

MEDICATION GUIDE

Doxepin (dox' e pin) Tablets

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

Doxepin tablets can cause serious side effects including:

After taking doxepin tablets, you may get up out of bed while not being fully awake and do an activity that you do not know you are doing. The next morning, you may not remember that you did anything during the night. You have a higher chance for doing these activities if you drink alcohol or take other medicines that make you sleepy with doxepin tablets. Reported activities include:

- driving a car ("sleep-driving")
- making and eating food
- talking on the phone
- having sex
- sleep-walking

Stop taking doxepin tablets and call your healthcare provider right away if you find out that you have done any of the above activities after taking doxepin tablets.

Important:

- Take doxepin tablets exactly as prescribed
 - Do not take more doxepin tablets than prescribed.

Take doxepin tablets 30 minutes before bedtime. After taking doxepin tablets, you should only do activities needed to get ready for bed.

What are doxepin tablets?

Doxepin tablets are a prescription medicine used to treat adults who have trouble staying asleep.

It is not known if doxepin tablets are safe and effective in children.

Do not take doxepin tablets if you:

- are allergic to any of the ingredients in doxepin tablets. See the end of this Medication Guide for a complete list of ingredients in doxepin tablets.
- take a monoamine oxidase inhibitor (MAOI) medicine or have taken an MAOI in the last 14 days (2 weeks). Ask your healthcare provider if you are not sure if your medicine is an MAOI.
- have an eye problem called narrow angle glaucoma that is not being treated or have trouble urinating that is severe.

Before taking doxepin tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have a history of depression, mental illness, or suicidal thoughts
- have severe sleep apnea
- have kidney or liver problems
- have a history of drug or alcohol abuse or addiction
- have a history of glaucoma or trouble urinating that is severe
- are pregnant or plan to become pregnant. Taking doxepin tablets in the third trimester of pregnancy may harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant during treatment with doxepin tablets.
 - Babies born to mothers who take certain medicines, including doxepin tablets, during the third trimester of pregnancy may have symptoms of sedation, such as breathing problems, sluggishness, low muscle tone, feeding problems, and withdrawal symptoms.
- are breastfeeding or plan to breastfeed. Doxepin can pass into your breast milk and may harm your baby. You should not breastfeed during treatment with doxepin tablets. Talk to your healthcare provider about the best way to feed your baby during treatment with doxepin tablets.

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

Doxepin tablets and other medicines may affect each other causing side effects. Doxepin tablets may affect the way other medicines work, and other medicines may affect how doxepin tablet works.

Especially tell your healthcare provider if you take:

- certain allergy medicines (antihistamines) or other medicines that can make you sleepy or affect your breathing

Know the medicines you take. Keep a list of your medicines with you to show your healthcare provider and pharmacist each time you get a new medicine.

How should I take doxepin tablets?

- Take doxepin tablets exactly as your healthcare provider tells you to take it.
- Your healthcare provider may change your dose if needed.
- **Take doxepin tablets within 30 minutes of bedtime.** After taking doxepin tablets, you should only do activities to get ready for bed.
- **Do not take doxepin tablets within 3 hours of a meal.** Doxepin tablets may make you sleepy the next day if taken with or right after a meal.
- **Call your healthcare provider if your sleep problems get worse or do not get better within 7 to 10 days.** This may mean that there is another condition causing your sleep problem.
- If you take too much doxepin tablets, call your healthcare provider or get medical help right away.

What should I avoid during treatment with doxepin tablets?

- You should not drink alcohol or take other medicines that may make you sleepy or dizzy during treatment with doxepin tablets because it may make your sleepiness or dizziness much worse.
- You should not drive, operate heavy machinery, or do other dangerous activities after taking doxepin tablets. **You may still feel sleepy the next day after taking doxepin tablets. Do not drive or do other dangerous activities after taking doxepin tablets until you feel fully awake.**

What are the possible side effects of doxepin tablets?

Doxepin tablets can cause serious side effects including:

- See “What is the most important information I should know about doxepin tablets?”
- **Risk of suicide and worsening of depression.** Worsening of depression, including suicidal thoughts and actions can happen during treatment with doxepin tablets. Call your healthcare provider right away if you have any thoughts of suicide, dying, or worsening depression.

The most common side effects of doxepin tablets include:

- drowsiness or tiredness
- nausea
- upper respiratory tract infection

Doxepin tablets may cause fertility problems in females and males, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility.

These are not all of the possible side effects of doxepin tablets. 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 doxepin tablets?

- Store doxepin tablets at room temperature between 68°F to 77° F (20°C to 25°C).
- Protect from light.

Doxepin tablets come in child-resistant bottle pack of 30's and 90's.

Keep doxepin tablets and all medicines out of the reach of children.

General Information about the safe and effective use of doxepin tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use doxepin tablets for a condition for which it was not prescribed. Do not give doxepin tablets 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 tablets that is written for healthcare professionals.

Please address medical inquiries to, drugsafety@vionausa.com or Tel.: 1-888-304-5011.

What are the ingredients in doxepin tablets?

Active Ingredient: doxepin hydrochloride, USP

Inactive Ingredients: FD&C Blue No.1 aluminium lake, lactose monohydrate, magnesium stearate, pregelatinized starch, sodium starch glycolate and talc. In addition 6 mg tablet also contains D&C Yellow No. 10 aluminium lake.

Medication Guide available at www.vionausa.com/medguides or call 1-888-304-5011.

Manufactured by:
Zydus Lifesciences Ltd.
Ahmedabad-382213, India

Distributed by:
Viona Pharmaceuticals Inc.
Cranford, NJ 07016

Rev.: 05/24

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