

## MEDICATION GUIDE

SILENOR® [si-leh-nor]

(doxepin)

tablets

### What is the most important information I should know about SILENOR?

**SILENOR can cause serious side effects including:**

**After taking SILENOR, 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 SILENOR. Reported activities include:

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

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

#### Important:

- Take SILENOR exactly as prescribed
  - Do not take more SILENOR than prescribed.

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

### What is SILENOR?

SILENOR is a prescription medicine used to treat adults who have trouble staying asleep.

It is not known if SILENOR is safe and effective in children.

### Do not take SILENOR if you:

- are allergic to any of the ingredients in SILENOR. See the end of this Medication Guide for a complete list of ingredients in SILENOR.
- 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 SILENOR, 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 SILENOR 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 SILENOR.
  - Babies born to mothers who take certain medicines, including SILENOR, 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. SILENOR can pass into your breast milk and may harm your baby. You should not breastfeed during treatment with SILENOR. Talk to your healthcare provider about the best way to feed your baby during treatment with SILENOR.

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

SILENOR and other medicines may affect each other causing side effects. SILENOR may affect the way other medicines work, and other medicines may affect how SILENOR 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 SILENOR?

- Take SILENOR exactly as your healthcare provider tells you to take it.
- Your healthcare provider may change your dose if needed.

- **Take SILENOR within 30 minutes of bedtime.** After taking SILENOR, you should only do activities to get ready for bed.
- **Do not take SILENOR within 3 hours of a meal.** SILENOR 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 SILENOR, call your healthcare provider or get medical help right away.

**What should I avoid during treatment with SILENOR?**

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

**What are the possible side effects of SILENOR?**

**SILENOR can cause serious side effects including:**

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

**The most common side effects of SILENOR include:**

- drowsiness or tiredness
- nausea
- upper respiratory tract infection

SILENOR 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 SILENOR. 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 SILENOR?**

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

**Keep SILENOR and all medicines out of the reach of children.**

**General Information about the safe and effective use of SILENOR.**

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

**What are the ingredients in SILENOR?**

**Active Ingredient:** doxepin hydrochloride

**Inactive Ingredients:** microcrystalline cellulose, colloidal silicon dioxide, and magnesium stearate. The 3 mg tablet also contains FD&C Blue No. 1. The 6 mg tablet also contains FD&C Yellow No. 10 and FD&C Blue No. 1.

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For more information, contact Currax Pharmaceuticals LLC at 1-800-793-2145.

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

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