

Medication Guide

DVORAH (dŭh-vor'-ŭh)

(acetaminophen, caffeine, and dihydrocodeine bitartrate tablets), CIII

DVORAH is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage moderate to moderately severe pain, when other pain treatments such as nonopioid 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 DVORAH:

- **Get emergency help right away if you take too much DVORAH (overdose).** When you first start taking DVORAH, 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.
- Taking DVORAH 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 DVORAH. They could die from taking it. Store DVORAH away from children and in a safe place to prevent stealing or abuse. Selling or giving away DVORAH is against the law.

Important Information Guiding Use in Pediatric Patients:

- Do not give DVORAH to a child younger than 12 years of age.
- Do not give DVORAH to a child younger than 18 years of age after surgery to remove the tonsils and/or adenoids.
- Avoid giving DVORAH to children between 12 to 18 years of age who have risk factors for breathing problems such as obstructive sleep apnea, obesity, or underlying lung problems.

Do not take DVORAH if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.
- previously had an allergic reaction to dihydrocodeine or acetaminophen.

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

- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.
- having been told by your healthcare provider that you are a "rapid metabolizer" of certain medicines.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** Prolonged use of DVORAH during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** Not recommended; may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking DVORAH with certain other medicines can cause serious side effects that could lead to death.

When taking DVORAH:

- Do not change your dose. Take DVORAH exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Take your prescribed dose of 2 DVORAH Tablets orally every 4 hours, as needed. 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 DVORAH regularly, do not stop taking DVORAH without talking to your healthcare provider.
- After you stop taking DVORAH, dispose the unused DVORAH in accordance with local state guidelines and/or regulations.

While taking DVORAH DO NOT:

- Drive or operate heavy machinery, until you know how DVORAH affect you. DVORAH 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 DVORAH may cause you to overdose and die.

The possible side effects of DVORAH:

- **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 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 DVORAH. 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

Manufactured for: Phlight Pharma, LLC.

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

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