- take pain medicines such as narcotics
- take cold or allergy medicines that contain antihistamines or cough suppressants
- take medicines for mental illness (anti-psychotics, anti-anxiety)
- drink alcohol
- take medicines for depression, including monoamine oxidase inhibitors (MAOIs) and tricyclics

Ask your healthcare provider if you are not sure if you take one of these medicines.

#### **How should I take TUSSIGON tablets?**

- Take TUSSIGON tablets exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how many TUSSIGON tablets to take and when to take it. Do not change your dose without talking to your healthcare provider.
- If you take too many TUSSIGON tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

#### **What should I avoid while taking TUSSIGON tablets?**

- **TUSSIGON tablets can cause you to be drowsy. Avoid driving a car or operating machinery during treatment with TUSSIGON tablets.**
- **Avoid drinking alcohol during treatment with TUSSIGON tablets. Drinking alcohol can increase your chances of having serious side effects.**

#### **What are the possible side effects of TUSSIGON tablets?**

**TUSSIGON tablets may cause serious side effects, including:**

- **See "What is the most important information I should know about TUSSIGON tablets?"**
- **Breathing problems (respiratory depression) which can lead to death.** Call your healthcare provider or get emergency treatment right away if you are sleeping more than usual, have shallow or slow breathing, or confusion.
- **Physical dependence or abuse.** Take TUSSIGON tablets exactly as your healthcare provider tells you to take it. Stopping TUSSIGON tablets suddenly could cause withdrawal symptoms.
- **Bowel problems including constipation or stomach pain.**
- **Increased intracranial pressure.**

**The most common side effects of TUSSIGON tablets include:**

- sleepiness
- confusion
- nausea and vomiting
- difficulty urinating
- trouble breathing

These are not all the possible side effects of TUSSIGON tablets.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store TUSSIGON tablets?**

- Store TUSSIGON tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep TUSSIGON tablets in a tightly closed, child-resistant container and out of the light.
- **Keep TUSSIGON tablets and all medicines out of the reach of children.**

**General information about the safe and effective use of TUSSIGON tablets.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TUSSIGON tablets for a condition for which they were not prescribed. Do not give TUSSIGON tablets to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about TUSSIGON tablets that is written for health professionals.

**What are the ingredients in TUSSIGON tablets?**

**Active ingredients:** hydrocodone bitartrate and homatropine methylbromide.

**Inactive ingredients:** Colloidal Silicon Dioxide NF, FD & C Blue No. 1 Aluminum Lake, Lactose Monohydrate NF, Microcrystalline Cellulose NF, Pregelatinized Starch NF, Stearic Acid NF, Talc USP.

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For more information, go to [www.pfizer.com](http://www.pfizer.com).

This Medication Guide has been approved by the U.S. Food and Drug Administration.

This product's label may have been updated. For current full prescribing information, please visit [www.pfizer.com](http://www.pfizer.com).



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