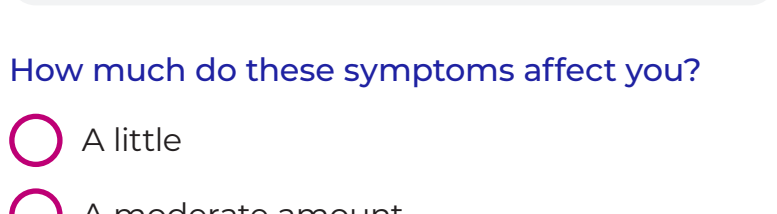


Talking to your healthcare provider about COBENFY

If you're an adult with schizophrenia and are experiencing symptoms, this guide can help you and your healthcare provider discuss if COBENFY may be right for you.

How are you feeling about how you're managing your schizophrenia?



Note any symptoms you are experiencing or have experienced recently.

How much do these symptoms affect you?

- ☐ A little
- ☐ A moderate amount
- ☐ A lot

Are you experiencing any of the following challenges?

- ☐ Dealing with overall symptoms
- ☐ Managing side effects
- ☐ Feeling unsupported
- ☐ Other challenges:

Are you experiencing any challenges that impact your ability to take your medication?

What are your goals when considering treatment?

For example **“Start improving my symptoms”**

What other treatment goals do you have?

Here are some questions you can ask your healthcare provider:

- How does COBENFY work?
- How might COBENFY help my symptoms?
- What side effects might I expect on COBENFY?
- What support is available if I'm on COBENFY?

Ask your healthcare provider if COBENFY may be right for you.

WHAT IS COBENFY (co-BEN-fee)?

COBENFY is an oral prescription medicine used to treat schizophrenia in adults.

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

IMPORTANT SAFETY INFORMATION

Do not take COBENFY if you:

- have urinary retention problems that cause your bladder to not empty completely or not empty at all
- have moderate or severe liver problems (impairment)
- have gastric retention problems that cause your stomach to empty slowly
- are allergic to COBENFY, xanomeline, or trospium chloride, or any of the ingredients in COBENFY
- have an eye problem called untreated narrow-angle glaucoma

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

- have an enlarged prostate, problems passing urine, or a blockage in your urinary bladder
- have liver problems
- have or have had gallstones or problems with your bile ducts or pancreas
- have stomach or intestinal problems, including constipation, ulcerative colitis, slow emptying of your stomach, or myasthenia gravis
- have an eye condition called narrow-angle glaucoma
- have kidney problems
- are pregnant or plan to become pregnant. It is not known if COBENFY may harm your unborn baby. Tell your healthcare provider if you become pregnant or think you are pregnant during treatment with COBENFY.
 - There is a pregnancy exposure registry for women who take COBENFY during pregnancy. The purpose of this registry is to collect information about the health of women exposed to COBENFY and their baby. If you become pregnant during treatment with COBENFY, your healthcare provider will register you by calling 1-866-961-2388 or online at <https://womensmentalhealth.org/research/pregnancyregistry/atypicalantipsychotic/>
- are breastfeeding or plan to breastfeed. It is not known if COBENFY passes into your breast milk or if it can harm your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking COBENFY with certain other medicines may increase your risk of side effects from COBENFY or the other medicine and may affect the way COBENFY or the other medicine works. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

What should I avoid while taking COBENFY?

Do not drive, operate heavy machinery, or do other dangerous activities until you know how COBENFY affects you. COBENFY may cause dizziness, confusion, seeing or hearing things that are not real (hallucinations), and sleepiness.

