

MEDICATION GUIDE

Doxepin Hydrochloride (dox' e pin hye'' droe klor' ide) Capsule

What is the most important information I should know about doxepin hydrochloride capsules?

Doxepin hydrochloride capsules can cause serious side effects, including:

Increased risk of suicidal thoughts and actions. Doxepin hydrochloride capsules and other antidepressant medicines may increase the risk of suicidal thoughts and actions in people 24 years of age and younger, especially within the first few months of treatment or when the dose is changed. Doxepin hydrochloride capsule is not for use in children.

How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?

- Pay close attention to any changes, especially sudden changes in mood, behavior, thoughts, or feelings, or if you develop suicidal thoughts or actions. This is very important when an antidepressant medicine is started or when the dose is changed.
- Call your health care provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings or if you develop suicidal thoughts or actions.
- Keep all follow-up visits with your health care provider as scheduled. Call your health care provider between visits as needed, especially if you have concerns about symptoms.

Call your health care provider or get emergency help right away if you or a family member have any of the following symptoms, especially if they are new, worse, or worry you:

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| ○ suicide attempts | ○ thoughts about suicide or dying |
| ○ acting aggressive, being angry, or violent | ○ acting on dangerous impulses |
| ○ new or worse depression | ○ new or worse anxiety |
| ○ panic attacks | ○ feeling very agitated or restless |
| ○ new or worse irritability | ○ trouble sleeping |
| ○ an extreme increase in activity or talking (mania) | ○ other unusual changes in behavior or mood |

See “What are the possible side effects of doxepin hydrochloride capsules?” for more information about side effects.

What is doxepin hydrochloride capsule?

Doxepin hydrochloride capsule is a prescription medicine used to treat adults with a certain type of depression called major depressive disorder (MDD).

It is not known if doxepin hydrochloride capsules are safe and effective for use in children.

Do not take doxepin hydrochloride capsules if you:

- are allergic to doxepin, or any of the ingredients in doxepin hydrochloride capsules. See the end of this Medication Guide for a complete list of ingredients in doxepin hydrochloride capsules
- have glaucoma
- have or have had trouble urinating
- are taking, or have stopped taking within the last 14 days, a medicine called a Monoamine Oxidase Inhibitor (MAOI), including the antibiotic linezolid or intravenous methylene blue
 - Ask your health care provider or pharmacist if you are not sure if you are taking an MAOI, including the antibiotic linezolid or intravenous methylene blue
 - **Do not start taking an MAOI for at least 14 days after you stop treatment with doxepin hydrochloride capsules.**

Before taking doxepin hydrochloride capsules, tell your health care provider about all your medical conditions, including if you:

- have, or have a family history of bipolar disorder, mania, or hypomania
- have or had depression, suicidal thoughts or behavior
- have kidney or liver problems
- have or had seizures or convulsions
- are pregnant or plan to become pregnant. Taking doxepin hydrochloride capsules during your third trimester of pregnancy may harm your unborn baby. Tell your health care provider if you become pregnant or think you may be pregnant during treatment with doxepin hydrochloride capsules.
 - Babies born to mothers who take certain medicines, including doxepin hydrochloride capsules, during the third trimester of pregnancy may have symptoms of sedation, such as breathing problems, sluggishness, low muscle tone, feeding problems, and withdrawal symptoms. Talk to your health care provider about the risks to your unborn or newborn baby if you take doxepin hydrochloride capsules during pregnancy.
 - There is a pregnancy registry for women who are exposed to doxepin hydrochloride capsules during pregnancy. The purpose of this registry is to collect information about the health of women exposed to doxepin hydrochloride capsules and their babies. If you become pregnant during treatment with doxepin hydrochloride capsules, talk to your health care provider about registering with the National Pregnancy Registry for Antidepressants. You can register by calling 1-866-961-2388 or visiting online at <https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/>
- are breastfeeding or plan to breastfeed. Doxepin hydrochloride can pass into your breast milk and harm your baby. Do not breastfeed during treatment with doxepin hydrochloride capsules. Talk to your health care provider about the best way to feed your baby during treatment with doxepin hydrochloride capsules.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Doxepin hydrochloride capsules and other medicines may affect each other causing possible serious side effects. Doxepin hydrochloride capsules may affect the way other medicines work and other medicines may affect the way doxepin hydrochloride capsule works.

