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Doxepin (systemic): Patient drug information

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(For additional information <u>see "Doxepin (systemic): Drug information"</u> and <u>see "Doxepin (systemic): Pediatric drug information"</u>)

Brand Names: US Silenor

Brand Names: Canada Silenor; Sinequan; Zonalon

Warning

- Drugs like this one have raised the chance of suicidal thoughts or actions in children and young adults.
 The risk may be greater in people who have had these thoughts or actions in the past. All people who
 take this drug need to be watched closely. Call the doctor right away if signs like low mood (depression),
 nervousness, restlessness, grouchiness, panic attacks, or changes in mood or actions are new or worse.
 Call the doctor right away if any thoughts or actions of suicide occur.
- This drug is not approved for use in children. Talk with the doctor.

What is this drug used for?

- · It is used to treat low mood (depression).
- · It is used to treat anxiety.
- · It is used to treat sleep problems.
- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

For all uses of this drug:

- If you have an allergy to doxepin or any other part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor
 about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough;
 swelling of face, lips, tongue, or throat; or any other signs.

- If you have any of these health problems: Trouble passing urine or glaucoma.
- · If you are taking any of these drugs: Linezolid or methylene blue.
- If you have taken certain drugs used for low mood (depression) like isocarboxazid, phenelzine, or tranylcypromine or drugs used for Parkinson's disease like selegiline or rasagiline in the last 14 days. Taking this drug within 14 days of those drugs can cause very bad high blood pressure.

For sleep problems:

- If you do not have time to get a full night's sleep.
- · If you have sleep apnea.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

For all uses of this drug:

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Avoid drinking alcohol while taking this drug.
- Talk with your doctor before you use other drugs and natural products that slow your actions.
- Some people may have a higher chance of eye problems with this drug. Your doctor may want you to have an eye exam to see if you have a higher chance of these eye problems. Call your doctor right away if you have eye pain, change in eyesight, or swelling or redness in or around the eye.
- This drug may make you sunburn more easily. Use care if you will be in the sun. Tell your doctor if you sunburn easily while taking this drug.
- If you have high blood sugar (diabetes), you will need to watch your blood sugar closely.
- · Tell your doctor if you have signs of high or low blood sugar like breath that smells like fruit, dizziness, fast breathing, fast heartbeat, feeling confused, feeling sleepy, feeling weak, flushing, headache, more thirsty or hungry, passing urine more often, shaking, or sweating.
- If you are 65 or older, use this drug with care. You could have more side effects.
- Tell your doctor if you are pregnant or plan on getting pregnant. You will need to talk about the benefits and risks of using this drug while you are pregnant.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

For sleep:

- Avoid driving and doing other tasks or actions that call for you to be alert after you take this drug. You may still feel sleepy the day after you take this drug. Avoid these tasks or actions until you feel fully awake.
- Use this drug for short periods of time. If signs show up again, talk with the doctor.
- If you have been taking this drug for many weeks, talk with your doctor before stopping. You may want to slowly stop this drug.
- Some people have done certain tasks or actions while they were not fully awake like driving, making and eating food, and having sex. Most of the time, people do not remember doing these things. Tell your doctor if this happens to you.

For other reasons:

- Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug
 affects you.
- · It may take several weeks to see the full effects.
- Do not stop taking this drug all of a sudden without calling your doctor. You may have a greater risk of side effects. If you need to stop this drug, you will want to slowly stop it as ordered by your doctor.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- · Signs of high or low blood pressure like very bad headache or dizziness, passing out, change in eyesight.
- · A fast heartbeat.
- · Trouble passing urine.
- · Feeling very tired or weak.
- · Very nervous and excitable.
- · Any unexplained bruising or bleeding.
- · Fever or chills.
- · Yellow skin or eyes.
- · Ringing in ears.
- Change in sex interest.
- · Enlarged breasts.
- · Nipple discharge.
- · Swelling of the testicles.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- · Feeling sleepy.
- · Dizziness.
- Upset stomach or throwing up.
- · Dry mouth.
- · Constipation.
- · Change in taste.
- · Loose stools (diarrhea).

- · Not hungry.
- · Mouth irritation or mouth sores.
- · Weight gain.
- · Sweating a lot.
- · Feeling tired or weak.
- · Flushing.
- · Hair loss.
- · Headache.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

For sleep:

- · Take within 30 minutes of bedtime.
- Do not take within 3 hours of a meal.

For other reasons:

- Take at bedtime if you are taking once a day.
- To gain the most benefit, do not miss doses.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.

Liquid:

- Measure liquid doses carefully. Use the measuring device that comes with this drug.
- Mix the dose with ¹/₂ cup (4 ounces/120 mL) of water, milk, or fruit juice and drink right away.
- After mixing, take your dose right away. Do not store for future use.
- Do not mix in any carbonated drinks or in grape juice.

What do I do if I miss a dose?

For sleep:

- If you take this drug on a regular basis, take a missed dose as soon as you think about it.
- If you will not be able to get a full night's sleep (at least 7 hours) after taking the missed dose, skip the
 missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.
- Many times this drug is taken on an as needed basis. Do not take more often than told by the doctor.

For other reasons:

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.

Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store at room temperature.
- · Protect from light.
- Store in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- · Keep a list of all your drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your doctor.
- · Talk with the doctor before starting any new drug, including prescription or OTC, natural products, or vitamins.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- · If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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