COBENFY may cause serious side effects, including:

- **Problems with emptying your bladder (urinary retention).** See **“Do not take COBENFY if you:”** COBENFY may cause your bladder to not empty completely or not empty at all. You are at increased risk for urinary retention if you are elderly, have a blockage in your bladder, have an enlarged prostate called benign prostatic hyperplasia (BPH), have bladder emptying problems from diabetes, or are taking higher doses of COBENFY. Urinary retention may increase your risk for getting a urinary tract infection. Call your healthcare provider or get emergency help right away if you get any signs or symptoms of urinary retention during treatment with COBENFY, including:
 - difficulty urinating
 - full bladder and difficulty emptying your bladder
 - urination in a weak stream or drips
 - pain when you urinate
 - urinating frequently
- **Risks in people with liver problems.** See **“Do not take COBENFY if you:”** It is not recommended that people with mild liver problems (impairment) take COBENFY because they have an increased risk of getting side effects from COBENFY. Your healthcare provider will check the liver enzyme levels in your blood before starting treatment and as needed during treatment with COBENFY. Tell your healthcare provider if you get any signs or symptoms of liver problems during treatment with COBENFY, including:
 - yellowing of your skin or the white part of your eyes
 - itching
 - dark urine
 - nausea or vomiting
 - pain and swelling in the upper right part of your stomach (abdomen)
 - loss of appetite
 - fever
 - light-colored stools
 - stomach pain that spreads to your back or to below your right shoulder
 - tiredness
- **Risks in people with bile duct and gallbladder problems (biliary disease).** COBENFY may cause a blockage in your bile ducts that could lead to gallstones, pancreatitis, and increases in your liver enzymes. Your healthcare provider will check your liver enzyme and bilirubin levels in your blood before starting treatment and as needed during treatment with COBENFY. Tell your healthcare provider if you get any signs or symptoms of biliary disorders during treatment with COBENFY, including:
 - stomach upset or burning (dyspepsia)
 - vomiting
 - pain in the upper right part of your stomach
 - nausea
- **Slow emptying of your stomach (decreased gastrointestinal motility).** See **“Do not take COBENFY if you:”** You are at increased risk for getting decreased gastrointestinal motility if you have ulcerative colitis, already have problems with slow stomach emptying, and have myasthenia gravis. Tell your healthcare provider if you get any signs and symptoms of decreased gastrointestinal motility during treatment with COBENFY, including:
 - constipation
 - a feeling of fullness after eating just a few bites
 - vomiting
 - acid reflux
 - nausea
 - stomach (abdominal) bloating
 - stomach (abdominal) pain
- **Serious allergic reactions (angioedema).** Angioedema may happen during treatment with COBENFY and can be life threatening. Stop taking COBENFY and call your healthcare provider or get emergency help right away if you get any of the following signs or symptoms of a serious allergic reaction during treatment with COBENFY, including:
 - hives
 - hoarseness or difficulty speaking
 - swelling of your face, lips, mouth, or tongue
 - breathing problems
 - swelling of your throat
- **An eye problem called narrow-angle glaucoma.** See **“Do not take COBENFY if you:”** If you already have narrow angles in your eyes, COBENFY may cause a sudden attack (acute angle closure) of glaucoma. Tell your healthcare provider if you get any signs or symptoms of narrow-angle glaucoma during treatment with COBENFY, including:
 - red eyes
 - nausea or vomiting
 - blurred vision
 - severe headache
 - seeing halos or bright colors around lights
 - eye pain or discomfort
- **Increases in heart rate.** COBENFY may increase your heart (pulse) rate. Your healthcare provider should check your heart rate before you start treatment and during treatment as needed. Tell your healthcare provider if you get a racing or pounding feeling in your chest during treatment with COBENFY.
- **Side effects in people with kidney problems.** People with kidney problems may have an increased risk of getting dry mouth, constipation, stomach upset or burning, urinary tract infection, and urinary retention during treatment with COBENFY.
- **Central nervous system problems.** See **“What should I avoid while taking COBENFY?”**

The most common side effects of COBENFY include:

- nausea
- diarrhea
- stomach upset or burning (dyspepsia)
- increased heart rate
- constipation
- dizziness
- vomiting
- heartburn (gastrointestinal reflux disease)
- high blood pressure
- stomach (abdominal) pain

Your healthcare provider may lower your dose or stop treatment with COBENFY if you get certain side effects.

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

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see the Full Prescribing Information, including Patient Information, for COBENFY.

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1629-US-2600006 01/26