MEDICATION GUIDE
FLOWTUSS® (floh-tus)
(hydrocodone bitartrate and guaifenesin) oral solution, C-II

What is the most important information I should know about FLOWTUSS?
- Taking FLOWTUSS with benzodiazepines, or other central nervous system depressants, including alcohol can cause severe drowsiness, breathing problems (respiratory depression), coma, and death.
- FLOWTUSS can cause you to be drowsy. Avoid driving a car or operating machinery during treatment with FLOWTUSS.
- Women who breastfeed should talk to their healthcare provider before taking FLOWTUSS.
- Call your healthcare provider or get emergency medical help right away if anyone taking FLOWTUSS has any of the symptoms below:
  - increased sleepiness
  - confusion
  - difficulty breathing
  - shallow breathing
  - limpness
  - your baby has difficulty breastfeeding
- Keep FLOWTUSS 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 FLOWTUSS, get emergency medical help right away.
- FLOWTUSS can cause serious side effects, including death.
- Take FLOWTUSS exactly as prescribed by your healthcare provider. If you take the wrong dose of FLOWTUSS, you could overdose and die.
- FLOWTUSS is not for children under 18 years of age.

What is FLOWTUSS?
- FLOWTUSS is a prescription medicine used to treat cough and loosen mucus that you can have with the common cold in adults. FLOWTUSS contains 2 medicines, hydrocodone and guaifenesin. Hydrocodone is a narcotic cough suppressant. Guaifenesin is an expectorant.
- FLOWTUSS is a federal controlled substance (C-II) because it contains hydrocodone that can be abused or lead to dependence. Keep FLOWTUSS in a safe place to prevent misuse and abuse. Selling or giving away FLOWTUSS may harm others, and is against the law. Tell your healthcare provider if you have abused or been dependent on alcohol, prescription medicines or street drugs.
- FLOWTUSS is not for children under 18 years of age. It is not known if FLOWTUSS is safe and effective in children.

Who should not take FLOWTUSS?
- Do not take FLOWTUSS if you are allergic to any of the ingredients in FLOWTUSS. See the end of this Medication Guide for a complete list of ingredients. You may have an increased risk of having an allergic reaction to FLOWTUSS if you are allergic to certain other opioid medicines.
- Do not take FLOWTUSS if you take a medicine for depression called a Monoamine Oxidase Inhibitor (MAOI) o Do not take an MAOI within 14 days after you stop taking FLOWTUSS.
  o Do not start FLOWTUSS if you stopped taking an MAOI in the last 14 days.

Before you take FLOWTUSS, tell your healthcare provider about all of your medical conditions, including if you:
- have lung or breathing problems
- have a drug dependence
- have had a head injury
- have pain in your stomach-area (abdomen)
- have a history of severe or persistent cough
- have prostate problems
- have problems with your urinary tract (urethral stricture)
- are pregnant or plan to become pregnant. It is not known if FLOWTUSS will harm your unborn baby. You and your healthcare provider should decide if you should take FLOWTUSS while you are pregnant.
- are breastfeeding or plan to breastfeed. Hydrocodone passes into your breast milk and may harm your baby. You and your healthcare provider should decide if you will take FLOWTUSS 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 FLOWTUSS with certain other medicines can cause side effects or affect how well FLOWTUSS or the other medicines work. Do not start or stop other medicines without talking to you 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
- take medicines for asthma, stomach or intestine problems.
Ask your healthcare provider if you are not sure if you take one of these medicines.

### How should I take FLOWTUSS?
- Take FLOWTUSS exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much FLOWTUSS to take and when to take it. Do not change your dose without talking to your healthcare provider.
- Take FLOWTUSS by mouth only.
- FLOWTUSS should be taken using an accurate milliliter measuring device.
- Ask your pharmacist to give you a measuring device to help you measure the correct amount of FLOWTUSS. Do not use a household teaspoon to measure your medicine. You may accidentally take too much.
- If you take too much FLOWTUSS, call your healthcare provider or go to the nearest hospital emergency room right away.

### What should I avoid while taking FLOWTUSS?
- FLOWTUSS can cause you to be drowsy. Avoid driving a car or operating machinery during treatment with FLOWTUSS.
- Avoid drinking alcohol during treatment with FLOWTUSS. Drinking alcohol can increase your chances of having serious side effects.

### What are the possible side effects of FLOWTUSS?
FLOWTUSS may cause serious side effects, including:

See “What is the most important information I should know about FLOWTUSS?”

- **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 FLOWTUSS exactly as your healthcare provider tells you to take it. Stopping FLOWTUSS suddenly could cause withdrawal symptoms.
- **Bowel problems including constipation or stomach pain.**
- **Increased intracranial pressure.**

The most common side effects of FLOWTUSS include:

- sleepiness
- confusion
- nausea and vomiting
- difficulty urinating
- trouble breathing
- dizziness
- headache
- decreased blood pressure
- diarrhea
- hot flush

These are not all the possible side effects of FLOWTUSS. 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 FLOWTUSS?
- Store FLOWTUSS at room temperature between 20° to 25°C (68° to 77°F).
- Keep FLOWTUSS in a tightly closed, child-resistant container and out of the light.
- Safely throw away medicine that is out of date or no longer needed.
- Keep FLOWTUSS and all medicines out of the reach of children.

### General information about the safe and effective use of FLOWTUSS.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use FLOWTUSS for a condition for which it was not prescribed. Do not give FLOWTUSS 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 FLOWTUSS that is written for health professionals.

### What are the ingredients in FLOWTUSS?
- **Active Ingredients:** hydrocodone bitartrate and guaifenesin.
- **Inactive Ingredients:** black raspberry flavor, citric acid, D&C Red #33, FD&C Blue #1, glycerin, methylparaben, polyethylene glycol, propylparaben, purified water, saccharin sodium, sodium citrate, and sorbitol.

Manufactured for: MISSION PHARMACAL COMPANY San Antonio, TX 78230 1355
For more information, go to www.flowtuss.com or call 1-800-298-1087.

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