

Doxepin: Important Patient Information

What is Doxepin?

Doxepin (Silenor) is a prescription medication primarily used for the treatment of depression, anxiety, and insomnia. It belongs to a class of medications called tricyclic antidepressants (TCAs). Doxepin works by affecting the balance of certain natural chemicals (neurotransmitters) in the brain to promote sleep and mood stability.

Black Box Warning

All antidepressants, including Doxepin, carry a black box warning regarding the increased risk of suicidal thoughts and behaviors in children, teenagers, and young adults under the age of 24. This occurs in **less than 1/132 patients** in this age group on antidepressants. Patients should closely monitor themselves for changes in mood, worsening depression, or unusual behavior, especially during the first few months of treatment or when dosage changes occur. If you or someone you know experiences suicidal thoughts, seek immediate medical help through 911 or 988.

Special Precautions Before Taking Doxepin

Before taking doxepin, inform your doctor and pharmacist about the following:

- **Allergies:** If you are allergic to doxepin, amoxapine, loxapine, or any ingredients in the medication.
- **Medication History:** If you are taking or have recently stopped taking a monoamine oxidase (MAO) inhibitor such as isocarboxazid (Marplan), phenelzine (Nardil), selegiline (Eldepryl, Emsam, Zelapar), tranylcypromine (Parnate), methylene blue (Provayblue), or linezolid (Zyvox). You must wait at least 14 days before switching between doxepin and an MAO inhibitor.
- **Other Medications:** Discuss any prescription or over-the-counter drugs, as some may require dosage adjustments or extra monitoring when taken with doxepin.
- **Medical Conditions:** If you have a history of heart rhythm abnormalities (arrhythmias), glaucoma, urinary retention, liver or kidney disease, depression, suicidal thoughts, sleep apnea, or substance abuse.
- **Pregnancy & Breastfeeding:** Inform your doctor if you are pregnant, planning to become pregnant, or breastfeeding.
- **Drowsiness & Impairment:** Doxepin may cause drowsiness. Avoid driving, operating machinery, or engaging in hazardous activities until you know how the medication affects you.

- **Alcohol Use:** Alcohol can enhance drowsiness and other side effects of doxepin. Avoid alcohol while taking this medication.
 - **Sleepwalking & Unusual Behaviors:** Some patients have engaged in activities like driving, eating, making phone calls, or having sex while not fully awake. If this occurs, contact your doctor immediately.
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Potential Side Effects of Doxepin

Doxepin may cause side effects. Inform your doctor if any of these symptoms persist or worsen:

- **Common Side Effects:**
 - Nausea
 - Dizziness
 - Dry mouth
 - Drowsiness
- **Serious Side Effects (Seek Immediate Medical Attention):**
 - Fast or irregular heartbeat
 - Confusion or agitation
 - Hallucinations
 - Difficulty urinating
 - Seizures

If you experience a serious side effect, you or your doctor may report it to the FDA's MedWatch Adverse Event Reporting program at www.fda.gov/Safety/MedWatch or by calling 1-800-332-1088.

Drug & Supplement Interactions

Medications That May Interact with Doxepin:

- **Sedatives & Sleep Aids:** Increased risk of drowsiness (e.g., benzodiazepines, opioids, antihistamines, muscle relaxants, zolpidem, eszopiclone).
- **Antidepressants & Antipsychotics:** May increase side effects, serotonin syndrome risk (e.g., SSRIs, SNRIs, MAOIs, lithium, atypical antipsychotics).
- **Blood Pressure Medications:** May enhance drowsiness or dizziness (e.g., beta-blockers, clonidine, diuretics).
- **Cimetidine (Tagamet):** May increase doxepin levels, leading to higher risk of side effects.
- **Thyroid Medications:** Potential alteration of effectiveness or side effects.

Common Supplements That May Interact with Doxepin:

- **St. John's Wort:** May reduce the effectiveness of doxepin and increase serotonin syndrome risk.
- **Melatonin:** May cause excessive drowsiness.
- **Magnesium & Calcium Supplements:** May interfere with medication absorption.
- **Valerian Root & Kava:** Increased sedation risk.
- **5-HTP & Tryptophan:** May contribute to serotonin syndrome.

Always consult your doctor before adding or stopping any medications or supplements while taking doxepin.

Important Safety Information

- **Do not abruptly stop taking doxepin** without medical guidance, as withdrawal symptoms may occur.
 - **Use caution in elderly patients**, as they may be more sensitive to its effects, including dizziness and confusion.
 - **Monitor for suicidal thoughts** or behavior changes, especially in young adults.
 - **Store medication properly** at room temperature, away from moisture and heat.
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In Case of Emergency/Overdose

If an overdose occurs, immediately contact poison control at **1-800-222-1222** or visit www.poisonhelp.org. Call **911** if the person has collapsed, had a seizure, has trouble breathing, or cannot be awakened.

Symptoms of Overdose:

- Irregular heartbeat
- Agitation or confusion
- Severe drowsiness or unconsciousness
- Hallucinations
- Seizures
- Vomiting
- Fever or cold body temperature