Medication Guide NORCO (nor koe')

Hydrocodone Bitartrate and Acetaminophen Tablets, USP 5 mg/325 mg CII

NORCO is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain severe enough to require an opioid pain medicine, when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.

Important information about NORCO:

- Get emergency help or call 911 right away if you take too much NORCO (overdose). When you first start taking NORCO, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.
- Taking NORCO with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
- Never give anyone else your NORCO. They could die from taking it. Selling or giving away NORCO is against the law.
- Store NORCO securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

Do not take NORCO if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.
- known hypersensitivity to hydrocodone or acetaminophen, or any ingredient in hydrocodone and acetaminophen tablets.

Before taking NORCO, tell your healthcare provider if you have a history of:

- head injury, seizures
- problems urinating

- liver, kidney, thyroid problems
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, opioid overdose, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** Prolonged use of NORCO during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breast-feeding.** Hydrocodone bitartrate and acetaminophen pass into breast milk and may harm your baby.
- living in a household where there are small children or someone who has abused street or prescription drugs.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking NORCO with certain other medicines can cause serious side effects that could lead to death.

When taking NORCO:

- Do not change your dose. Take NORCO exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Take your prescribed dose every four to six hours as needed for pain.
- Do not take more than your prescribed dose. If you miss a dose, take your next dose at your usual time.
- Call your healthcare provider if the dose you are taking does not control your pain.
- If you have been taking NORCO regularly, do not stop taking NORCO without talking to your healthcare provider.
- Dispose of expired, unwanted, or unused NORCO by promptly flushing down the toilet, if a drug takeback option is not readily available. Visit *www.fda.gov/drugdisposal* for additional information on disposal of unused medicines.

While taking NORCO DO NOT:

- Drive or operate heavy machinery, until you know how NORCO affects you. NORCO can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with NORCO may cause you to overdose and die.

The possible side effects of NORCO:

• constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help or call 911 right away if you have:

• trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

These are not all the possible side effects of NORCO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. For more information go to dailymed.nlm.nih.gov.

For more information call Allergan at 1-800-678-1605.

Manufactured by: Mikart, Inc. Atlanta, GA 30318

Distributed by: Allergan USA, Inc. Madison, NJ 07940

©2021 Allergan. All rights reserved.

NORCO® is a registered trademark of Allergan Sales, LLC.

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

Revised: 3/2021

v3.0MG913