Especially tell your health care provider if you take:

- medicines used to treat mood, anxiety, psychotic, or thought disorders, including selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs)
- medicines to treat migraine headaches known as triptans
- other tricyclic antidepressants
- tetracyclic antidepressants
- opioids
- lithium
- tryptophan
- buspirone
- St. John's Wort
- carbamazepine
- cimetidine
- tolazamide
- medicines that can cause drowsiness

Ask your health care provider if you are not sure if you are taking any of these medicines. Your health care provider can tell you if it is safe to take doxepin hydrochloride capsules with your other medicines.

Do not start or stop any other medicines during treatment with doxepin hydrochloride capsules without first talking to your healthcare provider.

Know the medicines you take. Keep a list of them to show to your healthcare providers when you start to take a new medicine.

How should I take doxepin hydrochloride capsules?

- Take doxepin hydrochloride capsules exactly as your health care provider tells you to take it. Do not change your dose or stop taking doxepin hydrochloride capsules without first talking to your healthcare provider.
- Your health care provider may need to change the dose of doxepin hydrochloride capsules until it is the right dose for you.
- If you miss a dose of doxepin hydrochloride capsules, take the missed dose as soon as you remember. If it is almost time for the next dose, do not take the missed dose and take your next dose at the regular time. Do not take two doses of doxepin hydrochloride capsules at the same time.
- If you take too much doxepin hydrochloride capsules, call your healthcare provider or Poison Help Line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What should I avoid while taking doxepin hydrochloride capsules?

- Do not drive a car or another motor vehicle, operate heavy machinery, or do dangerous activities while taking doxepin hydrochloride capsules. Doxepin hydrochloride capsules can cause sleepiness or may affect your ability to make decisions, think clearly, or react quickly.
- Do not drink alcohol during treatment with doxepin hydrochloride capsules. Drinking alcohol during treatment with doxepin hydrochloride capsules can increase your risk of having serious side effects.

What are the possible side effects of doxepin hydrochloride capsules?**Doxepin hydrochloride capsules can cause serious side effects, including:**

- See **“What is the most important information I should know about doxepin hydrochloride capsules?”**

- **Serotonin syndrome.** Taking doxepin hydrochloride capsules can cause a potentially life-threatening problem called serotonin syndrome. The risk of developing serotonin syndrome is increased when doxepin hydrochloride capsule is taken with certain other medicines. See **“Do not take doxepin hydrochloride capsules if you:”** Stop taking doxepin hydrochloride capsules and **call your healthcare provider or go to the nearest hospital emergency room right away** if you have any of the following signs and symptoms of serotonin syndrome:

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| o agitation | o seeing or hearing things that are not real (hallucinations) |
| o confusion | o coma |
| o fast heartbeat | o changes in blood pressure |
| o dizziness | o sweating |
| o flushing | o high body temperature (hyperthermia) |
| o shaking (tremors), stiff muscles, or muscle twitching | o loss of coordination |
| o seizures | o nausea, vomiting, diarrhea |

- **Eye problems (angle-closure glaucoma).** Doxepin hydrochloride capsules may cause a type of eye problem called angle-closure glaucoma in people with certain eye problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are. Call your healthcare provider if you have eye pain, changes in your vision, or swelling or redness in or around the eye.

- **Manic episodes.** Manic episodes may happen in people with bipolar disorder who take doxepin hydrochloride capsules. Symptoms may include:

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| o greatly increased energy | o severe trouble sleeping |
| o racing thoughts | o reckless behavior |
| o unusually grand ideas | o excessive happiness or irritability |
| o talking more or faster than usual | |

- **Seizures (convulsions)**

The most common side effects of doxepin hydrochloride capsules include:

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| • feeling overly sleepy | • constipation |
| • dry mouth | • tiredness |
| • dizziness | |

These are not all the possible side effects of doxepin hydrochloride capsules.

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

How should I store doxepin hydrochloride capsules?

- Store at controlled room temperature between 20°C to 25°C (68°F to 77°F).
- Keep doxepin hydrochloride capsules and all medicines out of the reach of children.
- Bottle of 100's count comes in a child-resistant package.

General Information about the safe and effective use of doxepin hydrochloride capsules.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not take doxepin hydrochloride capsules for a condition for which it was not prescribed. Do not give doxepin hydrochloride capsules 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 doxepin hydrochloride capsules that is written for health professionals.

What are the ingredients in doxepin hydrochloride capsules?

Active ingredient: doxepin hydrochloride

Inactive Ingredients: colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, pregelatinized starch and sodium lauryl sulfate. The capsule shell contains gelatin, iron oxide yellow, sodium lauryl sulfate and titanium dioxide. Additionally, 75 mg and 100 mg capsule shell also contains FD&C Blue 1. The capsule shells are printed with edible black ink containing iron oxide black, potassium hydroxide and shellac.

Manufactured by:

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Manufactured for:

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

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