

PATIENT INFORMATION	
EVOXAC (EE-voh-ZAK) (cevimeline hydrochloride) capsules, for oral use	EVOXAC (EE-voh-ZAK) (cevimeline hydrochloride) oral solution
What is EVOXAC? EVOXAC is a prescription medicine used to treat the symptoms of dry mouth in adults with Sjögren's disease. It is not known if EVOXAC is safe and effective in children.	
Do not take EVOXAC if you: • have certain eye conditions such as acute iritis and narrow-angle (angle-closure) glaucoma, in which small "pinpoint" pupil is not wanted. EVOXAC can cause tightening (constriction) of your eye pupils. • are allergic to cevimeline or any of the ingredients in EVOXAC. See the end of this Patient Information leaflet for a complete list of ingredients in EVOXAC. • have uncontrolled asthma.	
Before taking EVOXAC, tell your healthcare provider about all of your medical conditions, including if you: • have a history of a heart rhythm problem called atrial fibrillation or other heart or blood vessel problems. • have asthma, long-term (chronic) bronchitis, or chronic obstructive pulmonary disease • have a history of kidney stones or gallstones • have or think you have an inherited condition called CYP2D6 deficiency • are pregnant or plan to become pregnant. It is not known if EVOXAC will harm your unborn baby. • are breastfeeding or plan to breastfeed. It is not known if EVOXAC passes into your breast milk. Do not breastfeed during treatment with EVOXAC and for 1 day after your last dose. Talk to your healthcare provider about the best way to feed your baby during treatment with EVOXAC. Tell your healthcare provider about all the medicines you take , including prescription and over-the-counter medicines, vitamins, and herbal supplements. EVOXAC and other medicines may affect each other causing side effects. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.	
How should I take EVOXAC? • Take EVOXAC exactly as your healthcare provider tells you to. • Take EVOXAC with or without food. • If you are prescribed EVOXAC capsules: ○ Take 1 EVOXAC capsule by mouth three times a day. • If you are prescribed EVOXAC oral solution: ○ Take 5 mL of EVOXAC oral solution by mouth three times a day with a glass of water. • If you miss a dose of EVOXAC, take it as soon as you remember. If it is less than 4 hours before your next scheduled dose, skip the dose. Take the next dose at your regular scheduled time. Do not take 2 doses at the same time to make up for the missed dose. If you take too much EVOXAC, call your healthcare provider or the Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.	
What should I avoid while taking EVOXAC? • EVOXAC may cause changes in vision, especially at night. Do not drive or do other hazardous activities until you know how EVOXAC affects you.	
What are the possible side effects of EVOXAC? EVOXAC can cause serious side effects, including: • Heart rhythm and heart rate problems. Your healthcare provider will check you for heart rhythm and heart rate problems. Tell your healthcare provider if you get any of these symptoms: ○ Dizziness ○ feeling faint or lightheaded ○ tiredness or weakness ○ feeling that your heart is pounding or racing ○ chest discomfort ○ shortness of breath • Lung problems. EVOXAC can make it harder for air to move through your airways, cause the muscles in your lungs to tighten, and increase the amount of mucus in your lungs. Tell your healthcare provider if you develop: ○ trouble breathing or shortness of breath ○ wheezing ○ increased mucus • Changes in vision. See "What should I avoid while taking EVOXAC?"	

- **Cholinergic reactions (nervous system problems).** Your healthcare provider will check you for nervous system problems during treatment with EVOXAC. Tell your healthcare provider if you get any of the following symptoms:
 - headache
 - change in vision
 - watery eyes
 - sweating
 - breathing problems
 - stomach (abdominal) cramping or pain
 - nausea
 - vomiting
 - diarrhea
 - fast heartbeat
 - change in blood pressure
 - dizziness
 - shock
 - confusion
 - tremors

Especially tell your healthcare provider if you develop heavy sweating or sweat more than normal and drink fluids to keep hydrated.

The most common side effects of EVOXAC include:

- heavy sweating or sweating more than normal
- nausea
- swelling of the inside of your nose, throat or sinuses (sinusitis)
- upper respiratory tract infection
- runny nose
- stomach area (abdominal) pain
- urinary tract infection
- coughing
- vomiting
- injury
- back pain
- bronchitis
- joint pain (arthralgia)
- tired or lack of energy (fatigue)

These are not all of the possible side effects of EVOXAC.

Call your doctor for medical advice about side effects.

You may also report side effects to FDA at 1-800-FDA-1088.

How should I store EVOXAC?

- Store EVOXAC at room temperature between 68°F to 77°F (20°C to 25°C).
- EVOXAC capsules bottle and EVOXAC oral solution container have a child resistant closure.

Keep EVOXAC and all medicines out of the reach of children.

General information about the safe and effective use of EVOXAC.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use EVOXAC for a condition for which it was not prescribed. Do not give EVOXAC 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 EVOXAC that is written for health professionals.

What are the ingredients in EVOXAC?

Active ingredient: cevimeline hydrochloride

Inactive ingredients in the capsules: hydroxypropyl cellulose, lactose monohydrate, and magnesium stearate.

Inactive ingredients in the oral solution: anhydrous citric acid, carboxymethylcellulose sodium, edetate disodium, glycerin, masking agent flavor, methylparaben, propylparaben, propylene glycol, purified water, raspberry flavor, sodium citrate dihydrate, sodium thiosulfate, sorbitol solution 70%, sucralose. Each 5 mL of EVOXAC oral solution contains 10 mg of sodium.

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For more information, call 1-800-922-1038.

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